



Resume Book 2021

Amanda Brown Galgay

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Overview

A results-driven, creative, and dedicated Corporate Affairs leader with nearly 20 years of experience in biotech, pharma, and medical device companies charting new ground in science and medicine.

Deep experience across investor relations, media relations, patient advocacy, corporate identity and branding, executive communications, community relations, and issues management. Led investor relations to achieve multiple rounds of private financing; communications for FDA approvals and launches of first-in-class treatments; and award-winning employee engagement and communications campaigns driving measurable results in retention and engagement.

Professional Experience

Ohana Biosciences, a Flagship Pioneering Company

Vice President, Corporate Affairs

August 2019 – present

Built and lead the Corporate Affairs function, launching the company in 2020, achieving financing, scaling through organizational change, and readying for commercial launch of first product.

- Led company “unveiling,” publicly launching the company via comprehensive communications campaign, leading to results that set record for most media impressions of any recent Flagship company launch
- Built, launched, and maintain website and corporate social media strategy
- Established corporate identity and branding, pulling through internally via tools and ongoing training and support to ensure a consistent corporate voice
- Built and maintain investor engagement and tracking database, lead investor communications, and serve as key part of fundraising team working closely with Flagship Pioneering leadership to execute financing strategy
- Gained experience in multiple financing vehicles, including concurrent IPO and SPAC strategies
- Drive corporate news flow strategy, offsetting changes in pipeline and milestone achievement with creative ways to continue driving corporate positioning and visibility
- Key member of launch team to support SPERTILITY™, a first-in-class treatment launching in 2022; work closely with Commercial to execute product branding, market research, patient digital journey, and roadmap to commercialization
- Partner with HR on change management through changes in corporate strategy, financing, office moves, and COVID-19 operations
- Established patient advocacy function, working closely to define a novel approach in an underdeveloped advocacy field and build employee connection to the infertility space
- Support executive communications, working closely with new and building Leadership Team to evolve and strengthen corporate narrative, presentation delivery, and media training

Pear Therapeutics

Vice President, Investor Relations and Corporate Communications

March 2018 – August 2019

Built and led the corporate communications function as the company readied for a potential IPO, achieved clearance and commercialization for the world’s first two prescription digital therapeutics, and scaled the organization.

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- Led investor relations through two rounds of successful private financing, retaining founding investors and attracting new investors from multiple categories, achieving novel ways to attract and build sell-side support including achieving analyst coverage as a private company.
- Achieved considerable traction for company visibility and positioning through corporate media, including coverage in *The Financial Times*, *New York Times*, and throughout business and trade media (notable as a small, Series B-stage company)
- Drove dynamic editorial program to position and engage audiences in Pear's leadership in defining the nascent prescription digital therapeutics space, achieving inbound business development and media inquiries as a direct result
- Executed a successful executive communications program, placing executives in multiple and ongoing high-profile speaking engagements, ranging from keynote addresses at industry events to global platforms such as [TEDMED](#), SXSW, and Fortune Brainstorm Health
- Partnered closely with HR to lead employee communications, events, and training as the company tripled in size within two years
- Built and maintained all corporate channels, including corporate website, product websites, corporate social media channels, and shared channels with commercialization partners
- Executed shared communications strategy for products with joint commercialization partners, Sandoz and Novartis, to achieve considerable media attention and traction

Pfizer Inc.

Director, Worldwide Research and Development Communications June 2016 – March 2018

Led communications on behalf of Pfizer in Massachusetts, based at the company's R&D hub in Kendall Square. Responsible for building internal and external communications strategy to unite its research units and functions, address recruitment and retention challenges, and improve local market visibility. Member of leadership team for worldwide research and development, policy and reputation communications.

In Massachusetts:

- Led efforts to enhance local external visibility and corporate reputation, including: external branding and messaging, media outreach, placing scientists in top-tier speaking opportunities, advertising strategy, and support of HR recruitment strategy.
- Oversaw local community relations including revamping giving strategy and working with Pfizer Foundation to improve local-level relationships
- Partnered with state government relations to support policy and legislative work

On behalf of Pfizer corporate:

- Drove Pfizer's scientific reputation through corporate social/digital channels including: GetScience.com, @Pfizer, Facebook and LinkedIn
- Supported executive communications, including those on behalf of Pfizer's President of Worldwide Research and Development, as well as Chief Scientific Officers
- Supported communications for gene therapy franchise and new R&D manufacturing sites in U.S.

Vertex Pharmaceuticals

Director, Corporate Communications

August 2013 – June 2016

Led employee communications on behalf of company renowned for culture and employee engagement. Managed team of eight cross-functional professionals, including executive communications, culture and employee engagement, special events, corporate branding and the Thomas M. Menino Learning Lab.

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- Oversaw editorial planning and strategy for all internal channels, including weekly newsletter, intranet, digital programming, and ongoing series such as town halls and lecture series
- Extensive use of data and analytics to understand colleague sentiment and engagement, and to drive change in HR and communications approaches
- Drove strategy to bolster employee engagement during time of uncertainty for the company (on the heels of Orkambi launch) and organizational change
- HR partner, responsible for leading communications around executive onboarding, organizational changes, driving annual employee and external “top places to work” surveys
- Responsible for executive communications and presentations, including business updates, town halls, and senior leader meetings, and dignitary/VIP events
- Managed employee volunteerism and the Thomas M. Menino Learning Lab, including its partnership with the Boston Public Schools, BottomLine, and other STEM-focused organizations

Biogen

Senior Manager, Corporate Communications

January 2012 – August 2013

During a time of tremendous growth and transformation for the company, served as a primary corporate spokesperson on issues specific to the business, pipeline and financials.

- Developed public relations programs to highlight company profile, securing health, science and business-related placements in mainstream and trade publications. Key achievement: *Forbes* cover story
- Supported pipeline communications, including programs for ALS, MS and Alzheimer’s. Key placement: CMO interview on the Charlie Rose show “Brain Series”
- Communications lead for Business Development deals and activity
- Supported corporate citizenship strategy, including development of annual Corporate Citizenship report. Achieved inclusion in the Dow Jones Sustainability Index – at the time, the first and only U.S. biotech company to do so.
- Planned and organized media and special events, including community events, press events and briefings.
- Supported financial communications including quarterly earnings and Annual Report; served as day-to-day press contact for CFO. Key placement: *Fortune* profile
- Oversaw corporate advertising, including development of ads for print, radio and online.
- Worked to establish company-wide social media governance committee to evaluate and advise on emerging social media initiatives.
- Led website strategy for corporate site and supporting microsites.

FleishmanHillard

Vice President

August 2005 – December 2011

Worked in the St. Louis (corporate headquarters), Washington D.C. and Boston offices, beginning as an intern and leaving as a Vice President overseeing key accounts. Gained experience spanning leading digital strategy and marketing on behalf of the agency to providing public affairs and communications counsel to world- and industry-leading brands. Highlights:

- During the 2006 primary and 2008 presidential election, served as spokesperson on behalf of leading provider of electronic voting machines. Provided onsite media support at election sites and managed all reactive media.

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- Served as lead spokesperson for a national provider of healthcare to prisons and jails, handling highly sensitive and litigious issues. Worked with the client to handle several major media investigations including from Vanity Fair and 60 Minutes.
- On behalf of the nation's largest private non-profit health system supported communications strategy around health reform during 2008 election season.
- On behalf of a Fortune 10 client, served as key member of state public affairs team focused on digital grassroots strategy.

Missouri Attorney General's Office

Press Aide

January 2003 – August 2005

Served as press aide on behalf of longest-serving Attorney General, who went on to serve as Missouri Governor from 2009-2017.

Overview

University of Missouri-Columbia

Bachelor of Arts, Political Science and Biology

Master of Arts (ongoing), Journalism

Anthony C R Phillips

Greater Boston Area

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Information Technology Leader

Senior Information Technology Leader with many years of experience constructing innovative data and communication architectures to align with and support corporate strategic goals. Key team leader and contributor in acquisitions, migrations, and divestitures. Reduced costs through innovation and consolidation; improved resource management. Enabled a security model for application and data access management through multifactor and single sign on solutions. Always seeking to innovate, motivate, train and encourage.

Technical Skills

- Architected, built, and administered Amazon Web Services environments to support corporate goals
 - Migrated companies to SaaS, IaaS, and Hosted Solutions
 - Designed and implemented security solutions for Multifactor Identity and Access Management
 - Sourced, designed and constructed Data Centers and migrated business systems and data
 - Procured and built hyperconverged site solutions
 - Implemented, deployed, and migrated businesses between Microsoft and Google GSuite Platforms
 - Led, built, and motivated teams through business acquisitions, migrations, and divestitures
-

Selected Accomplishments

- **Computational Biology Ecosystem:** Was hired by Ohana to construct a state of the art AWS backbone to support all of the Research programs in the business. Consolidated all of the Research cloud environments into a secure, controlled AWS architecture. Worked with external agencies such as the NIH to create controlled data research environments. Enabled the Ohana Research team to move at a limitless rate of speed.
- **Cloud Migration Strategy:** AMAG's mission was to become a completely Cloud-enabled company. This was accomplished through the construction of an entirely new and innovative cloud stack in SaaS, IaaS, hosted and AWS Solutions. AMAG was fully deployed into the Cloud within 18 months, well before the rest of the Life Sciences industry. This gave us the freedom to focus on new technologies, acquisitions, and helped us to **reduce operational costs in excess of \$500k annually.**
- **Single Sign-on Security Initiative:** Early adopter of Okta in 2010 led to a new paradigm in single sign-on and multifactor solutions. Helped Okta develop their new and expanding platform, with design and technology recommendations. Advised Okta to incorporate an LDAP/Universal Directory into their architecture. **In 2013 AMAG was awarded the Okta "Pioneer" award in recognition of our work and contributions to their product.**
- **Mergers, Acquisitions, and Divestiture:** AMAG had 2 major corporate acquisitions, Lumara Health and Cord Blood Registry. With a small IT team, executed due diligence and site assessments and successfully migrated the entirety of Lumara Health. **We completed this in under 6 months reducing operating costs by \$360k per year.** Cord Blood's entire infrastructure needed to be re-architected; **I designed and migrated them onto a newer**

platform reducing costs by \$480K per year. We ultimately sold Cord Blood and I led the process of separating their business from AMAG's and built out their own segregated Cloud Infrastructure.

Professional Experience

Ohana Biosciences, A Flagship Company, Cambridge, MA

2020-2021

A Flagship startup looking to develop 3 parallel therapies. Sperm fertility, isolate sperm disease and male sperm contraception.

Senior Director Frontier Computing

- Worked as the partner to the VP, IT to build out the entire infrastructure and service catalogue for Ohana.
- Internalized all IT services from our MSP to become independent; upgraded the entire IT environment.
- Introduced GSuite Workspace and Okta stack for unification and single sign-on.
- Enabled several MFA technologies including Yubikey and push Authenticators to enable our Security Model.
- Introduced Beyond identity for password less sign-ons across the enterprise.
- Built AWS Stack to include HPC Parallel compute cluster and enabled EFS File services.
- Archived all business data sets through AWS Storage Gateway to S3 buckets and Glacier tiered storage.
- Migrated the entire company to a new facility in August of the pandemic.

United States Air Force, Kesselrun Project, Det 12 Hanscom Airforce Base

2019-2020

Information Technology Specialist - Secret Clearance

On the Business Operations and Support Team, led the process of bringing cloud applications and support services to the Development Operations and Security Operations teams.

- Supported all enterprise cloud applications.
- Built out and supported highly available and redundant communications platform; fully documented build-out and upgrade to high-availability cluster
- Maintained and managed all RDS application databases, with backup, upgrades, and maintenance cycles on cloud platforms.
- Upgraded Application load-balancers on enterprise applications stack.
- Implemented Change Control Mechanism policy, process and procedure for business unit.
- Developed the Wiki for all site services focused on team responsibilities.
- Generated application version-control documentation, subject matter expert leadership, and application support matrix.

AMAG Pharmaceuticals, Lexington and Waltham, MA

2010 - 2019

AMAG Pharmaceuticals, Inc. developed products for the treatment of iron-deficiency anemia in adult patients. AMAG expanded its portfolio with the acquisition of several companies and moved into Women's Health and Health in expectant mothers. AMAG began with 140 employees and through growth and acquisition grew to a size of over 800. AMAG was an early cloud adopter and through its acquisitions, incorporated separate businesses into its cloud model. AMAG grew to 4 Sites and Data Centers. In August 2018, AMAG sold Cord Blood and reduced the architecture environment back to a single site with an IT Team of 20 with all our applications and services in the Cloud.

Director Infrastructure and Operations - 2017 - 2019

Reporting to the VP of IT, managed a team of 15 employees for all Cloud, Infrastructure, Networks, Telecommunications and Help Desk Services across multiple sites.

- Managed IT Infrastructure, networking and Helpdesk service and teams across all sites.
- Helped design and build San Francisco's new site office, selected circuit providers, power, and cooling.
- Managed capital budget and inventory management of all infrastructure, networks, software, and services.
- Collaborated with vendors and contract management on selection, procurement, and migration of services.
- Guidance in hiring, selection, training, and career development of team members.
- Primary contributor in SOX audits, compliance, and other regulatory requirements.
- Participated in budget and reforecast cycles with leaders of company functions.
- Assessed and selected Cisco/PURE Flashstack for Waltham site deployment upgrade.

Associate Director, Senior Cloud Architect - 2016 - 2017

Reporting to the CIO, managed a team of 6 employees for all Cloud, Infrastructure, Networks and Telecommunications services across multiple sites.

- Migrated business operations and services from onsite to SaaS, IaaS, and hosted application solutions.
- Architected project management for the migration of data centers and site upgrades.
- Drafted Functional Requirement Specifications for software evaluations and assessment in selection process.
- Governed and implemented security standards and policies.
- Controlled management of inventory and software licensing.
- Selected PURE Storage for site to site replication, migration and disaster recovery strategy.
- Procured UCS blades for server compute farms within Cord Blood Registry.
- **Received a "Value in Actions" Award for managing our Telephony Call Tree Migration in Canada.**

Cloud Architect, Senior Cloud Architect - 2010 - 2016

Reporting to the Director of IT, responsible for moving on-site services from VMWare to off-site Cloud services. Led teams through 2 major acquisitions.

- Constructed a Universal Cloud Backup Layer (UCBL) - first of its kind in Amazon Web Services SaaS backups.
- Deployed a comprehensive AWS infrastructure.
- Authored high level written communications, work instructions, policies, and procedures.
- Instrumental in testing and selection of SaaS vendors.
- Designed, developed, and built out AMAG's AWS legacy applications platforms.
- Migrated off of our internal Microsoft Windows, Exchange, and Office platform to G Suite's cloud solution.
- Implemented and moved backups off of the internal Netbackup tape library to Vaultlogix and Rubrik.
- Developed Certificate Services and installation scripts for wireless authentication at all sites.

Former Companies and Roles:

- **Ribbon Networks (Sonus Networks)** - IT Systems Administrator, Swindon UK, Chelmsford and Westford MA
- **Lattice Semiconductor** - IT Systems Engineer, Corsham and Chippenham, UK
- **SunGard (Vivista)** - Application Support Engineer, Chippenham, UK
- **Ministry of Defence (MOD) Fujitsu (ICL)** - (Security Clearance) Site Systems Manager & Security Officer, UK
- **Her Majesty's Royal Air Force** - Personnel Administrator, UK and Overseas

- ITIL V3 University of Greenwich, London, UK - Business Information Technology II
- Cisco - CCNA, CCDA Sun Certified Systems Administrator Solaris 8
- GCSE's Penwith Technical College, UK Advanced Architect AWS Training
- Military College - Personnel Administrator NetApp Administrator Training
- Microsoft – MCP+I, MCSA:Exchange, MCSE CISSP Training

BRENDAN ST. AMANT

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Life sciences leader and trusted advisor with diverse in-house experience who strengthens the risk management profile of companies

LEGAL EXPERIENCE

Ohana Biosciences, Inc. (Flagship Pioneering company), Cambridge, MA

Vice President, Head of Legal (December 2019 – Present)

Member of leadership team reporting to CEO in clinical stage, commercializing company who advises the board of directors, executives, and colleagues across a variety of complex business, legal and compliance issues in the following areas:

- Lead drafting and negotiation on all life science agreements (SRAs/academic collaborations, IP license term sheets, MTAs, MSAs, manufacturing/3PL, CROs, employment agreements, consulting arrangements, NDAs, etc.)
- Act as legal business partner to all functions (e.g., commercial, corporate affairs, finance, clinical, medical affairs)
- Lead Medical-Legal-Regulatory process and review corporate marketing materials, investor materials, disease state materials, publications, press releases, and other external communications for compliance with applicable laws, regulations, and industry guidance
- Support disclosure and due diligence process for corporate financings
- Manage patent and trademark strategy across three programs in biologic and medical device space
- Design and implement compliance program for company, including launch of Code of Conduct, policies, training strategy, anonymous reporting system, and HCP engagement process
- Institute and chair quarterly and periodic compliance meetings with senior leadership
- Advise on all employment law and human resource issues (hiring, performance management, terminations), draft and implement related core policies (harassment and discrimination, reasonable accommodation, PFMLA), and training regarding same in partnership with HR
- Advise on privacy issues related to clinical trials, research specimens, and employee data
- Present trainings on confidentiality protection, smart communications, and other relevant issues
- Direct strategy on all pre-litigation and dispute resolution matters
- Lead contract approval and management process
- Create and update core contract templates
- Legal representative on various cross-functional committees (510k submission, InfoSec, data management)
- Crisis leadership on company's Covid-19 response (legal and operational)
- Manage outside counsel and vendors (when necessary) within a limited budget

Vertex Pharmaceuticals Inc., Boston, MA

Director & Sr. Counsel; Interim Company Employment Lawyer (July 2017 – November 2019)

Led or collaborated on wide array of legal and risk initiatives, including:

- Co-led compliance assessments and audits of high-risk areas and markets, including corporate affairs, patient advocacy, and sales and marketing in the U.S. and international jurisdictions
- Assisted in negotiations of vendor, collaboration, and specialty pharmacy agreements
- Developed and modified policies (e.g., patient assistance programs) to reflect enforcement priorities
- Developed and delivered trainings on False Claims Act, securities, employment, and other issues
- Handled affirmative and defensive litigation, pre-dispute matters, and internal investigations
- Assisted market access team with drug pricing/transparency issues
- Acted as interim head of employment law function for six months
- Advised on privacy issues, including data processing agreements and incident response
- Member of corporate strategic transactions working group
- Co-led annual Enterprise Risk Management project
- Co-led high profile company initiative to identify and protect most sensitive information and data
- Assisted with implementation of records information management initiatives

BRENDAN ST. AMANT

LEGAL EXPERIENCE (cont.)

Donnelly, Conroy & Gelhaar, LLP, Boston, MA

Partner (December 2016 – July 2017); *Associate* (November 2011 – November 2016)

Represented clients in all aspects of business and employment disputes in state and federal courts, including business advising. Represented clients during investigations by the U.S. Attorney's Office, FINRA, OSHA, and the Ethics Commission. Matters included representing and/or defending:

- Witnesses before the U.S. Attorney's Office during healthcare fraud/Anti-Kickback investigations, including around government reimbursement, sales rep compensation, and patient assistance programs
- Companies in breach of contract litigation
- Companies in derivative shareholder litigation
- A healthcare services company in trade secret dispute with medical product supplier
- Companies during FINRA requests and responses
- A global information content provider in an action for misappropriation and unfair competition by business rival
- A developer of software for embedded devices against an infringing licensee
- A high technology manufacturer pursuing claims against a foreign distributor

Goodwin Procter LLP, Boston, MA

Associate (January 2010 – November 2011)

Represented clients in various stages of business and securities litigation.

The Hon. Alvin W. Thompson, Chief, U.S. District Court, Hartford, CT

Law Clerk (August 2008 – September 2009)

Assisted Judge in the research and drafting of published opinions.

EDUCATION

Harvard Law School, Cambridge, MA

Juris Doctor, 2008

Harvard Kennedy School of Government, Cambridge, MA

Master of Public Policy, 2008

Cornell University, Ithaca, NY

Bachelor of Arts in History, magna cum laude, 2000

OTHER EXPERIENCE

U.S. Peace Corps, Niger, West Africa

Community Health Agent and Trainer (January 2002 – April 2004)

Secured funding for and managed construction, furnishing, and operation of rural health facility for the village of Tiguèye (est. pop. 5,000). Designed and delivered health presentations for local donors and Peace Corps trainees. Wrote and secured USAID and Catholic Relief Services funding grants for local development projects.

Sewickley Academy, Sewickley, PA

High School Teacher (August 2000 – June 2001)

Taught four sections of World Civilizations class to ninth grade students. Coached soccer, basketball, and track.

SELECTED WORKS

"Ruling Implements Novel Procedure for Trade Secrets Designations," Massachusetts Lawyers Weekly (Jun. 16, 2016) (co-author with T. Christopher Donnelly)

"The New SEC 'Individual Cooperation' Guidelines: Risks and Opportunities," Securities Fraud 2010, Boston Bar Association CLE (Apr. 6, 2010) (co-author with John J. Falvey)

"The Misplaced Role of Identity Theft in Triggering Public Notice of Database Breaches," 44 Harvard Journal on Legislation 505 (2007) [cited in over fifteen treatises and law review articles]

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SELECTED LEADERSHIP **Massachusetts Continuing Legal Education, Inc.**, Boston, MA
First Vice President (2020 – Present), *Secretary* (2017 – 2020) and *Trustee* (2013 – Present)

Boston Bar Association Business and Commercial Litigation Section, Boston, MA
Steering Committee Member (2016 – 2017)

Boston Bar Association Reentry Education Program, Boston, MA
Steering Committee Member (2014 – 2017)

City of Cambridge Human Rights Commission, Cambridge, MA
Commissioner (2012 – 2014)

East Cambridge Scholarship Fund, Cambridge, MA
Trustee (2011 – 2014)

PERSONAL Interests include hiking and camping, beginning birding, and other outdoor activities.

Brooke Wilcox

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Corporate Operations Specialist: **Information Technology, Digital Support, and Office Management**

Selected achievements

- Establishing BrookeAcademyTraining (BAT) Program
- Executive Support & Administrative Efficiency
- Managing Ohana COVID testing & tracing programs
- Directing & Facilitating Office Relocations
- Software Collaboration Optimization
- Implementing new Help Desk system for Ohana

Professional Experience

Digital Experience Manager, Ohana Biosciences - Cambridge, MA - February 2021 - Present

Ohana's platform is a unique combination of biology and technology never before applied to reproductive health which has revealed breakthrough discoveries that impact the most important aspects of the reproductive journey: fertility, pregnancy and child health, and contraception.

- Provide world-class IT customer service to employees
- Primary support and Subject Matter Expert for all Ohana core SaaS applications
- Established Ohana's first internal IT training program - BrookeAcademy - which:
 - Provides onboarding "Foundations Training" (Google suite, Slack, Zoom) for all new employees
 - Provides monthly in-depth training on various platforms (Asana, Airtable, Box, Google, Lucidchart, Lucidspark, Slack, Snagit, among others)
 - Provides 1:1 trainings as needed and requested
- Facilitate IT department updates to the company on a quarterly basis (or as needed)
- Responsible for internal communications for any software platform changes, outages, or updates
- Build and deliver laptops and necessary equipment to all new employees
- Manage all IT assets in centralized online location
- Associate lead for Information Security team

Corporate Office Manager and Executive Assistant - Ohana Biosciences - October 2018 - February 2021

- Managed all aspects of the office environment and its functionality including: appearance and cleanliness, employee safety, visitor reception - serving as the first point of contact for all employees, visitors and vendors
- Partnered closely with Lab Manager in all office communications with the Lab Team; collaborated on office safety and evacuation procedures
- Managed all office-related vendors in relation to office functionality
- Managed day-to-day interactions between employees and others including: external vendors, purchasing, IT, HR, Finance and Legal Service providers
- Ensured operations security by maintaining office ID badges, parking passes, and egress access
- Partnered with COVID-Taskforce to develop and deploy platform for daily health screenings and contact tracing
- Directed and facilitated 3 separate office moves including a mid-pandemic full corporate relocation
- Coordinated and managed all office seating arrangements as well as hoteling desks
- Managed conference room schedule and booking reservations
- Liaised with building management and landlord on all ongoing facilities-related issues, including maintenance, repair, cleaning and upkeep
- Managed Administrative Assistants as direct reports; held weekly meetings for updates, planned monthly happy hours, office sponsored events, general admin guidance and mentorship
- Supported Ohana's CEO, CMO, CSO, and VP of Research as it relates to; calendar management, liaising with Board of Directors, medical advisors, potential investors, clients, and other key players as required for the business
- Served as a key resource in assisting the CEO and executive team by seamlessly managing full, complex, and ever-changing calendars, related to internal and external meetings
- Developed and maintained professional working relationships with all internal staff members and external affiliates

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Office Manager - Linedata - New York, NY - December 2015 - October 2018

- Managed all aspects of the New York office including operations.
- Served as Executive Assistant to Paris CEO.
- Managed four Administrative Assistants for each North American office; held weekly meetings for updates, planned monthly happy hours, office sponsored events, general admin guidance, et al.
- Managed all vendor relations and services for North American offices.
- Facilitated and executed all communications for Linedata's Wellness Program in conjunction with Tufts health care.
- Managed North American Corporate Travel: managed executive travel, prepared expenses, and managed hotel contracts and relationships.

Office Manager - Seleni Institute - New York, NY - April 2015 - December 2015

- Supervised all office needs, reception backup and IT support.
- Managed and developed the Summer Intern Program: Onboarding and training interns on organization policies and procedures, 1:1 meetings with each intern, planning lunch & learn presentations, providing midterm and final evaluations for each intern and their presentations.
- Managed and collaborated in all events, promotions, and special activities.
- Facilities Management: managed all vendors and relationships, maintained facilities handbook, managed ordering, stocking and maintenance of supplies and purchases

Receptionist and Office Administrator - Linedata - New York, NY - October 2011 - April 2015

- Supervised daily office needs, answering phones, scheduling, greeting clients, all ordering supplies and pantry; worked with building management, deliveries, all vendors and services,
- Managed scheduling for all conference rooms, troubleshooting IT equipment.
- Managed Executive travel, coordinator for all North America Corporate Travel and hotel contracts.
- Processed expense reports for Executives.
- Planned and coordinated all office functions and events; Assistant Event Coordinator for Linedata's Client events.
- Managed budget for weekly orders, massages, events and petty cash.
- Writer/Editor of *Lifelines'* bi-monthly wellness newsletter.

Private Voice and Piano Instructor - Wilcox Studios - Beverly, MA & New York, NY - January 2009 - August 2018

- Developed curricula for individual students, coaching them in preparation for auditions, competitions, and performance - teaching a variety of styles and techniques, including fundamentals such as ear training and sight reading.

EDUCATION

Longy School of Music

Master of Music in Opera Performance

Cambridge, MA

May 2008

Gordon College

Bachelor of Music in Vocal Performance

Wenham, MA

May 2004

Cabrillo College

Associates of Arts in Music, with Honors

Soquel, CA

May 2001

CERTIFICATIONS

ITIL® 4 Foundation

April 2021

SKILLS

Administrator/Power User in the following: Asana, Airtable, Box, Docusign, Envoy, Google Suite, Lucidchart, Lucidspark, Mac OS/iOS, Microsoft Office, RingCentral, Slack, Snagit, Windows10, Zoom

Caren Black Deardorf

Lexington, MA

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Executive Profile

Inspirational, authentic biotech/biopharma executive who leads organizations in driving company and asset value creation across variety of product modalities, range of therapeutic areas in the U.S. and abroad. Over 25 years of demonstrated leadership leading teams in a matrix and consistently meeting and exceeding ambitious goals in world-class product launches of novel therapeutics. Exceptional internal and external stakeholder management. Inquisitive and collaborative team-player with strong executive team experience. Enterprise-wide leader who establishes and refines strategy, develops talent across an organization and successfully implements a corporate vision to bring meaningful therapies to patients.

Highlights of Expertise & Experience

- **Organization building & Champion of Corporate Reputation:**
 - Experienced in capital formation and board engagement in entrepreneurial start-up environment for Ohana Biosciences, a disruptive company in reproductive health
 - Key executive responsible for crafting and communicating corporate story to investors in fundraising
 - Led external communication strategy for spinal muscular atrophy (SMA) program through significant patient community pressure and creation of Expanded Access Program, largest for a rare disease
 - Built strong external stakeholder networks (KOLs, Advocacy Organizations, Payers, Influencers) for multiple brands at Biogen strengthening corporate reputation in Neurology
 - Significant international experience defining & establishing overall corporate footprint in key markets as well as planning and executing multiple global product launches
- **Set Strategy & Develop Markets for Novel Products**
 - Recognized leader of high performing cross-functional teams including SPINRAZA® (nusinersen) global program team across clinical development, global regulatory filings, and launch execution
 - Deep understanding of complex, high-tech products (small mol, ASOs, biologics, device)
 - Significant expertise building and developing “from scratch” new markets with first to market products
 - Significant role in business development diligence, deal structuring and alliance management
- **Inspirational and Visionary Leader:**
 - Built and led teams of >30 people and developed and managed budgets of >\$25M, P&L of >\$2B
 - Executive leadership across broad functions encompassing program leadership, commercial & corporate strategy, new product planning, and brand leadership
 - Exceptional communicator who can inspire teams, drive change throughout organizations and create innovative solutions with a focus on the patient
 - Culture builder -driven to establish inclusive, fun and collaborative culture where people thrive and grow
- **Consistent Delivery of Exceptional Results:**
 - Achieved exceptional results in SPINRAZA® global launch reaching \$1.7B and securing reimbursement in over 30 countries within 2 years of launch, unprecedented timelines in key countries.
 - Led global launch of Tecfidera® (dimethyl fumarate) reaching >\$1B in US sales within 12 months, one of the most successful drug launches in US history
 - Member of Board of Directors, Pan Mass Challenge, which has raised over \$700M to support Dana Farber Cancer Institute

Career Experience

Ohana Biosciences, Cambridge, MA

May 2019- present

Chief Commercial Officer

Key member of the executive leadership team, establishing the corporate vision and roadmap for pipeline, commercialization, and funding strategy. Responsible for shaping all aspects of the commercial strategy including first launch for Ohana in the field of Fertility/Reproductive Health.

Accomplishments

- Provide strategic commercial direction to R&D organization and lead long-range planning and portfolio prioritization efforts including horizon scanning for future opportunities.
- Manage New Product Planning function enabling data-driven and crisp decision making on R&D investment
- Significant board-level engagement on corporate and commercial strategy
- Developed and communicated impactful commercial strategy in fundraising and BD efforts
- Delivered first commercial launch plan including organizational design and staged build-out.
- As enterprise-wide leader helped build a strong, dynamic culture and company.

Biogen, Cambridge, MA

2011-2019

Vice President, Global Product Development & Commercialization Lead, SPINRAZA® and SMA Portfolio (2017-2019)

Global leader charged with executing the global launch of SPINRAZA, establishing the first therapy for SMA. Achieved \$1.7B in first 2 years exceeding all internal & external targets. Led SPINRAZA global program team across execution of late-stage development, Expanded Access Program (EAP), global registrations, commercial and medical affairs strategy, launch planning & execution, lifecycle management.

Accomplishments

- “Built from scratch” the SMA Market, establishing treatment centers, treatment administration process, reimbursement, account management model and expanded market through disease state awareness.
- Determined the global footprint strategy & filing plans including regional affiliate structure and geographic expansion into APAC, Latam.
- Member global pricing council that set and approved pricing framework, supported affiliate negotiations
- Owned global asset P&L with Regional leads; Partnered effectively with regions to exceed sales targets. Achieved reimbursement in ~30 countries within first 2 years of launch - unprecedented timelines in key countries.
- Managed Global Marketing team who established global strategy & delivered launch platform
- Represented Biogen for the SMA programs with media, investors, and patient advocacy organizations.
- Set strategy for the SMA Portfolio in partnership with R&D including internal gene therapy program, external business development evaluations, investment and prioritization.

Sr Director, Global Brand Lead SPINRAZA® (2015- 2017)

Responsible for development of global commercial strategy and execution for Biogen’s launch of SPINRAZA (nusinersen) in the rare orphan disease *Spinal Muscular Atrophy* (SMA). Managed global marketing team of 5 and budget of \$10 million.

Accomplishments

- Key member of Internal EAP Advisory Board that designed and executed a global Expanded Access Program (EAP) , the largest ever run, enabling treatment of over 900 infants with SMA
- Established global marketing and cross-functional launch team. Ensured launch readiness within accelerated regulatory timelines across US, EU and Japan.
- Commercial champion on Program Team; key voice on optimizing trial design, regulatory strategy and long-term value for the asset. Drove integrated Long-Range Planning including revenue and LCM investment plans. Alliance manager with partner, Ionis Pharmaceuticals.

Sr Director, Global Brand Lead TECFIDERA® (2013-2015)

Led the global brand team responsible for global launch strategy and affiliate readiness for TECFIDERA across US, EU, Japan and affiliates. Achieved \$1 Billion in U.S. sales within 12 months, making it one of the most successful drug launches in U.S. history.

Accomplishments

- Developed global positioning, messaging and promotional campaign
- Cultivated strong cross-functional and regional relationships that allowed for a tightly aligned launch strategy worldwide.
- Key member of the cross-functional Program Team, providing commercial leadership to key decisions on LCM, launch sequence and pricing strategy
- Commercial lead on global pricing council that established pricing framework and approved affiliate pricing.

Sr Director, U.S. Brand Lead Dexpramipexole (ALS) (2011-2013)

Responsible for development of Brand and U.S. Commercial launch strategy for novel product in Ph III for ALS, a rare orphan disease. Work halted due to disappointing Ph III results.

Accomplishments

- Established cross-functional launch team and plan under critically accelerated time frames.
- Designed novel go-to-market model including field team, patient-centric “beyond the pill” patient support program and commercial operations.
- Led cross-functional team of 15, directly managed U.S. brand team. Alliance manager.

Additional Career Experience

Biogen, Director, Neurology Commercial Operations **2009-2011**

CD Strategic Biotech Marketing **2005-2009**

Commercial consultant on early and late-stage products with various biopharma companies

Biogen Idec, Cambridge, MA **1994-2005**

Director of U.S. Marketing, MS Franchise 1.5 years

Associate Director- Director of U.S. Marketing, TYSABRI® Launch 2 years

Associate Director, New Product Planning 3 years

International Marketing Manager – AVONEX® EU Launch, Paris, FRANCE 2 years

Marketing Associate - AVONEX® U.S. Launch 2 years

Tufts University European Center Associate Director, Talloires, FRANCE **6 years**

Education

M.B.A, Babson College- Olin Graduate School of Business, Wellesley, MA

B.S., Biology (Premed) with French concentration, Tufts University, Medford, MA

Personal and Professional Affiliations

- Committed to community & philanthropy as long-time board member, 20-year rider of Pan Mass Challenge (major philanthropic org that has raised >\$700M benefiting Dana Farber Cancer Institute).
- Member, Board of Directors of the MacJannet Foundation for international education
- Lived and worked in France. Moderate fluency in French
- Interests include volunteerism, cycling, fly-fishing, hiking

Chalyse L. Bush

Cambridge, MA

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(617) 955-9196

SUMMARY

Certified clinical research professional with cross-functional management and executive reporting experiences, including a track-record of assessing, organizing, and managing high-priority preclinical and clinical projects for small & mid-sized biotech companies. Professional history of 'wearing many hats' to fulfill corporate objectives, including clinical trial supervision, internal & external project management, and filling knowledge gaps across the organization through multiple promotions and final reporting into CMO.

Most recently served as center-point between clinical, manufacturing, quality and regulatory teams for the completion of pivotal Phase 2 study. Led scientific program management for clinical study development, start-up and subsequently managed investigator site relations. Experience assessing clinical trial risk determination, forecasting clinical development budgets, timeline tracking, and liaising across departments for study monitoring & completion.

Passionate about team cohesion, providing solutions for complex issues, maintaining study alignment, and propelling novel science.

PROFESSIONAL EXPERIENCE

Ohana Biosciences- Cambridge, MA

Promoted to Clinical Trial Associate

June 2019- Present

- Leads and collaborates on the day-to-day supervision of all clinical study operations including but not limited to, monitoring, subject eligibility, data management, protocol deviations, investigator/site inquiries and manufacturing.
- Liaises between clinical and lab teams, as scientific and clinical study SME to provide collaborative actions across teams.
- Functions as lead clinical site and monitor trainer, preparing all training materials and providing on-site training to laboratory staff.
- Tracks study metrics and trends using eCRF, monitoring reports, central lab reports and master trackers.
- Prepares study documents and manages completion; protocols, IB, consent forms, IFU/DFU, feasibility questionnaires, etc.
- Oversees CRO & vendor management by facilitating internal audits, co-monitoring, participating in budget & data management meetings, and monitoring the timely filing of essential study documents in eTMF.
- Performs all clinical study related tasks needed.
- Ensures compliance with applicable SOPs and protocols as well as in accordance with ICH GCP and Federal regulations.

Promoted to Clinical Project Associate

January 2019- June 2019

- Coordinated with investigator sites for collection of study materials, to set up site visits, and to facilitate connections with KOLs.
- Executed study tasks, aware of priorities and timelines, and maintained shadow TMF file & trackers.
- Reviewed documents for completeness, accuracy, and compliance with protocol and appropriate regulations.
- Provided support to the study team with various tasks including management of clinical supplies and preparing study metrics, agendas, and minutes.
- Responsible for various tasks including preparing confidentiality agreements, clinical study agreements and reviewing invoices and SOWs.

Flow Cytometry Specialist & Research Associate II

August 2017- Jan 2019

- Sole operator and manager of cell sorter and analyzer.
- Primary point person for flow cytometry vendors and provided significant guidance to research team.
- Led research projects related to sperm quality and fertility in a highly collaborative environment.
- Designed and executed sperm-based assays and presented results to all research staff.
- Provided critical training and supervision to scientists with flow cytometry projects.

X-Chem Pharmaceuticals- Waltham, MA

Biochemistry Research Associate

May 2015- February 2016

- Performed various biochemical assays to determine potency & mechanism of action of unknown compounds
- Prepared assay protocols and calculations.
- Analyzed target proteins with various biophysical assays using Nanodrop, SEC, and various instruments.
- Analyzed data using Excel, Magellan, Prism, etc. and presented data to internal teams and pharma partners.

EDUCATION

Northeastern University
BS in Biochemistry– May 2017

CLINICAL RESEARCH EXPERIENCE

Therapeutic Area	Indication	Phase
Reproductive Endocrinology	IVF, male factor infertility, intracytoplasmic sperm injection, sperm preparation	Phase II
Men's Health & Infertility	Contraception (non-hormonal)	Preclinical

TECHNICAL SKILLS

Electronica Data Capture (EDC)	Oracle, Inform Omni
Clinical Trial Management System (CTMS)	SureClinical, Medidata
Electronic Trial Management (ETMF)	SureClinical
Other:	Microsoft 365 (Excel, Word, Powerpoint), Google workspace
Other:	MedDRA & WHO licensing

TRAINING & CERTIFICATIONS

Year	Course/Title	Provider
2021	GCP for Clinical Trials with Investigational Drugs & Devices	CITI
2021	Phase I Research: Protecting Subjects & Understanding Research	CITI
2021	Protection of Human Subjects	CITI
2021	Biomedical Responsible Conduct of Research	CITI
2020	SureClinical eTMF	SureClinical
2020	Certified Clinical Research Associate	Accreditation Council for Clinical Research & Education
2019	Oracle Inform GTM 5.5 for Sponsors Users	Oracle
2019	ICH GCP	NIDA Clinical Trials Network
2017	GCP- Good Clinical Practice	CITI

CHRIS FOX

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SUMMARY

Entrepreneurial marketing and sales leader with commercialization expertise in start-up and large companies in the laboratory services, and clinical diagnostics industries. Skills and experience include; P&L management, strategic planning, market development, go-to-market strategy, branding & naming, product management, product development and launch (globally & domestically), KOL development, publication strategy, patient advocacy, sales operations, sales training, large account management, billing and reimbursement. Ability to manage with broad, top-level view and in-depth perspective. Strong in analytic and critical thinking skills, and verbal and written communication.

PROFESSIONAL EXPERIENCE

IDbyDNA, INC., SAN FRANCISCO, CA

2017-Present

Head of Marketing

IDbyDNA is an early-phase infectious disease diagnostics startup that has developed new genomic and data analysis technologies to enable more accurate and more comprehensive ID testing. I was recruited to build the commercial organization and its capabilities, launch the first product and prepare the company to for series B financing.

- Created business model, go-to-market strategy, and developed business and marketing plans.
- Developed naming, branding & architecture, positioning, messaging, and created collateral.
- Led the creation and development of commercial processes linking and aligning Sales, Marketing, Client Services, Medical Affairs, Finance, and Lab Ops functions. This included CRM process development and implementation, customer acquisition, sample logistics, laboratory operations (including Laboratory Information System selection and implementation), and billing & invoicing.
- Created product portfolio definition and product pipeline plan.

QUEST DIAGNOSTICS, INC., MADISON, NJ

2015-2017

Director, Women's and Reproductive Health Clinical Franchise, Prenatal Genetics

Recruited to return to Quest to manage a \$150MM P&L for inherited genetic disease testing services. Responsible for the lifecycle management of existing offerings and managing the cross-functional development and market introduction of new genetic test and services.

- Exceeded 2015 volume and revenue goals to achieve the highest attainment numbers for all test portfolios in the W&RH Franchise. Exceeded 2016 plan at 108% and delivered growth to the portfolio for the first time in 4 years.
- Headed product development team responsible for the creation and launch of new products.
- Led a team to drive profitability by reducing waste and driving standardization across sites and technology platforms resulting in ~30% cost savings.
- Headed group charged with addressing reimbursement denials enterprise wide. Developed a program to navigate prior authorizations resulting the collection of \$1MM of additional revenue per year.
- Created commercial plans including lead generation and targeting, sales training, positioning, messaging, print and web-based collateral, KOL development, patient advocacy, and medical education programming.
- Managed strategic partnerships with reference labs and large accounts including pricing and setting terms of agreement.

FOUNDATION MEDICINE, INC., CAMBRIDGE, MA

2013-2014

Associate Director, Marketing

Recruited to this cancer genomics start-up pre-IPO to develop commercial functions including payor marketing, patient advocacy, international marketing, product management and sales operations. The company IPOed in September 2013, raising \$106MM at a valuation of ~\$900MM. Roche acquired a 56.3% stake for \$1.2B in January 2015.

- Launched the FoundationOne[®] Heme assay for hematologic malignancies, sarcomas and pediatric cancers and the FoundationOne[®] solid tumor assay product update. Sales exceeded goal achieving \$9.4MM and 233% year-over-year growth for Q2 2014.
- Created payor engagement and education strategy, international marketing functions and managed patient advocacy and marketing communications before transitioning responsibilities as the team expanded.

- Drove clinical marketing and medical education in concert with the Medical Affairs team to educate and manage relationships with KOLs and customers.
 - Created the company's speakers' bureau and developed medical education capabilities including webinars, company sponsored talks, white papers, and CME programming.
 - Executed clinical meeting strategy; championed USCAP, ASCO, AMP and ASH congresses.
 - Collaborated with R&D and medical affairs functions on publication management strategy.
- Enabled 45-member sales team to increase effectiveness and efficiency to help exceed revenue goals.
 - Worked with the National Accounts team to develop and deliver terms of agreement to facilitate partnerships with large accounts and GPOs.
 - Created CRM capabilities and process automation using salesforce.com; including sales literature fulfillment, meeting exhibition and speaker program execution.
 - Developed and executed sales training program including disease, product, market and competition.

ROCHE TISSUE DIAGNOSTICS (FORMERLY MTM LABORATORIES, INC.) 2009-2013

Recruited to MTM Laboratories, a German IVD start-up, to lead marketing for the US/Canadian subsidiary. Developed the pre-market and prepared a PMA launch for p16 biomarker-based products for cervical cancer (trade name CINtec®). Grew sales 220% Reported to the CEO of MTM Laboratories, which was acquired by Roche in August 2011 for €190MM.

Sr. Manager, Cervical Cancer International Business Team- Roche, TUCSON, AZ 2012-2013

Promoted to aid in integrating MTM's acquired cervical cancer screening products into the Roche portfolio of assays. Headed strategic and clinical-based marketing for the newly created Roche cervical cancer-screening portfolio. Drove organizational changes and provided expertise to enable Roche to market to clinicians, a segment they had previously not addressed.

- Led a cross-business unit collaboration with Roche Molecular Diagnostics to promote a cervical cancer testing portfolio comprised of CINtec® p16 products with the existing Roche cobas® HPV assay to gain market position against competitors.
- Launched new products globally and on-market products into previously unaddressed regions.

Marketing Head, North America –MTM Laboratories, WESTBOROUGH, MA 2009-2012

- Developed resonant branding, positioning and messaging platform based on market research. Delivered a full portfolio of marketing collateral to support communication plan including website.
- Recruited and maintained relationships with KOLs to: publish data, deliver educational programming, serve in advisory roles, and petition organizations to issue guidelines (CAP-ASCCP guidelines issued 8/2012).
- Drove sales force effectiveness. Developed training content, created sales methodology and the hired trainers. Developed CRM system, created account management, and territory planning tools and reports.

QUEST DIAGNOSTICS, INC., MADISON, NJ 2004-2008

Product Manager, Prenatal Genetics (2006-2008)

Promoted to transform a \$150MM, strategically important Prenatal Genetics portfolio with two years of declining sales into a proactive, market-driven, prospering business. Delivered 10% growth and achieved aggressive annual sales targets.

Associate Product Manager, HIV/STD (2004-2006)

Managed a \$240MM product portfolio of HIV and STD tests and services to the office-based physician market. Achieved 8% growth for a mature business that had delivered 6% growth for the prior five years.

MERCK & CO., INC., WESTCHESTER COUNTY, NY 1998 – 2001

Professional Sales Representative

Promoted a \$12MM portfolio of pharmaceutical products to office-based physicians. Consistently achieved and surpassed territory goals.

EDUCATION

MBA Marketing, Mays Business School, Texas A&M University, COLLEGE STATION, TX 2003

- Elected *President* of the MBA Association

BS Biology (Molecular and Genetics), Rider University, LAWRENCEVILLE, NJ 1997

CLAUDIA CREMERS, PHD

Arlington, MA 02474

[LinkedIn Profile](#)

Work authorization: Permanent resident/ US green card holder

734.239.5908

claudiacremers@gmail.com

Bilingual: English/German

PROJECT LEADER-PLATFORM DEVELOPMENT

Energetic, innovative and goal-oriented biochemist/biologist with 10+ years of comprehensive experience in elucidation of protein function, disease mechanism, drug discovery, and project management. Project leader for early drug discovery programs, defining the strategy and implementation of *in vivo/in vitro* models to drive target validation, hit-to-lead, and lead optimization. Experience in building out platforms (cell surface profiling and cell separation) to meet company needs. Advanced expertise in protein production, biochemical/biophysical characterization, and *in vitro* and *in vivo* functional analysis. Passionate about learning and exploring new scientific areas and technologies. Enthusiastic team player and engaging leader, adept at providing nurturing leadership while actively learning from team members, with a proven ability to deliver on goals, advance multiple projects in parallel, and successfully manage multidisciplinary teams.

PROFESSIONAL EXPERIENCE

OHANA BIOSCIENCES (FORMERLY KNOWN AS VL34 INC.), CAMBRIDGE, MA

Reproductive medicine start-up developing products for male fertility enhancement, offspring health and male contraception

PRINCIPAL SCIENTIST, PROJECT LEAD

AUG. 2020 - PRESENT

Leading the platform development efforts for cell surface profiling and cell separation, driving the strategy, hiring, budget and research.

- Leading the team and overall strategy /long range planning for development and use of novel libraries of sperm surface binders enabling detailed profiling of the sperm cell surface (surface profiling)
- Advanced biologics platforms for cell surface profiling using immunization strategies and polyclonal and monoclonal antibody validation (ELISA, FACS); built in-house capabilities for screening technologies (phage display) and binder modification (DNA-barcoding) approaches for paired binding and sequencing technologies (immunoprofiling)
- Leading the cell separation technology team, managing 2 PhD level scientists to provide microfluidic sperm preparation from POC to commercial prototype development using a variety of separation modalities including inertial focusing, droplet fluidics and surface marker dependent separation
- Collaborating effectively across a matrixed research and development team including legal, marketing and manufacturing teammates to drive program strategy and projects forward

SENIOR SCIENTIST, PROJECT LEAD

JAN. 2017 – AUG. 2020

Identification and validation of targets for male contraceptives and offspring health platform, development and implementation of strategy for biologics in pre-clinical stage; spearheading and leading the microfluidic cell separation technology platform.

- Buildup in-house capabilities for protein purification and biochemical/biophysical characterization
- Spearheading multiple early-stage biological target identification campaigns for male contraceptive and offspring health platforms in their conception, target validation, binder generation, and screening and binder validation, resulting in clear Go/No-Go decisions on > 10 targets in pre-clinical stage.
- Directed biologics development; identifying binder development strategies (protein vs peptide, immunization vs display platform campaigns), antigen and binder production, and *in vitro* validation and characterization of identified binders (ELISA, FACS)
- Investigated genotype-phenotype correlation in sperm, which involved isolation of sperm populations using FACS and characterization of resultant populations by quantitative LC-MS/MS
- Launched and directed microfluidic sperm separation technology platform development from idea to conceptualization, initiation and oversight of research collaboration with laboratories at MIT, which led to establishing capabilities in-house, with three team members assessing four different separation approaches
- Hiring, mentoring, training, and directing three junior and experienced scientists through line-management; facilitating their development and advancement while nurturing their independence; leveraging matrix management of junior scientists at a project level to assure that timelines and deliverables are met
- Successfully established and maintained relationships and directed projects with CROs, KOLs and academic groups

CLAUDIA CREMERS, PHD

UNIVERSITY OF MICHIGAN, ANN ARBOR, MI

POSTDOCTORAL RESEARCH FELLOW – BIOCHEMISTRY

AUG. 2012 – AUG. 2016

Investigated the influence of inorganic polyphosphate (polyP) on amyloid fibril formation in various systems from human disease associated amyloids to functional amyloids in bacteria.

- Spearheaded and managed 3 research projects elucidating the (1) *in vitro* effect on polyphosphate on amyloidogenic proteins, (2) influence of polyphosphate on biofilm formation in bacteria, and (3) *ex vivo* amyloid cytotoxicity in mammalian neurons
- Deciphered the influence of small molecule interactions with amyloidogenic proteins using numerous biochemical & biophysical techniques, and developed enzymatic assays to quantify low amounts of polyP in brain samples
- Organized and directed two external academic research collaborations. Internally mentored, trained and directed four junior scientists

UNIVERSITY OF MICHIGAN, ANN ARBOR, MI/TECHNISCHE UNIVERSITÄT MÜNCHEN, MUNICH, GERMANY

VISITING GRADUATE STUDENT RESEARCHER - BIOCHEMISTRY

JAN. 2008 – AUG. 2012

Clarified the function and unfolding mechanism of the molecular chaperone Hsp33; explored chaperone dependent client binding, release, and refolding.

- Developed and implemented biochemical/biophysical/enzymatic assays to determine the molecular folding mechanism of proteins on/with molecular chaperones and developed assays to elucidate Hsp33's physiological role in bacteria
- Collaborated with multiple research groups (internal and external) to achieve research goals
- Trained and mentored 7 undergraduate students and junior researchers to conduct independent research

EDUCATION & TRAINING

Ph.D. in Biochemistry/Molecular Biology , Technische Universität München, Munich, Germany	2012
Diplom (equivalent to MS) in Biology , Leibniz Universität Hannover, Hannover, Germany	2007
Major: Microbiology; Minors: Biochemistry and Virology	
Vordiplom in Biology/Biological Sciences , University of Düsseldorf, Düsseldorf, Germany	2003

SKILLS AND TECHNIQUES

Biochemistry

- Recombinant protein production and purification from various cellular compartments and sources (*E. coli*, mammalian cell culture) using subcellular fractionation, differential density centrifugation, and separation technologies by FPLC (native and affinity purifications, AKTA) and RP-HPLC
- Biochemical characterization of proteins and protein function by UV/visible spectroscopy, circular dichroism (CD) for structural and stability studies, fluorescence spectroscopy and anisotropy, dynamic light scattering (DLS), ELISA (direct and indirect), LC-MSMS analysis (SILAC, HRM, PRM), enzymatic assays (including establishment of medium and high throughput assays), protein-protein and protein-small molecule interaction studies (ForteBio Octet (BLI), isothermal titration calorimetry (ITC), microscale thermophoresis (MST))

Genetics, Molecular and Cell biology

- Culturing and handling of pro- and eukaryotic cells as well as their genetic manipulation (protein overexpression, shRNA)
- Handling and manipulation of primary cells for *ex vivo* analysis
- Cell biology techniques including multicolor flow cytometry and cell sorting (FACS), cell proliferation and viability assays, qPCR, immunofluorescence (IF) localization analysis
- Cell-based assay design and development for functional characterization/readout; screening and testing of biologic hits (medium throughput), immune based and functional assays development

Other Skills

- Validation of microfluidic modalities, 3D-printing
- GraphPad Prism, SigmaPlot, BLAST, ImageJ, Microsoft work suit, Adobe creative cloud, Benchling (ELN), Smartsheets, ASANA
- Working knowledge of many online tools including ExPASy, CDSSTR, Swiss PDB, PyMol, NCBI, UniPort, EcoGene

CLAUDIA CREMERS, PHD

SELECTED PUBLICATIONS

- Bhutani K, Stansifer K, Ticau S, Bojic L, Villani C, Slisz J, **Cremers CM**, Roy C, Donovan J, Fiske B and Friedman R; Widespread haploid-biased gene expression in mammalian spermatogenesis associated with frequent selective sweeps and evolutionary conflict. *Science*, 2021 Mar 5; Vol. 371(6533):eabb 1723
- Moayed F, Bezrukavnikov S, Naqvi MM, Groitl B, **Cremers CM**, Kramer G, Ghosh K, Jakob U, Tans SJ; The Anti-Aggregation Holdase Hsp33 Promotes the Formation of Folded Protein Structures *Biophys. J.* 2020 Jan 7; 118(1):85-95
- Cremers CM**, Knoefler D, Gates S, Martin N, Dahl JU, Lempart J, Xie L, Chapman MR, Galvan V, Southworth DR, Jakob U; Polyphosphate: A Conserved Modifier of Amyloidogenic Processes. *Mol. Cell.* 2016 Sept 1; 63(5):768-80
- Cremers CM**, Knoefler D, Vitvitsky V, Banerjee R, Jakob U; Bile Salts Exert Their Antimicrobial Properties Through Protein Unfolding and *in vivo* Disulfide Stress. *Proc. Natl. Acad. Sci. U S A.* 2014 Apr 22; 111(16); E1610-9
- Gray MJ, Wholey WY, Wagner NO, **Cremers CM**, Mueller-Schickert A, Hock NT, Krieger AG, Smith EM, Bender RA, Bardwell JCA, Jakob U; Polyphosphate is a Primordial Chaperone. *Mol. Cell.* 2014 Mar 6; 53(5):689-99
- Cremers CM**, and Jakob U; Oxidant Sensing by Reversible Disulfide Bond Formation. *J. Biol. Chem.* 2013 Sep 13;288(37):26489-96
- Reichmann D, Xu Y, **Cremers CM**, Ilbert M, Mittelman R, Fitzgerald MC, Jakob U; Order out of Disorder – Working Cycle of an Intrinsically Unfolded Chaperone. *Cell.* 2012 Mar 2;148(5): 947-57
- Cremers CM**, Reichmann D, Hausmann J, Ilbert M, Jakob U; Unfolding of Metastable Linker Region is at the Core of Hsp33 Activation as a Redox –Regulated Chaperone. *J. Biol. Chem.* 2010 Apr 9; 285(15):11243-51

DANA MARIE LORD, PHD

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Phone: (585) 507-6677

Summary of Qualifications

- Protein/antibody engineer and structural biologist with 7 years of demonstrated performance in biologics R&D
- Highly experienced in antibody discovery, protein design/engineering/production, biochemical/biophysical characterization, and structural determination and analysis
- Extensive knowledge of antibody structure and biology
- Cross-functional project and team management in biopharma R&D

Professional Skills

- Leadership: Manager of current protein engineering team; project lead experience of various targets from different therapeutic areas; track record of setting and meeting deadlines, producing deliverables, and communicating results to research leaders and senior management; mentorship experience
- Protein production: Construct design and engineering; molecular cloning and site-directed mutagenesis; expression (*E. coli* and mammalian transient transfections); purification (affinity, ion exchange, SEC, etc.); conjugation and labeling
- Protein characterization: Solubility and aggregation (DLS, SEC-MALS); thermostability and folding (DSF, CD); affinity and kinetics (Western blot, SPR, ELISA, BLI, ITC); *in vitro* functional activity assays
- Antibody discovery: CRO and in-house project management of various antibody campaigns: hybridoma, B-cell cloning, phage display; Project lead experience for both target ID/validation and lead candidate identification
- Structural biology: X-ray crystallography; NMR; SAXS; *in silico* modeling and prediction; structure-based antibody engineering; epitope mapping and analysis; Cryo-EM (data processing)

Experience

2019-Present **Senior Scientist – Principal Scientist, Ohana Biosciences**

- *In silico* sequence and structure analysis, protein construct design/engineering, homology modeling
- CRO management for antibody discovery campaigns, molecular biology, and outsourced protein expression/production
- Manager of protein engineering team including two research associates and a Scientist II
- Lead team to produce all in-house antibodies/antigens and execute protein characterization (QC, developability), binding/screening assays, and *in vitro* functional assays
- Strategy development for target ID, target validation, candidate identification, program timelines, and monitoring of key milestones and decision points

2014-2019 **Scientist – Senior Scientist, Sanofi Genzyme (Protein Engineering, Biologics Research)**

- Purified, characterized (via biophysical and biochemical assays), and optimized constructs of antigens, Fab:antigen complexes, and various other drug target proteins
- Designed and set-up crystallization experiments, collected x-ray diffraction datasets, and completed all steps of structure determination process
- Performed structural analysis for structure-based protein engineering and communicated results to other members in R&D in order to optimize lead therapeutic candidates
- Biologics research lead for Oncology therapeutic area project. Planned antibody discovery strategy and coordinated and contributed to experimental execution. Analyzed data to determine lead candidates for the project team

2009-2014 **Graduate Student, Brown University (Molecular Pharmacology & Physiology)**

The Molecular Basis of MqsR Toxicity in Biofilm Pathogenesis.

- Determined the structure and molecular mechanism of action of multiple biofilm proteins including MqsR/MqsA, GhoS/GhoT, McbR, and BdcA

Education

2009-2014 **Doctor of Philosophy, Brown University**
Molecular Pharmacology and Physiology Graduate Program
Providence, RI
Dissertation Advisor: Rebecca Page, Ph.D

2005-2009 **Bachelor of Science, University of Rochester**
Major: Biochemistry, Minor: Psychology
Rochester, NY

Publications

1. Stefano JE, **Lord DM**, Zhou Y, Jaworski J, Hopke J, Travaline T, Zhang N, Wong K, Lennon A, He T, Bric-Furlong E, Cherrie C, Magnay T, Remy E, Brondyk W, Qiu H, Radošević K. (2020). A highly potent CD73 biparatopic antibody blocks organization of the enzyme active site through dual mechanisms. *Journal of Biological Chemistry* 295(52):18379-18389.
2. Ramasubramanian A, Tennyson R, Magnay M, Kathuria S, Travaline T, Jain A, **Lord DM**, Salemi M, Sullivan C, Magnay T, Hu J, Bric-Furlong E, Rival P, Zhou Y, Hoffmann D, Brondyk W, Radošević K, Chowdhury PS. (2020). Bringing the Heavy Chain to Light: Creating a Symmetric, Bivalent IgG-Like Bispecific. *Antibodies* 9(4):62.
3. Wu L, Seung E, Xu L, Rao E, **Lord DM**, Wei RR, Cortez-Retamozo V, Ospina B, Posternak V, Ulinski G, Piepenhagen P, Francesconi E, El-Murr N, Beil C, Kirby P, Li A, Fretland J, Vicente R, Deng G, Dabdoubi T, Cameron B, T Bertrand, Ferrari P, Pouzieux S, Lemoine C, Prades C, Park A, Qiu H, Song Z, Zhang B, Sun F, Chiron M, Rao S, Radošević K, Yang Z, Nabel GJ. (2020). Trispecific antibodies enhance the therapeutic efficacy of tumor-directed T cells through T cell receptor co-stimulation. *Nature Cancer* 1, 86–98.
4. **Lord DM**, Bird JJ, Honey DM, Best A, Park A, Wei RR, Qiu H. (2018). Structure-based engineering to restore high affinity binding of an isoform-selective anti-TGFβ1 antibody. *mAbs* 10(3):444-452.
5. Zhang R, **Lord DM**, Bajaj R, Peti W, Page R, Sello JK. (2017). A peculiar IclR family transcription factor regulates para-hydroxybenzoate catabolism in *Streptomyces coelicolor*. *Nucleic Acids Research* 46(3):1501-1512.
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8. **Lord DM**, Uzgoren Baran A, Wood TK, Peti W, Page R. (2014). McbR/YncC activates biofilm formation through its function as a GntR transcriptional regulator. *Biochemistry* 53(46):7223-31.
9. **Lord DM**, Uzgoren Baran A, Wood TK, Peti W, Page R. (2014). BdcA, a protein important for *Escherichia coli* biofilm dispersal, is a short-chain dehydrogenase/reductase that binds specifically to NADPH. *PLoS One* 9(9): e105751.
10. Wang X, **Lord DM**, Hong SH, Peti W, Benedik MJ, Page R, Wood TK. (2013). Type II Toxin/Antitoxin MqsR/MqsA Controls Type V Toxin/Antitoxin GhoT/GhoS. *Environmental Microbiology and Environmental Microbiology Reports* 15(6):1734-44.
11. Brown BL, **Lord DM**, Grigoriu S, Peti W, Page R. (2012). The *E. coli* toxin MqsR destabilizes the transcriptional repression complex formed between the antitoxin MqsA and the *mqsRA* operon promoter. *Journal of Biological Chemistry* 288(2):1286-94.
12. Wang X, **Lord DM**, Cheng HY, Osbourne DO, Hong SH, Sanchez-Torres V, Quiroga C, Zheng K, Herrmann T, Peti W, Benedik MJ, Page R, Wood TK. (2012). A new type V toxin-antitoxin system where mRNA for toxin GhoT is cleaved by antitoxin GhoS. *Nature Chemical Biology* 8(10):855-61.

Oral Presentations

1. Structure-Based Engineering to Restore High Affinity Binding of an Isoform-Selective Anti-TGF β 1 Antibody. Discovery on Target: Antibodies Against Membrane Protein Targets, Boston, Massachusetts, September 2017.
2. Structural insights into a novel mechanism of toxicity and neutralization of MqsR, a ribonuclease toxin. American Crystallographic Association, Honolulu, Hawaii, July 2013.

Poster Presentations

1. **Lord DM**, Zheng K, Peti W, Page R. Structural and functional analysis of a novel antitoxin, GhoS. New York Structural Biology Discussion Group, New York, New York, January 2012.
2. **Lord DM**, Page R. Elucidating key regulators in biofilm formation and dispersal. XXII Congress and General Assembly of International Union of Crystallography, Madrid, Spain, August 2011.

Daniel T.-N. Chen, Ph.D.

Cambridge, MA | (267) 258-6003 | dan.chen@gmail.com | [linkedin](#) | [GoogleScholar](#)

SUMMARY:

- Computational Biologist with significant wetlab experience
- Expertise in data analysis/visualization, machine learning, quantitative imaging, laboratory informatics architecture
- Seeking research opportunities at the intersection of biotech, Machine Learning, and AI

EDUCATION:

Ph.D., Physics, **University of Pennsylvania** 1999-2010

B.A., Physics, **University of California Berkeley** 1994-1998

EXPERIENCE:

Ohana Biosciences Inc., Cambridge, MA Feb 2019 – April 2021
Senior Scientist, Computational Biology

- Developed machine learning approaches for analysis of sperm motility image data from ideation to clinical stage, resulting in successful clinical trial execution and 1 patent filing
- Partnered with Clinical team to analyze trial outcomes, including subgroup analyses and surfacing latent signals
- Partnered with experimentalists across multiple research teams to develop bespoke data analysis and visualization pipelines for data types including Flow Cytometry, Quantitative Imaging, Microfluidics, and Metabolomics
- Spearheaded onboarding of Benchling ELN and build out of automated data analysis pipelines

Confer Health Inc., Boston, MA Mar 2017 – July 2018
Senior Scientist

- Technical lead in developing clinical-grade immunodiagnostic assay with application in next-generation pregnancy testing
- Experience working under QMS adhering to FDA medical device regulatory guidelines, SOP creation
- Experience working in cross-functional teams in pre-clinical trial planning and execution

Luminova Inc./Harvard University, Cambridge, MA Nov 2016 – June 2017
Imaging Data Consultant

- Delivered bespoke machine learning pipeline in Matlab to automate detection and classification of images of embryonic cell division state
- Predicted cell division state with ~85% accuracy using deep neural network in Python TensorFlow

Brandeis University, Dept. of Physics, Waltham, MA

Sept 2010 – Nov 2016

Postdoctoral Fellow - Advisors: Zvonimir Dogic & Daniela Nicastro

- Lead interdisciplinary studies in sperm motility and biomolecular materials with extensive publication track record (2 first author, 2 co-authored), including mentoring graduate and undergraduate student thesis research.
- Director of Light Microscopy Facility for 7-optical microscope facility with 20 users

University of Pennsylvania, Dept. of Physics, Philadelphia, PA

Sept 1999 – Aug 2010

Research Assistant – Advisor: Arjun G. Yodh

- Experimental and Computational research centered on rheology and biophysical characterization of soft materials.
- 7 publications (4 first author, 3 co-author)

SKILLS:

-
- **Laboratory:** Microscopy (Fluorescence, Confocal), Microfluidics, Rheology, Assay Development, Protein Purification, Bioconjugation Chemistry
 - **Computational:** Python (pandas, numpy, scikitlearn, JupyterLabs), R (tidyverse, shiny), Matlab, SQL, Linux shell scripting, AWS Serverless (Lambda, S3, API Gateway), Benchling API + Insights

SELECTED PUBLICATIONS (13 TOTAL, >3000 CITATIONS):

D.T.N. Chen, M. Heymann, D. Nicastro, S. Fraden, Z. Dogic.. ATP Consumption of Eukaryotic Flagella Measured at a Single-Cell Level. *Biophys. J.* 109 (12): 2562 (2015)

T. Sanchez*, **D.T.N. Chen***, S. Decamp*, M. Heymann, Z. Dogic. Spontaneous Motion in Hierarchically Assembled Active Matter. *Nature* 491: 431-434 (2012) (* Equal Contribution)

D.T.N. Chen, Q. Wen, P. A. Janmey, J.C. Crocker, A.G. Yodh. Rheology of Soft Materials. *Annual Review of Condensed Matter Physics* 1: 301-322. (2010)

K. T. Wu, J.B. Hishamunda, **D.T.N. Chen**, S.J. DeCamp, Y.W. Chang, A. Fernández- Nieves, S. Fraden, Z. Dogic. Transition from turbulent to coherent flows in confined three-dimensional active fluids. *Science*, 355(6331) (2017)

PATENTS:

Magnetic Particle-based Immunoassay and methods of using the same (US Patent App 16750629 , published 5-21-2020)

Methods for screening sperm for assisted reproduction (US Patent App 16878471, published 3-4-2021)

Dave McManus

SUMMARY

Multi-dimensional, strategic-minded, proactive leader with a hands-on operational style. Passionate in building and transforming organizations in high-growth, fast-paced environments. Nearly 20 years of delivering high-quality results in public accounting and privately-held life science companies. Experience in private equity & debt fundraising, M&A transactions, initial SEC registration, and post-acquisition integrations. Keen ability to operate effectively under time restraints, with a high-level of attention to detail. Certified Public Accountant, Massachusetts license # 23486 (inactive).

EXPERIENCE

January 2011 – Present

Good Start Genetics, Inc.
(acquired by Invitae Corp., August 2017) - Cambridge, MA
Executive Director, Corporate Controller
\$40M+ annual revenues, ~150 employees at peak

- Joined early stage (employee #11) as the company's Finance leader; reporting to CEO; served in capacity until CFO was hired in 2012. Interim head of finance from July 2015 - January 2016 during search for a new CFO. During course of tenure had either direct oversight or shared responsibilities of billing & reimbursement, human resources, IT, and facilities management. Served in officer roles as Treasurer and Secretary.
- Significant contributor to evaluation and diligence on exit opportunities which led to the acquisition of Good Start Genetics by Invitae Corp. (NYSE: NVTA) in August 2017. Retained by Invitae post-acquisition, leading the successful integrations of finance and billing functions, as well as providing key support for ongoing consolidation of the companies across all operations.
- Routinely interfaced and served as "key business partner" with all functions within the company. Converged with corporate development and other senior leaders to analyze strategic opportunities. Recently led the development & implementation of a billing service enhancement which delivered 20%+ unit volume growth immediately following launch in January 2017, propelling the company to a position for exit.
- Significant contributor to securing \$14M Series B (2012), total \$57M of debt (2012 – 2017).
- Extensive involvement in confidential S-1 filing, including secondary filings; IPO foregone for continued private funding (2014).
- Created and maintained company's accounting infrastructure, including policies and processes, internal controls, financial planning & reporting; evolved from a pre-commercial setting to accommodate accelerated growth featuring multiple products and markets, reaching \$40+ million annual revenues within three years following initial commercial launch.
- Lead monthly financial statement closing processes, including MD&A commentary, enabling consistent distribution of financial reporting packages to the Board of Directors, investors, and management within 10 business days following month-end.
- Primary interface with external auditors, consistently delivered high-quality financial statements with unqualified opinions.
- Coordinated annual budgeting, periodic forecasting, and long-range financial planning exercises.
- Regularly interacted with investors, Board of Directors, and Audit Committee, including presenting at meetings.
- Managed all tax compliance and filings, including income, excise, franchise, sales & use taxes; also oversaw insurance and risk management, debt covenant and reporting obligations, equity and stock options, and 409(a) valuations.
- Trustee and Plan Administrator for 401(k) plan; member of internal committee evaluating employee compensation programs and benefits.

August 2008 – December 2010 **VisEn Medical Inc.**
(acquired by PerkinElmer, Inc., July 2010) - Bedford, MA
Controller
\$10-\$20M annual revenues, ~50 employees

- Alongside the CEO & CFO, contributed to the successful completion of acquisition by PerkinElmer, Inc. (NYSE: PKI) in July 2010.
- Interfaced significantly with external parties and managed due diligence process leading up to the successful close of merger transaction.
- Played a key role in several equity financing rounds totaling \$10 million, as well as involvement in various corporate strategic partnership projects.
- Managed the daily accounting & finance operations, including sales and revenue recognition, purchasing, cash and banking management, receivables collections, inventory/cost accounting, payroll, and foreign subsidiary transactions.
- Conducted monthly and annual financial statement closing processes, and prepared financial reporting packages for distribution to senior management.
- Directed the annual financial statement audit; lead a project to complete four years of audits within 6 months in connection with obtaining debt financing.
- Coordinated the annual budgeting and periodic forecasting processes.
- Managed other significant areas within the accounting & finance function, including tax and regulatory compliance, foreign subsidiary administration and statutory reporting compliance, insurance and risk management, debt covenant and reporting obligations, equity and stock options, and 409(a) valuations.
- Developed and implemented the initial set of policies and procedures to provide structure and internal controls consistent with the company's size and maturity.
- Oversaw the outsourcing of the Information Technology function and managed the relationship with the third-party service provider.

January 2001 – August 2008 **Sullivan Bille, P.C. – Tewksbury, MA**
Manager, Audit (2006 – 2008)
Senior and Staff Accountant, Audit (2001 – 2006)

- Directed and executed financial statement audits for privately-held entities within the manufacturing and biotech/life sciences fields, with revenues up to \$100 million.
- Supervised, developed and trained staff consisting of approximately 10 C.P.A.'s.
- Interacted with clients at senior executive and board/audit committee levels.
- Prepared and presented audit reports and constructive internal control recommendations to officers and directors at clients.
- Responsible for interpretation and communication of changes to accounting and auditing standards for the firm through the preparation of memos and seminars.
- One of the youngest in firm's history to be promoted to Manager.

EDUCATION **University of Massachusetts, Lowell - Lowell, Massachusetts**
Bachelor of Science – Accounting (2000)

Doris Le

doris.le95@gmail.com ▪ www.linkedin.com/in/doris-le ▪ (561) 543-4477

Professional Summary

Detail-driven, highly adaptable project manager with experience in hands-on biologics research and chemical engineering. Skilled in building project plans, creating timelines, managing meetings, and tracking progress, resources, risks, and milestones across diverse projects in fast-paced, dynamic environments. Most recent experience in a clinical-stage biotech working on cross-functional teams in a matrix organization. Committed to solving tough problems by applying a strong work ethic, putting the team first, communicating effectively, and fostering a positive work atmosphere.

Skills include:

Project management apps (Smartsheets, Asana)	MS Office Suite	Google Suite
Written, verbal communication	Performance tracking	Project scheduling
Time management	Meeting facilitation	OnePager Express

Experience

Ohana Biosciences, Inc.

Project Management Associate

Cambridge, MA

March 2019 – Present

Managed project aspects for two cross-functional teams – R&D and Commercial – as well as the organization's portfolio.

- Generated and updated a monthly portfolio report detailing milestones, risks, and mitigation strategies by communicating with leaders across two R&D programs and five research projects.
- Collaborated with Program Director to manage an 18-member research team. Developed and maintained project schedules, facilitated research and strategy team meetings, and compiled and managed meeting documentation.
- Coordinated Commercial product launch team by maintaining project schedule in Smartsheets, building automated dashboards, facilitating meetings and their documentation, and tracking key activities and issues across eight functions.

Senior Research Associate, Antibody Therapeutics

July 2018 – Present

Played major role as project lead and team member in antibody therapeutic hit-to-lead and lead optimization programs.

- Advanced methods for antibody binding and functional screening on two different primary cell types from various species and tested 100+ antibodies across four targets to support Ohana's contraception program.
- Developed, optimized, and validated flow cytometry, immune-cell killing, and bead-based assays to measure and characterize cellular heterogeneity and drive technical proof-of-concepts to support four projects spanning two programs.
- Trained team members across several teams on these techniques as a reliable source of high-quality data and expertise.

Research Associate

September 2017 – July 2018

- Established robust methods for antibody staining and detection by flow cytometry, cell sorting, and immunofluorescence (IF) microscopy by testing multiple antibodies across 10+ targets.
- Expressed, purified, and tested scFvs by ELISA, IF microscopy, and flow cytometry.

Wits University, HIV Pathogenesis Unit

Intern, Biochemistry

Johannesburg, South Africa

June 2017 – August 2017

- Analyzed the biophysical modifications of a redox-exchanged CD4 variant by amide hydrogen-deuterium exchange mass spectrometry to measure induced changes in conformational dynamics. Coauthored one publication.
- Expressed, purified, and characterized several broadly neutralizing HIV antibodies by ELISA and western blot.

David H. Koch Institute for Integrative Cancer Research, Wittrup Lab

Undergraduate Researcher, Protein Engineering

Cambridge, MA

January 2014 – June 2017

- Established library design criteria to improve clinical developability of antibodies. Coauthored two publications.
- Combined yeast surface display and noncanonical amino acids to establish a high-throughput, versatile new method that can be used to develop and characterize bioconjugates, leading to coauthor in publication.

Sanofi Genzyme (through Pro-Unlimited)
Intern, Biological Mass Spectrometry

Framingham, MA
May 2016 – August 2016

- Designed and implemented experiments independently to investigate mass spectrometry as an alternative method for assessing N-terminal residues of proteins.

Visterra Inc.
Intern, Protein Engineering

Cambridge, MA
June 2015 – September 2015

- Established methods for the generation of yeast surface display libraries for antibody discovery and developed mammalian cell-based assays for high-throughput screening and qualitative analysis of candidate antibodies.

Education & Certifications

PMP certification
(In progress)

Project Management Institute
Expected September 2021

Massachusetts Institute of Technology
Bachelor of Science in Chemical Engineering

Cambridge, MA
September 2013 – June 2017

Publications

Owen, G. R., **Le, D.**, Stoychev, S., Cerutti, N. M., and Papathanasopoulos, M. (2018) Redox exchange of the disulfides of human two-domain CD4 regulates the conformational dynamics of each domain, providing insight into its mechanisms of control. *Biochemical and Biophysical Research Communications* 497, 811–817.

Kelly, R. L., **Le, D.**, Zhao, J., and Wittrup, K. D. (2018) Reduction of Nonspecificity Motifs in Synthetic Antibody Libraries. *Journal of Molecular Biology* 430, 119–130.

Kelly, R. L., Zhao, J., **Le, D.**, and Wittrup, K. D. (2017) Nonspecificity in a nonimmune human scFv repertoire. *mAbs* 9, 1029–1035.

Van Deventer, J. A., **Le, D. N.**, Zhao, J., Kehoe, H. P., and Kelly, R. L. (2016) A platform for constructing, evaluating, and screening bioconjugates on the yeast surface. *Protein Engineering, Design and Selection* 29, 485–494.

Elma Feric Bojic, PhD

Arlington, MA | 617.645.9879 | elma.feric@gmail.com | www.linkedin.com/in/elmaferic/

Summary

- Creative and curious scientist with 15 years of small molecule therapeutic development and discovery research experience in academia and industry.
- Proven track record of project management and independent design, validation and execution of *in vitro* (molecular, cellular, and electrophysiological) assays that supported discovery and advanced lead compounds into development.
- Managed teams and platform design to support research and discovery efforts while continuously meeting deadlines months ahead of time.
- Strategic thinker with demonstrated ability to manage cross-functional and multi-center collaborations in a fast-paced and dynamic setting.
- Passionate about enhancing scientific research as a way to improve patient lives.

Relevant Work Experience

Scientist II

September 2019 – Present

Ohana Biosciences, Cambridge, MA

- Project team lead identifying types and sources of DNA damage in sperm as possible diagnostic and/or prognostic biomarkers to enable go/no go decisions. Continuously enable program progression ahead of deadlines.
- Develop *in vitro*, biochemical, molecular and cellular assays to evaluate potential biomarkers and characterize them for potential therapeutic activity.
- Participate on cross-functional project teams and collaborate on multiple projects to help identify non-invasive marker for sperm quality and support assay implementation.
- Support and manage external collaborations.
- Direct and indirect supervision of research staff, continuously ensuring smooth integration into company culture and career development.

Laboratory Head and Graduate Researcher

September 2014 – October 2018

International Burch University Department of Genetics and Bioengineering, Sarajevo, Bosnia and Herzegovina

- Supervised research staff (5 researchers and 20 undergraduate volunteers) outlining all daily activities to support research and publication goals.
- Established and ensured adherence to ISO standards for all laboratory procedures that enabled safer and more efficient use and sharing of lab space and improved communication among scientific staff.
- Communicated with external experts to ensure optimal equipment functioning that lowered laboratory expenses by 30 – 40%.
- Designed laboratory exercises, student lesson plans, lessons, and syllabi for several courses during the semester and the entire academic year.
- Lectured up to five department courses per semester. Consistently maintained high student ratings.

Visiting Doctorate Fellow

May 2016

University of Wurzburg Center for Mental Health, Wurzburg, Germany

- Generated project timelines and budgets; established processes to streamline workflow to ensure execution within budget and in a decreased time by 50%.
- Responsible for coordinating a multicenter collaboration between five locations in Europe ensuring task execution as a subject matter expert.
- Planned and established standardized patient blood collection and performed DNA extractions of 700+ samples that enabled further genetic analyses of 20 novel genetic markers.
- Designed genetic experiments to genotype DNA from PTSD patients' blood that drove characterization of 20 novel mutations and 10+ scientific publications.

Associate Scientist

March 2010 – July 2014

Senior Research Associate

May 2008 – March 2010

Amgen Inc. Department of Neuroscience, Cambridge, MA

- Designed and validated manual patch clamp and automated electrophysiology assays using various high-throughput and low-throughput platforms (PatchXpress, IonWorks Quattro and Barracuda, IonFlux) that enabled the advancement of 2 lead compounds into development.
- Designed and executed molecular and cellular biology assays that enabled discovery efforts and better understanding of disease target.
- Independently developed and validated the team's first Dynaflo Resolve System to overcome sticky compound issues and enabled higher manual patch throughput.
- Established Amgen's first IonFlux platform from the ground up and enabled validation and testing of fast ligand-gated targets.
- Successfully supported several drug discovery projects within pain-related biology by implementing assays that effectively investigated the effects of potential lead compounds on ligand and voltage gated ion channels.
- Managed workflow and communicated resources across the team.
- Trained five team members in molecular biology and electrophysiology techniques.
- Effectively communicated scientific data and timelines via presentations to a broad range of audiences.

Staff Scientist

June 2005 – May 2008

Massachusetts General Hospital/Harvard Medical School Department of Molecular Biology, Boston, MA

- Developed, designed, and conducted molecular biology research projects that resulted in second-author publication within one year.
- Supported instrumentation, data management, laboratory operations and general administration.
- Trained research assistants and post-doctoral students in pertinent experimental and laboratory procedures and advised on optimal use of methodology and equipment.

Education

PhD, Genetics & Bioengineering	(2017) – International Burch University
MS, Biotechnology	(2013) – Harvard University
BA, Neuroscience, BA in Psychology	(2005) – Brandeis University

Techniques, Software & Instrumentation

Molecular Biology

- RNA and DNA isolation
- cDNA synthesis
- PCR, primer and vector construction
- Q-PCR
- RT-PCR
- DNA sequencing
- Northern and Southern blots
- Morpholino construct and microinjections

Cell Biology

- Flow cytometry
- Cell signaling assays

Gene Editing

- Transfections, Cloning

Proteins

- Western blots
- Antibody characterization
- SDS-PAGE
- Protein extraction

Cell Culture

- Mammalian cells (acutely dissociated as well as cultured)
- Stable cell line generation
- Lentivirus generation and transduction on cell lines

Imaging

- Confocal microscopy
- Live cell time-lapse imaging
- Epifluorescence
- Immunohistochemistry

Electrophysiology

- Manual
- Automated (PatchXpress, IonFlux, IonWorks)
- Current/voltage relationships of acutely dissociated and cultured mammalian cells
- Slices

Anatomy/Surgeries

- Tissue Cryo, Vibratome sectioning
- Microsurgeries
- Nerve ligation surgeries
- Vertebrate dissection

Animal Handling

- Mouse, Rat handling
- Frog injections, egg harvest
- Zebrafish, Frog handling

Affiliations &/ Hobbies

- Avid runner, biker, swimmer who actively participates in triathlons.
- Founded Amgen biking club and scheduled weekly training rides and arranged group discounts at local vendors for Amgen cycling club members.
- Undercover artist whose doodles/sketches have been featured at a local café.
- European/American polyglot who is fluent in three languages (English, Bosnian, German) and who is unafraid to explore and look for beauty all over the globe.

Emily Rogers

esdrogers@yahoo.com | 802-272-6736 | Shrewsbury, MA

SUMMARY

Creative and thoughtful People Operations Coordinator with 1+ years of experience at an early-stage biotech company. Experienced in building team culture, talent discovery, and onboarding along with administrative duties. Looking for opportunities to grow in HR and work towards a SHRM certification.

EDUCATION

Lasell College

Bachelor of Science, Hospitality and Event Management, cum laude

Newton, MA

September 2006 - May 2010

SKILLS

Google Suite, Microsoft Office Suite, ADP, US Able Life, EVerify, Lever, LucidChart, Asana, Canva, Slack, Box, Prendio

PROFESSIONAL EXPERIENCE

Ohana Biosciences

People Operations Coordinator

Cambridge, MA

February 2020 - Present

Culture & Engagement

- Beginning in March 2020, partnered with VP of People, VP of IT, and People team to evolve approach to connecting Ohanites across the company, launching touchpoints including weekly Town Halls, bi-annual Wellness Challenge, summer Storytime/STEAM activities for families & more.
- Organized and facilitated our first Wellness Challenge in July 2020. Researched and programed an app with activities for the mind, body, and connection to others. Organized teams, shared registration and challenge details, tracked points and awarded individual and team prizes. The Wellness Challenge is now a bi-annual event with prizes alternating between physical prizes for Ohanites, and donations to local charities on behalf of winning teams.
- Partnered with Talent Discovery & People Operations Manager and StoriTel (external consultant) to create Ohana's core value icons and social media templates.
- Assisted with analyzing employee engagement through bi-annual Pulse Surveys and annual Culture Survey.
- Scheduled and actively participated in employee "Collectives" focused on People, Culture, and Events.
- Assisted with launching our DE&I Collective in late 2020 and became co-leader of this collective in April 2021.
- Organized and promoted volunteer opportunities with Life Science Cares through our DE&I Collective.
- Organized virtual going away parties and baby showers for Ohanites. Collected well wishes and memories from others and compiled these into books and cards as mementos.
- Researched companies and pricing for Ohana Swag. Compiled options and placed orders for general swag, prizes, and holiday "cozy boxes".

Talent Discovery

- As part of the Talent Discovery team, contributed to hiring 15+ employees during a time of rapid growth in a highly competitive talent market.
- Collaborated with Senior Talent Discovery Partner, Talent Discovery & People Operations Manager and external agencies on a variety of searches across levels and disciplines.
- Managed Ohana's job postings on Lever (Ohana's candidate management platform), Massbio, and LinkedIn.
- Utilized Lever to screen candidate applications and move them through the hiring process.
- Ensured a high-touch candidate experience differentiating Ohana from competitors. Scheduled video screens, interviews and sent candidates detailed schedules along with CDA's to sign.
- Shared our culture story during interviews, facilitated phone screens and reference checks.

Onboarding & Benefits

- Responsible for all new hire onboarding transactions, using ADP, E-Verify, and USABLE Life.
- Ran the new hire orientation program virtually to set up new hires for a smooth launch: explained benefits offerings, culture collectives, and integration agendas.
- Prepared new employee files, ensuring all required documentation was collected and maintained.
- Partnered with VP of People, Senior Talent Discovery Partner, VP of IT, and People team to evolve and adopt the onboarding program to virtual environment due to COVID-19.
- Facilitated short-term disability claims with USABLE Life, followed up to ensure claim payments.
- Assisted with off-boarding employees, including preparing separations documents, compiling information for employee folders, terminating accounts in USABLE Life and Lever, and scheduling exit interviews.

Administrative

- Partnered with Office Manager, IT, EA/Office Manager and People team to execute seamless office move in Sept. 2020.
- General administrative duties for the VP of People, Talent Discovery & People Operations Manager, Senior Director of Regulatory Affairs, and Senior Director of Marketing. Including complex scheduling with external vendors, sending and tracking CDA's, and daily calendar management.
- Organized catering for an outdoor event with 110 take home meals for employees and their families.
- Submitted purchase orders and invoices to facilitate payments for swag, trainings, external vendors.
- Created a variety of materials on Canva to promote social events, trainings, our Wellness Challenge, etc.
- Ordered snacks for the office and coordinated Instacart deliveries with the on-site Manager.

Legal Sea Foods

Private Events Sales Manager

MA, NJ, PA, ATL

August 2014 - January 2020

- Annual Sales Volume: \$2M individually/\$8M company wide.
- Contracted 1000+ events per year ranging from small intimate dinners to full restaurant buy-outs.
- Managed event calendars for 9-13 restaurants including multiple out of state locations.
- Responsible for capturing leads, planning menu and event details, creating an excellent guest experience.

- Developed and implemented a training program for Restaurant Management and event staff.
- Sourced outside vendors for enhancements to guests' experiences.
- Created and implemented catering menu to drive sales outside of the restaurant.
- Prospected MLB Team Dieticians to generate \$50,000 in catering sales to Fenway Park in 2019.
- Researched Pharmaceutical laws and designed compliant menus to increase Pharma sales to \$120,000 in 2019.
- Invoiced and collected payments for Corporate Accounts.

Legal Sea Foods*Assistant General Manager***South Shore, Dedham MA***August 2013 - August 2014*

- Assisted with new restaurant openings at Lynnfield C Bar and Hingham C Bar.
- Trained and developed multiple Managers in Training.
- Responsible for interviewing, hiring, orientation, new hire paperwork, training, and developing staff.
- Managed weekly SLF and DLC reports; build FOH Schedules based on forecasts.
- Oversaw Private Dining Events, ensured proper staffing, menu item availability, successful Event execution.
- Managing guest complaints effectively and efficiently.
- Uphold safety, sanitation, and food quality standards at all times.
- Responsible for the Host and Server Assistant schedules.
- Promoted teamwork and sales building by coaching teams to reach goals.

Legal Sea Foods*Restaurant Manager, South Shore, Dedham, Framingham, Chestnut Hill**March 2012 - August 2013**Key Associate, Legal Sea Foods, Braintree, MA**January 2011 - March 2012**Hostess/ Server Legal Sea Foods, Chestnut Hill, MA**August 2009 - January 2011*

References are readily available upon request.

Eric R. Shen

eshen918@gmail.com • (908) 447-3026 • Boston, MA

Summary

A results-oriented business professional that is passionate about the intersection of healthcare and technology, with a continued appetite to acquire new skills while refining existing ones. Well-versed in organizational development, strategic planning, and new opportunity evaluation with experience in partnerships, licensing & operations. Key strengths include: analysis-based decision-making, driven temperament, applicable problem solving, meticulous planning, and execution.

Experiences

Ohana Biosciences, Inc.
(A Flagship Pioneering Company)

Boston, MA
Sept 2019 - Present



ASSOCIATE DIRECTOR, STRATEGIC & OPERATIONAL EXCELLENCE (Sept 2020 – Current)
SENIOR MANAGER, STRATEGIC & OPERATIONAL EXCELLENCE (Sept 2019 – Sept 2020)

- › Managing updates to the company's short term (1-2 years) & long term (5+ years) strategies through functional collaboration to convey key inflection points / milestones, assumptions, risks, and interdependencies identified.
- › Influencing the development of investor and sell-side tactics with key executive stakeholders including the CEO.
 - Establishing workstreams with executive team members leading to the creation and maintenance of key strategic documents dictating the company's approach on a granular level for diligence via data room.
 - Monitoring interactions by continuously updating backgrounders, conversations, and firm activities through a relational database of 200+ firms developed on Air Table.
 - Continuously refining corporate positioning and messaging flow by proposing new ideas for key strategic materials based off feedback gathered from various internal and external parties.
- › Organizing and driving the rhythm of decision making and outputs of leadership team to update the board of directors on key corporate initiatives and decisions made each quarter.
- › Maintaining a foundational knowledge base of the research projects from concepts to data outputs by facilitating weekly strategic R&D meetings to translate learnings into informational updates to the leadership team.
- › Leveraging project management & business improvement capabilities to monitor progress of all ongoing activities, prioritizing based on need, and implementing course corrections when necessary.
- › Building business cases and business development pitches based on competitive intelligence searches and analysis through various functional lenses ultimately leading to a proposal / recommendation to leadership.

Pear Therapeutics, Inc.
Boston, MA
Jun 2016 – Sept 2019



SENIOR ASSOCIATE, CORPORATE DEVELOPMENT (Jan 2019 – Sept 2019)
ASSOCIATE, CORPORATE DEVELOPMENT (Apr 2018 – Jan 2019)
BUSINESS OPERATIONS ANALYST (Jun 2016 – Apr 2018)

- › Evaluated deliverables in the form of comprehensive business cases to support inbound and outbound deal execution leading to partnerships across big pharma, private companies, and academic institutions.
 - Produced 30+ potential digital therapeutic use cases through analysis of the current landscape of post-POC therapeutics, sensors, and software algorithms prioritized based on current clinical data, intellectual property, technical capabilities, commercial opportunity, and platform integration feasibility.
 - Due diligence through qualitative and quantitative assessment of potential opportunities (Financial modeling, deal comparables, TPP generation, high level market research, competitive positioning & pricing analysis).
- › Gathered and synthesized cross-functional input across relevant internal core teams and departments for presentations, proposals, budgets, and other strategic corporate documents for board members & executives.
- › Conducted comprehensive portfolio strategies consisting of examining ~30 disease areas for potential commercial opportunity based on unmet needs within the industries, potential partners, and revenue potential.
- › Keeping a detailed knowledge base of digital health companies and current deal landscape (pharma to financing) by generating monthly competitive intelligence reports, reviewing analyst research, and attending conferences.
- › Managed 30+ due diligence discussions and routinely updated documentation related to diligence including patent and trademark portfolio refreshes with IP counsel and periodic updates to content being disclosed by department.
- › Drove territory sizing for reSET® & reSET-O®'s commercial team by data analysis of billing codes via physician group data bases to understand key accounts to focus on that would allow for efficient penetration of the market.
- › Supported De Novo and 510K Submission of reSET® & reSET-O® leading to the market authorization of the first and second prescription digital therapeutic with claims by the FDA.
- › Spearheaded various ad-hoc strategic projects exclusively with the CEO including potential expansion opportunities, new product ideation, etc.

Education

Brandeis University
Waltham, MA

BACHELOR OF ARTS (BA) – BIOLOGY; MINOR IN BUSINESS

Aug 2012 – May 2016

Extracurricular Activities

- › **TAMID Pro:** Mentor
- › **Brandeis University Varsity Fencing Team:** Saber Fencer
- › **Brandeis TAMID Club:** Member of the Fund
- › **Jewish Big Brothers Big Sisters of Greater Boston:** Mentor
- › **Old Silver VC:** Venture advisor making investment recommendations for early stage startups focused on biotech, digital health, artificial intelligence, and material sciences. Founded by Michael Langer.
- › **Medical Marvels:** Fundraising support to develop an IMAX film which highlights character-driven stories of patients and scientists and the important medical breakthroughs made.
- › **MassChallenge:** US online judge to evaluate the startup applications for the Austin, Boston, Houston and Rhode Island accelerator programs.
- › **Member, Board of Trustees – The Charlesview Condominiums:** Operationally refining decision making processes related to risk analysis, vendor selection, prioritization of usage of funds, and communication to stakeholders of the property.

Publications

- › **Draft genome of the most devastating insect pest of coffee worldwide: the coffee berry borer, *Hypothenemus hampei*** (<https://www.nature.com/articles/srep12525>)

Skills

- › **Languages:** English (Native), Mandarin Chinese (Intermediate)
- › **Data Analysis:** Biopython, MEGA 6.06, Clustal X 2.1, IGV 2.3.34, Prism
- › **Design:** Adobe Photoshop, Adobe Illustrator, Invision, Sketch
- › **Technical:** Microsoft Office Suite (PowerPoint, Excel, Word), Airtable, LucidCharts, SmartSheets, Asana

Awards

- › **All Academic Recognition - Men's Fencing (2015):** Recognition of outstanding achievement and exceptional commitment to academic and athletic excellence
- › **Brandeis University Commitment to Service Award (2016):** Recognition of outstanding dedication to service in the community
- › **Pear-in-a-Pinch Award Recipient (2018):** The most versatile, indispensable "jack of all trades".
- › **Ohana Core Value Award (2020):** Lending help across multiple parts of the organization to ensure the entire Ohana organization is successful



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ADDRESS

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LINKEDIN

<https://www.linkedin.com/in/eshen94/>

Faith Thomas

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PROFESSIONAL SUMMARY

Research associate with a demonstrated history of working in the industry (1 year) and academia (4 year) centered on In Vivo/immunoassay practices. Proficiently/moderately skilled in variety of lab animal technique (mice, rats, and pigs) encompassing the following: Basic animal handling, tissue harvesting, euthanasia, blood draws (IV, intracardiac), anesthesia, intubation, IVF/IUI/Embryo transfers in mice, surgery in small animal models and surgical support in large animal. Moderately skilled in assay development/immunoassays, flow cytometry/flowjo, IF imaging, and project management. Strong research knowledge in utilizing animal models with a Bachelor's degree focused in Animal Sciences from University of Illinois at Urbana-Champaign.

EDUCATION

University of Illinois at Urbana-Champaign

August 2013- December 2016

Bachelor of Science in Animal Sciences

RELEVANT EXPERIENCE

Ohana Biosciences - Senior Research Associate - In Vivo Team

Cambridge, MA

May 2020 - Present

- Integral member of a three-person team tasked with routinely performing IVF, ICSI, IUI, embryo transfers & blood draws in mice to study the impact of in-house developed antibodies on preventing fertilization
- Standardize CD-46 conjugated antibody binding assays to assess the mechanism of action in hyperactivated sperm and perform analysis via flow cytometry/flowjo and IF microscopy
- Routinely treat sperm with in-house made media to analyze the motility impact via CASA and flow cytometry.
- Support antibody discovery and fertility improvement efforts in the form of conducting and designing in vivo and in vitro experiments, analyzing data, and presenting findings through team meetings
- Maintain a detailed electronic laboratory notebook
- Participated in diversity collectives to support and enrich a healthy work environment.

Translational Research Laboratory, Boston Children's Hospital- Research Assistant

Boston, MA

October 2019 - May 2020

- Collaborated with various principal investigators and post-doctoral researchers to accomplish animal studies (rat, swine) regarding the development and use of injectable oxygen microbubbles in treating hypovolemic shock and hypoxia
- Scheduled and conducted in vivo experiments required by the protocols including: examinations, surgeries, treatments, and sample collections
- Conducted the following procedures in rat models: anesthetization, intubation, femoral and venous catheterization, sternotomy, and pressure probe placement, euthanasia, and necropsy
- Conducted the following procedures in swine models: assist surgeon with jugular catheter placement, prepped sterile surgical tools, draw IV blood and run for CBC, Chemistry, ROTEM, and blood smears
- Analyzed CBC for platelet agglutination via flow cytometry
- Analyzed and collected datasets from CBC, Chemistry, ROTEM panels, blood pressure, and cardiac output via Prism

Faith Thomas

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Laboratory of Comparative Genomics, University of Illinois - Research Coordinator

Urbana, IL

March 2017 - September 2019

- Oversaw and managed logistics in studies using a novel transgenic swine model that recapitulates human cancer through the development of cell specific tumors (hepatocellular carcinoma, soft tissue sarcoma, lung tumors, etc)
- Maintained and completed all documents associated with university guidelines (IACUC and IBC) and government guidelines (USDA, FDA, DOD)
- Conducted basic cell culture techniques including: Adenoviral transfection, and cell passaging.
- Anesthetized, handled, and performed SQ injections of mice under ABL2 conditions
- Performed pre-op, post-op, and surgical care for swine surgeries encompassing: assist surgeon with liver resection (preparing sterile tools, PPE, etc) anesthesia monitoring, intubation, and dosing antibiotics

Laboratory of Pediatric Nutrition, University of Illinois - Research Assistant

Urbana, IL

August 2016 - May 2017

- Assisted in translational maternal health studies using neonatal piglet model to analyze intestinal development and host-microbe interactions in the neonate
- Efficiently completed protocols in DNA isolation and real-time PCR on neonatal stool
- Analyzed and measured intestinal villi sizes of H & E histology slides to study the effect of dietary additive in formula
- Provided necessary health maintenance (immunizations/supplements) to neonatal piglets
- Sterile collected intestinal tissue post-mortem for gut microflora analysis

PUBLICATIONS

Gaba R.C., Mendoza-Elias N., Regan D.P., Garcia K.D., Lokken R.P., Schwind R.M., Eichner M., **Thomas F.M.**, Rund L.A., Schook L.B., & Schachtschneider K.M. (2018). Characterization of an Inducible Alcoholic Liver Fibrosis Model for Hepatocellular Carcinoma Investigation in a Transgenic Porcine Tumorigenic Platform. *Journal of Vascular and Interventional Radiology*, 29(8), 1194-1202. doi: 10.1016/j.jvir.2018.03.007

FELIPE A. NAVARRETE

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pipenavar@gmail.com

RESEARCH SCIENTIST

Proven success driving innovation and translational groundbreaking advancement within the male fertility segment through scientific, manufacturing and clinical research. Track record of delivering:

- Patented devices and translated from animal model to a product used in human in-vitro fertilization setting.
- Fully supported solutions to scale and manufacture the initial product
- Helped design clinical trial by delivering protocols to be use in the clinic.
- Supported clinical and quality team for 510k submission by writing and performing technical reports

SKILLS

- In vitro fertilization assays
- Sperm capacitation and oocyte manipulation
- Sperm and oocyte cryopreservation
- Embryo Culture and embryo transfer
- Microinjection and micromanipulation procedures
- Small animal management (weaning, genotyping procedures)
- Pre-clinical in vivo PK/PD/efficacy relationship studies
- Cell signaling and assay development
- Western blot, PCR, RT-PCR, radioactive assays, immune assays, immunofluorescence, flow cytometer (FACS), cell culture and enzyme-linked immune assay, protein extraction assays and transfections assays.
- Sigma Plot Stats software, Mac OS and PC software proficient.
- Languages: Spanish Native and English proficient
- Google scholar:
https://scholar.google.com/citations?view_op=list_works&hl=en&user=4GMjeisAAAJ&gmla=AJsN-F6sfQPTM5dfe76t_Lrv-so6LeF9aDKp-w4anbcFiW-gmCVyUipc6-swqEXpBiFqJJTQEGDUirXrw1U7yOfp03XfHzvBk0bugpJ9WIO4ZbAs5qNiYN-FTpJaPOmwmXNZlimVjw2a
- Scopus:

<https://www.scopus.com/authid/detail.uri?authorId=55836766300>

PROFESSIONAL EXPERIENCE

April 2019 to present **Ohana Biosciences Inc.**

Senior Scientist- Team Leader

Management

- Lead multiple project teams and managed two research associates. With my mentoring, one associate has become more independent and is currently being evaluated for promotion; the other has greatly increased job satisfaction and performance and now is pursuing a PhD.
- Used deep knowledge of reproductive biology literature to identify potential new product areas, including a novel family health project (currently in research and development).
- Manages and/or coordinates workflow on projects from other team leaders
- **Be a team player by delegating, writing and performing experiments for research, manufacturing and clinical teams in order to perform the clinical trial that started October 2019**
- <https://clinicaltrials.gov/ct2/show/NCT04142112>
- Design, teach and write experiments for younger researchers
- Write and support lawyers with the submission of patents

Lab work

- Design and execute different assays such as, in vivo pharmacology (PK/PD), Cell signaling assays, embryo culture, RNA seq and sequencing.
- Develop different biological assays such calcium, reactive oxidative species, antibody bonding, phospho-proteomics and high content imaging by using different instruments such as biotek plate reader, cytoflex, Zeiss microscopy and narishige microinjector.

Mouse models

- Oversaw and/or coordinates workflow between research and animal model needs
- Established mouse colony and protocols; obtained, validated, and performed experiments on mouse models from repositories and academic collaborators.
- An Institutional Animal Care and Use Committee (IACUC) chair

Innovation

- Used 10% of the time to develop new ideas and test hypothesis by extrapolating sperm research into other diseases such as cancer
- Generate data enough in order to prove a correlation between sperm biomarkers and cancer cell lines by targeting antibody-dependent cell-mediated cytotoxicity (ADCC).

July 2017–March. 2019 **Ohana Biosciences Inc.**

Scientist

- **Established a new method for human sperm capacitation and designed a new In-Vitro Fertilization (IVF) Sperm Preparation Kit that is on clinical trial.**

- Established non-surgical embryo transfer for mice.
- Performed RNA and DNA seq for single and bulk cells
- Performed CASA analysis on mouse, bovine, horse and human sperm.
- Established a new method for bovine sperm capacitation.
- Pioneered and developed in-vitro bovine sperm capacitation.
- Achieved a new in-vitro fertilization that is able to improve embryo development in vitro.
- Develop new media for bovine sperm in-vitro capacitation.
- Maintain 6 mice colonies by weaning and genotyping them.
- Arranged mice ordering
- Designed and modeled artificial insemination in infertile mice model.

EDUCATION

September 2017	PhD, Animal Biotechnology & Biomedical Sciences College of Natural sciences, University Massachusetts Amherst May, 2017	
May 2010	Bachelor of Science, Animal sciences College of Natural science, University Massachusetts Amherst	
	Northeastern University Biology Department, 2008-2009	Boston, MA
May 2008	Roxbury Community College Associate degree in Liberal arts	Boston, MA

RESEARCH EXPERIENCE

January 2016 -June 2017 **Graduate Research Assistant, Reproductive Biology Lab**

- Established a new method for human sperm capacitation.
- Establish a fast way to check the presence of PLZ human sperm factor by immunofluorescence.
- Performed CASA analysis on mouse, bovine, horse and human sperm.
- Established a new method for bovine sperm capacitation.
- Pioneered and developed in-vitro bovine sperm capacitation that is able to activate bovine oocyte from ICSI.
- Achieved a new in-vitro fertilization that is able to improve embryo development in vitro.
- Develop new media for bovine sperm in-vitro capacitation.

January 2011-June 2017 **Graduate Research Assistant, Reproductive Biology Lab**

- Established non-surgical embryo transfer for mice.
- Pioneered and developed in-vitro fertilization assay for infertile mice.
- Improved sperm cryopreservation.
- Improved sperm fertility after freeze-thawing process.
- Achieved the molecular pathway of calcium signaling in sperm capacitation.
- Designed and modeled artificial insemination in infertile mice model.
- Improved the rate of blastocyst stage from in-vitro fertilization.
- Improved artificial insemination in mice.
- Performed Microinjection in mouse and bovine oocytes.
- Performed ICSI.
- Performed calcium oscillations on mouse and bovine oocytes.
- Performed western Blots, PCR, RT-PCR, radioactive assays, immune assays, immunofluorescence, flow cytometer, cell culture and enzyme-linked immunoassay.
- Maintain 4 mice colonies by weaning and genotyping them.
- Arranged mice ordering.
- Implemented lab safety check ups.

Spring 2009

Undergrad Research, University of Massachusetts Amherst

- Conducted a polymerase chain reaction (PCR).
- **Analyzed DNA sequence.**
- **Collected blood from sheep for PCR.**
- Diagnosed spongiform encephalopathy susceptibility in sheep.

TEACHING and ACADEMIC EXPERIENCE

2017- Present

Peer-Review Journals

- Reproductive Biomedicine Online journal
 - Peer reviewed: 1 article
- Molecular Reproduction and development journal
 - Peer reviewed: 5 articles
- Molecular Human Reproduction journal
 - Peer reviewed: 1 article
- Andrology
 - Peer reviewed: 3 articles

2011- 2017

**Research Assistant, Dr. Pablo Visconti Lab
Amherst, MA**

- Trained and advised undergrads, PhD students, post Doctorates, and visitor scientists in the lab techniques.
- Performed and developed classes for undergraduate's students in the lab.
- Illustrated and assigned projects to visitor's scientists.
- Advised and helped newer PhD students in the lab to understand lab techniques and results.

Spring 2015

**Teaching Assistant, Marine Biological laboratory
Woods hole, MA**

- Organized, checked and prepared reagents for the class.
- Tutored and advised students on any of the technique protocol.
- Teach how capacitate sperm from mouse model.
- Teach In Vitro Fertilization.

Spring 2015

Teaching Assistant, undergraduate level course Animal Cell & Molecular Biology

- Organized, checked and prepared reagents for the class.
- Tutored and advise students on any step of the technique protocols.

Spring- 2014

Teaching Assistant, undergraduate level course Biotechnology Lab

- Organized, checked and prepared reagents for the class.
- Tutored and advise students on any step of the technique protocols.
- Developed and adapted western blot protocol for the class.

Spring- 2013

Teaching Assistant, undergraduate level course Animal Cell & Molecular Biology

- Conducted office hours to help students understand and solve homework problems.
- Prepared and graded homework and exams solutions.

Fall- 2011

Teaching Assistant, undergraduate level course physiology of reproduction

- Led discussion, laboratory, and review sessions to clarify basic reproductive physiology principles.

ENTREPRENEUR EXPERIENCE

Spring- 2017

**UMass Final Innovation Challenge Winner
The Berthiaume Center for Entrepreneurship**

University of Massachusetts Amherst

- Spring- 2017 **Accelerator Towards a Company**
Isenberg School of Management
Amherst, MA
- Fall- 2016 **Innovation Challenge Seed Pitch winner**
Berthiaume Center for Entrepreneurship
Amherst, MA
- Fall- 2016 **Science-Based Entrepreneurship and the Lean Launchpad**
Isenberg School of Management
Amherst, MA

UNIVERSITY SERVICE

- May- 2014 **Veterinary and Animal Sciences Department Retreat Organizer**
University of Massachusetts Amherst
Amherst, MA

PATENTS

- U.S. Patent Application Serial No.: [US16/089,862](#) Filed April 1, 2016
U.S. Patent Application Serial No.: [US16/282,217](#) Filed November

SCHOLARSHIPS AND AWARDS

- Spring- 2019 **The House of Representatives Recognition for Contribution and Dedication to the Study of Science**
The Commonwealth of Massachusetts
- Fall- 2017 **Latino 30 under 30**
El Mundo Boston
<https://www.latino30under30.com/felipenavarrete>
- Summer- 2017 **Boston City Council Recognition for Outstanding Academic Achievements**
City of Boston, Ma
- Spring- 2017 **UMass Final Innovation Challenge**
The Berthiaume Center for Entrepreneurship
University of Massachusetts Amherst

Technologies inc.” **Raised 20k toward seed funding start up “Sperm Capacitation**
<https://www.umass.edu/tto/start-companies/umass-amherst-start-companies>

Fall- 2016 **UMass Seed Pitch**
The Berthiaume Center for Entrepreneurship
University of Massachusetts Amherst
Raised 2k toward seed funding start up “Sperm Capacitation
Technologies inc.”

Fall- 2016 **Hong Fellowship Award**
University of Massachusetts Amherst
10 K funding for 1 semester research

Spring- 2016 **NIH Travel Award**
American Society of Andrology Conference

Fall- 2015 **Snoeyenbos Award**
University of Massachusetts Amherst

Spring- 2010 **Chancellor's, Director's and Dean's Scholarship**
University of Massachusetts Amherst

Summer-2007 **Summer Academic Enrichment Program Scholarship**
Northeastern University

Spring-2007 **International student scholarship**
Roxbury Community College

CONFERENCES

Fall-2019 **American Society for Reproductive Medicine (ASRM) Conference**
Philadelphia, USA

Summer-2019 **European Society of Human Reproduction and Embryology Conference**
Vienna, Austria

Spring-2018 **The International Symposium on Spermatology**
Karolinska University Hospital
Stockholm, Sweden

Spring-2017 **Early-Stage Life Sciences Conference**

Massachusetts Technology Transfer Center
Merck Laboratories, Boston, MA

- Spring-2016 **Reproductive and Developmental Genomics Conference**
Poster Title “Transient exposure to calcium ionophore enables in vitro fertilization in sterile mouse models”
Cornell University, NY
- Spring-2016 **Massachusetts Life Sciences Innovation Day**
Poster Title “How to make an infertile mouse fertile?”
Boston, MA
- Spring-2016 **American Society of Andrology Conference**
Poster Title “Transient exposure to calcium ionophore enables in vitro fertilization in sterile mouse models”
NIH Travel Award (**best posters**)
New Orleans, LA
- Summer-2015 **Gordon Conference**
Fertilization & Activation of Development
Poster Title “Biphasic Role of Calcium II in Mouse Sperm Capacitation Signaling Pathways” (this poster contains all the advances done in the previous two years and it is different to the one presented in 2013 in the same conference).
Holderness, MA
- Spring-2014 **Veterinary & Animal Sciences Retreat**
Poster Title “Biphasic Role of Calmodulin and Calcineurin in Mouse Sperm Capacitation Signaling Pathways”
Amherst, MA
- Summer- 2013 **Gordon Conference**
Fertilization & Activation of Development
Poster Title “Biphasic Role of Calcium ions in Mouse Sperm Capacitation Signaling Pathways”
Holderness, NH
- Spring- 2012 **Veterinary & Animal Sciences Retreat**
Poster Title “Role of Calcium in sperm capacitation”
Amherst, MA

PUBLICATIONS

David M. Hidalgo, Ana Romarowski, María G. Gervasi, **Felipe Navarrete**, Melanie Balbach, Ana M. Salicioni, Lonny R. Levin, Jochen Buck, Pablo E. Visconti. *Capacitation increases glucose consumption in murine sperm*. Mol Reprod Dev. 2020;1–11.

FA Navarrete, L Aguila, D Martin-Hidalgo, D Tourzani, GM Luque, . *Transient sperm starvation improves the outcome of assisted reproductive technologies*. Frontiers in cell and developmental biology 2019 7, 262

García-Vázquez FA, Soriano-Úbeda C, Laguna-Barraza R, Izquierdo-Rico MJ, **Navarrete FA**, Visconti PE4, Gutiérrez-Adán A2, Coy P1. *Tissue plasminogen activator (tPA) of paternal origin is necessary for the success of in vitro but not of in vivo fertilisation in the mouse*. Reprod Fertil Dev. 2019 Mar;31(3):433-442

C Sánchez-Cárdenas, F Montoya, **F A Navarrete**, A Hernández-Cruz, G Corkidi, P E Visconti, A Darszon, *Intracellular Ca²⁺ threshold reversibly switches flagellar beat off and on*, Biology of Reproduction, Volume 99, Issue 5, November 2018, Pages 1010–1021

Águila, L., Felmer, R., Arias, M., **Navarrete, F.**, Martin-Hidalgo, D., Lee, H., Visconti, P., & Fissore, R. (2017). *Defective sperm head decondensation undermines the success of ICSI in the bovine*, Reproduction, 154(3), 307-318.

Alaa Hachem, Jonathan Godwin, Margarida Ruas, Hoi Chang Lee, Minerva Ferrer Buitrago, Goli Ardestani, Andrew Bassett, Sebastian Fox, **Felipe Navarrete**, Petra de Sutter, Björn Heindryckx, Rafael Fissore, John Parrington (2017). *PLC ζ is the physiological trigger of the Ca²⁺ oscillations that induce embryogenesis in mammals but conception can occur in its absence*. Development 2017 144: 2914-2924.

Felipe A. Navarrete, Antonio Alvau, Hoi Chang Lee, Lonny R. Levin, Jochen Buck, Patricia Martin-De Leon, Celia M. Santi, Dario Krapf, Jesse Mager, Rafael Fissore, Ana M. Salicioni, Alberto Darszon,* and Pablo E. Visconti 2016 *Transient exposure to calcium ionophore enables in vitro fertilization in sterile mouse models*. **Scientific Reports**

Lavoisier Ramos-Espiritu, Silke Kleinboelting, **Felipe A. Navarrete**, Antonio Alvau, Pablo E. Visconti, Federica Valsecchi, Anatoly Starkov, Giovanni Manfredi, Hannes Buck1, Carolina Adura, Jonathan H. Zippin, Joop van den Heuvel, J. Fraser Glickman, Clemens Steegborn, Lonny R. Levin, Jochen Buck. 2016. *Discovery of LRE1 as a specific and allosteric inhibitor of soluble adenylyl cyclase*. **Nature Chem Biology** (In Press)

Antonio Alvau, Maria Agustina Battistone, Maria Gracia Gervasi, **Felipe A. Navarrete**, Peter A. Greer, Alberto Darszon, Diego Krapf, Ana Maria Salicioni, Patricia S. Cuasnicu, Pablo E. Visconti. *The tyrosine kinase FER is responsible for the capacitation-associated increase in tyrosine phosphorylation in murine sperm* **Development** 2016 143: 2325-2333; doi: 10.1242/dev.136499

Escoffier, J., **Navarrete, F.**, Haddad, D., Santi, C. M., Darszon, A., & Visconti, P. E. (2015).

Flow Cytometry Analysis Reveals That Only a Subpopulation of Mouse Sperm Undergoes Hyperpolarization During Capacitation. **Biology of Reproduction**, 92(5), 121. <http://doi.org/10.1095/biolreprod.114.127266>

Navarrete, F. A., García-Vázquez, F. A., Alvau, A., Escoffier, J., Krapf, D., Sánchez-Cárdenas, C., ... Visconti, P. E. (2015). *Biphasic Role of Calcium in Mouse Sperm Capacitation Signaling Pathways.* **Journal of Cellular Physiology**, 230(8), 1758–1769. <http://doi.org/10.1002/jcp.24873>

Battistone, M. A., Da Ros, V. G., Salicioni, A. M., **Navarrete, F. A.**, Krapf, D., Visconti, P. E., & Cuasnicú, P. S. (2013). *Functional human sperm capacitation requires both bicarbonate-dependent PKA activation and down-regulation of Ser/Thr phosphatases by Src family kinases.* **Molecular Human Reproduction**, 19(9), 570–580. <http://doi.org/10.1093/molehr/gat033>

Wertheimer, E., Krapf, D., de la Vega-Beltran, J. L., Sánchez-Cárdenas, C., **Navarrete, F. A.**, Haddad, D., ... Visconti, P. E. (2013). *Compartmentalization of Distinct cAMP Signaling Pathways in Mammalian Sperm.* **The Journal of Biological Chemistry**, 288(49), 35307–35320. <http://doi.org/10.1074/jbc.M113.489476>

Escoffier, J., Krapf, D., **Navarrete, F. A.**, Darszon, A., & Visconti, P. E. (2012). *Flow cytometry analysis reveals a decrease in intracellular sodium during sperm capacitation.* **Journal of Cell Science**, 125(2), 473–485. <http://doi.org/10.1242/jcs.093344>

KEY SKILLS

Regulatory Strategy & Leadership
Territory Identification & Strategy
Alliance Management Strategy
CMC Strategy & Quality Guidance
CMO Relationship Management & Alignment
Life Cycle Management

Regulatory Evaluation of New Products
Class II and III Medical Devices
EU MDR & CE Mark
FDA 510(k) Submissions
Medical Device Software & Digital Health
FCC Wireless Medical Device Submissions

EXPERIENCE

Ohana Biosciences

January 2020 – Present

Senior Director, Regulatory Affairs

- Develop the global regulatory strategy for individual programs (device and therapeutics) including preparing the programs for successful registration in all major global markets
- Provide strategic regulatory leadership for all clinical development projects
- Lead communications and submissions with regulatory agencies
- Interpret and communicate regulatory expectations to internal and external stakeholders

Renovia Inc.

March 2017 - January 2020

Director of Regulatory and Technical Excellence

Previous titles: Director of Quality and Regulatory; Director of Business Integrity, Compliance and Quality; Privacy Officer

Responsible for the creation, development, implementation, and day to day management of the following departments and programs:

- **Regulatory:** Strategize, lead and execute medical device regulatory program including: Develop and implement regulatory strategy for class II devices; Preparation of different submissions to the FDA including pre-submissions and pre-market notifications; Correspondence with FDA at all levels (reports, notifications, meetings, inspections, etc.); Ensure compliance with medical device regulations (ISO 13485/21 CFR 820); Evaluate complaints for reportability to regulatory agencies; Serve as the regulatory expert on Promotional Review Committee evaluating all materials to ensure compliance with regulatory advertising guidelines.
- **Technical Excellence:** Collaborate with clinical trial team members to support multi-center clinical trial(s) including: Perform inspection and verification of functionality of clinical devices prior to distribution to sites; Evaluation and investigation of device complaints made by subjects or clinical trials sites; Material creation and implementation of solutions to streamline resolution of complaints; Created and implemented a clinical trial dashboard to keep track of all metrics related to clinical trial(s) such as subject adherence, complaints and investigations. Provided technical expertise to patients related to device hardware, software and mobile applications.
- **Quality:** Management Representative; Developed, implemented and maintained ISO 13485 / 21 CFR 820 compliant quality system; Selected, implemented and validated 21 CFR part 11 compliant electronic QMS; Collaborated extensively with suppliers for contracted design as well as manufacturing activities (GMP); Oversight of supplier controls including quality agreements and audits; Oversight of third-party testing for biocompatibility and safety testing.
- **Compliance:** Ensure compliance with various state and federal laws and regulations, applicable to a commercial medical device company, including, but not limited to: Food, Drug, and Cosmetic Act, Sunshine Act; HIPAA/HITECH; Anti-Kickback Statute; as well as industry guidance (AdvaMed Code; PhRMA Code); Developed, implemented, and maintained corporate compliance program;

Provided training for all employees on Compliance program upon hire and at quarterly all company meetings.

- **Business Integrity:** Manage the Promotional Review Committee (MLR) and ensure all materials are appropriately reviewed by subject matter experts and approved prior to external distribution, including version control; Work collaboratively with Clinical, Medical Affairs, Commercial, and field teams; Project Management.

OvaScience Inc.

August 2016 - March 2017

Senior Regulatory Compliance Specialist

- Assisted the Senior Corporate Counsel with management of the regulatory program for HCT/Ps, including regulatory preparation, review and clearance for commercial launch in Canada, Japan, Panama, Spain, Turkey, United Arab Emirates and the United Kingdom.
- Responsible for the development and implementation of a comprehensive corporate compliance program, including essential policies and procedures. Key areas of focus included:
 - Education on Foreign Corrupt Practices Act, Sunshine Act, Anti-Kickback Statute and False Claims Act as they related to Health Care Provider Interactions; Development and implementation of a third-party due diligence program; establishment of a Privacy and Data Security program; and proactively identifying potential areas of risk and creating a mitigation plan.

Beth Israel Deaconess Medical Center

September 2014- July 2016

Senior Research Compliance Specialist, Office of Compliance and Business Conduct

- Responsible for contributing to the success of the research compliance program at BIDMC. This includes conducting investigations, risk assessments and audits as well as oversight and monitoring of current programs in addition to developing the program to meet the ever-changing regulatory environment.
- Contributed to the development of the annual compliance work plan; Conducted scheduled audits; Developed and delivered compliance training based on audit findings, risk assessments and annual work plan.
- Key areas of compliance focus at Beth Israel included but were not limited to:
 - DEA and MDPH Controlled Substances: Created and implemented program for oversight of controlled substances used in research. Executed monitoring activities to ensure success of program.
 - Global Trade Controls – OFAC: Created and implemented due diligence program to ensure all parties associated with BIDMC were cleared.
 - Export Controls –EAR/ITAR: Created and implemented research export control program. Educated researchers on export control regulations and provided assistance, as needed, to ensure compliance with regulations.
 - Research Safety: Created and implemented program for increasing education about personal protective equipment awareness. Supported researchers in overcoming barriers to access and compliance.

Pfizer Inc

June 2012 – August 2014

Regulatory Compliance Lead, Kendall Square; Senior Scientist, Comparative Medicine, Worldwide Research and Development

- Direct responsibility for, and regulatory oversight of, the Kendall Square Animal Care and Use Program.

Gina Prochilo-Cawston MS, PMP, CHRC
Cell: 617-671-5829 Email: gcawston@mac.com

- Responsible for all regulatory reports, both internal and external.
- Review and implement essential policies and procedures for the site, including the Business Continuity and Disaster Preparedness plans, as key member of the Site Leadership Team.
- Work collaboratively to harmonize guidelines and practices across Pfizer's Massachusetts's sites as a member of the Massachusetts Advisory Board.
- Act as the regulatory subject matter expert on Global Teams.
- Perform mock site visits and program reviews to help prepare other Pfizer sites prior to external inspections/reviews.

Boston University

December 2007 – June 2012

Manager, Animal Welfare Assurance

- Responsible for semi-annual reports to the Institutional Official, as well as annual reports to agencies such as AAALAC, DPH, OLAW, and USDA.
- Conduct post-approval monitoring of research protocols and ensure compliance
- Serve as the key representative for applications and inspections by regulatory agencies such as the Centers for Disease Control (CDC) and Department of Public Health.
- Work collaboratively with the Institutional Biosafety Committee, Conflict of Interest Committee, Laboratory Safety Committee, and the Radiation Safety Committee to ensure compliance with all regulations across the university.

Massachusetts General Hospital

Embryologist; 2006-2007

- Performed oocyte retrievals, andrology and cryopreservation
- Evaluated quality of patient embryo's;
- Prepared media and culture plates;
- Performed and maintained quality control practices;
- Followed GDP, GCP, and GLP requirements to comply with hospital policies and external accreditations.

Brigham and Women's Hospital

Embryologist; 2003-2006

- Assisted senior embryologist in performing patient procedures in the surgical suite;
- Trained assistant embryologists;
- Performed andrology and cryopreservation;
- Prepared charts for all patient cases;
- Performed and maintained quality control practices;
- Inventory Control;
- Followed GDP, GCP, and GLP requirements to comply with hospital policies and external accreditations.

EDUCATION & CERTIFICATIONS

2009 – **Master of Science**, Biomedical Sciences
Eastern Virginia Medical School, Virginia

2016 – Certified in Healthcare Research Compliance
(**CHRC**), Health Care Compliance Association

2003 – **Bachelor of Science**, Biology
University of Massachusetts, Massachusetts

2013 – Project Management Professional (**PMP**),
Project Management Institute

Gregory Kuzma

223 Northern Blvd.
Newburyport, MA 01950
Phone: (603) 315-8059
E-mail: gkuzma58@gmail.com

Work Related Experience:

Ohana Biosciences Inc.

Senior Manager of Lab Operations

Brighton, MA
12/2019 – present

Responsible for day to day operations, facilities planning/design/construction, employee training, maintenance, service contracts, equipment calibration, and compliance with/permitting with all applicable standards including OSHA, DEP, and environmental regulations. Instituted covid response plans and response. Assist in trouble shooting and developing manufacturing processes.

Achievements:

Investigated and resolved vivarium issues which caused a decline in mouse fertility and embryo development.
Developed CO2 overlay for GMP manufacturing process.

QLB Biotherapeutics Inc.

Operations Manager

Brighton, MA
3/2017 – 12/2019

Responsible for day to day operations, purchasing, vivarium, IT, facilities planning/design/construction, employee training, waste water systems operations, maintenance, service contracts, equipment calibration, and compliance with/permitting with all applicable standards including OSHA, DEP, and environmental regulations.

Achievements:

Setup bioreactor production area for CHO antibody production from 5 liter to 200 liter scale.

Vedanta Biosciences Inc.

Laboratory Manager

Cambridge, MA
4/2016 – 3/2017

Responsible for day to day operations, purchasing, IT, facilities planning/design/construction, employee training, waste water systems operations, maintenance, service contracts, equipment calibration, and compliance with/permitting with all applicable standards including OSHA, DEP, and environmental regulations.

Achievements:

Redesign and renovation of clean room space to meet GLP standards.
Developed and optimized clean room anaerobic bacteria growth, purification and lyophilization.

Merrimack College

Laboratory Manager, Biology

North Andover, MA
1/2015-4/2016

Day to day operations, lab setup, budgets, purchasing, employee and student training, compliance with all applicable standards including OSHA, DEP, MWRA and environmental regulations. Setup of student laboratories.

Achievements:

Developed and instituted chemical and biological safety programs for students and staff.

NanoTerra Inc.
Laboratory Manager / Researcher

Brighton, MA
3/2012 – 7/2014

Responsible for day to day operations, budgets, purchasing, vivarium, IT, facilities planning/construction, employee training, waste water systems operations, maintenance, service contracts, equipment calibration, and compliance with/permitting with all applicable standards including OSHA, DEP, and environmental regulations.

Achievements:

The design and development of small-scale bioreactors using multilayer scaffolding systems.

Aileron Therapeutics Inc.
Laboratory Operations and EHS Manager

Cambridge, MA
12/2010 – 2/2012

Responsible for day to day operations, purchasing, IT, facilities planning/construction, employee training, waste water systems operations, maintenance, service contracts, equipment calibration, and compliance with/permitting with all applicable standards including OSHA, DEP, and environmental regulations.

Achievements:

Design and construction of a 6,000 sf laboratory space which involved asbestos remediation.

Resolved ongoing facility issues, including waste water systems, and HVAC systems.

Surface Logix Inc.
Laboratory Operations Manager

Brighton, MA
10/2007 – 11/2010

Responsible for day to day operations, budgets, purchasing, vivarium, IT, facilities planning, employee training, waste water systems operations, maintenance, service contracts, equipment calibration, and compliance with/permitting with all applicable standards including OSHA, DEP, and environmental regulations.

Achievements:

Maintained and improved compound management system for small molecules.

Took over IT operations. Decommissioned laboratory including BL2 and radioactive use areas.

Axia College of the University of Phoenix
Faculty, Biology and Nutrition

Phoenix, AZ
12/2007 – 8/2012

Online instructor in the biology and nutrition departments.

Unicorn Stream Consulting
Owner/ Consultant

Newburyport, MA
1996 – 10/2007

Biotech consulting. Facilities permitting and design.
Laboratory relocation. FDA, GMP, GLP compliance.
Product design and testing.
Document and instrument control systems.
GLP/GMP software, database and data acquisition systems.

Achievements:

Developed GLP systems and document control for Biometrix Corporation.

The design and optimization of pipette tips for Corning Corp.

Developed onsite pipette calibration software and systems for Pipette Calibration Services Inc., now part of Mettler Toledo.

Moved 48 laboratories over a 2 week period to MGH Chalestown

Unicorn Stream Calibration

Owner

Weare, NH
2001 - 2004

Calibration of pipettes compliant with GLP, GMP standards.
Created GLP/GMP complaint systems including data acquisition,
materials, noncompliance and SOP's.

Achievements:

Developed onsite pipette calibration software and systems for Pipette
Calibration Services Inc., now part of Mettler Toledo.

LSEnterprises, Ltd. (now SIMCO Electronics)

VP / Cofounder

Cambridge, MA
1991 - 1996

Calibration of laboratory equipment. Responsible for all
aspects of production, including training and management
of over 30 employees. Created GLP/GMP complaint systems
including data acquisition, materials, noncompliance and SOP's.

Achievements:

Developed all GLP systems, including software, for the calibration
of volumetric dispensing devises.
MassBio prime vender for pipet calibration for 10 years.
Consulted with NAVLAP to develop standards for accreditation
for pipette calibration.
Managed company growth from inception to a multimillion dollar
company.

Immulogic Pharmaceutical Corp.

Laboratory Manager

Cambridge, MA
Palo Alto , CA
1990 – 1991

Responsible for day to day operations, budgets, purchasing,
facilities planning, employee training and compliance with all
applicable standards including OSHA, NRC, and EPA regulations.

Achievements:

Oversaw the redesign and construction of 2,000 sf of office space.
Negotiated and facilitated decommissioning of 6,000 sf of lab
space.

Enzytech/ Opta Inc.

Laboratory Manager

Cambridge, MA
1988 - 1990

Responsible for day to day operations, purchasing, IT, vivarium,
facilities planning/design/construction/site location/ lease negotiations,
employee training, waste water systems operations, maintenance, service
contracts, equipment calibration, and compliance with/permitting with all
applicable standards including OSHA, DEP, NRC and environmental
regulations.

Achievements:

Located and oversaw the design and construction of a new 45,000 sf
lab/office space 7.
Invented a protein based fat substitute marketed under the trade name
Lita. Invented a system for oral delivery of drugs using a protein based
micelle system.

Integrated Genetics, Inc.

Associate Research Scientist, Protein Engineering

Framingham, MA
1986 - 1989

Produce, transfect, purify and test 2nd generation Tissue
Plasminogen Activators (tPA). Analyze and present results.

Brigham and Women's Hospital, Cardiovascular Research
Senior Research Technician

Boston, MA
1983 - 1984

Design, execute and interpret experiments dealing with cardiac development, receptors, and ion channels.

Children's Hospital, Dept. of Neurobiology
Research Technician

Boston, MA
1981 - 1983

Design, execute and interpret experiments dealing with brain development, receptors, and ion channels.

Marine Biological Lab., NIH Biophysics
Investigator

Woods Hole, MA
1980 - 1980

Design, execute and interpret experiments dealing with the biochemical and morphological changes in the brain occurring with associative learning.

Certifications:

DOT certified
HAZMAT/ HAZWOPER trained
RCRA trained

Education:

New England College
Graduate Education Program, Biology and Special Education
Degree granted: NH title 4 and 5 teaching certification high school and secondary school

Henniker, NH
2003 - 2004

Northeastern University
Masters in Biology
Degree granted: Masters of Science, Health Science

Boston, MA
9/84 - 5/86
June 1986

Massachusetts Institute of Technology
Interdisciplinary Science Program Biology
Degree granted: none

Cambridge, MA
9/80 - 6/81

Marine Biological Laboratory
January Neurobiology Course
Degree granted: Certificate

Woods Hole, MA
1/80
January 1980

Marine Biological Laboratory
January Animal Behavior Course
Degree granted: Certificate

Woods Hole, MA
1/79
January 1979

University of California, Riverside
Bachelors of Science, Biology
Degree granted: Bachelors of Science

Riverside, CA
9/78 - 12/79
December 1979

Case Western Reserve University
Bachelors of Science, Biology, Astronomy
Degree Granted: none

Cleveland, OH
9/76 - 6/78

Publications:

Livingston, D., Kuzma, G., et. al. (1987). A modified human tissue plasminogen activator with extended half-life. IN VIVO. Biotechnology, Vol. 5.

Galper, J., Kuzma, G. (1984, 1985). Lipoprotein modulation of sodium channel and muscarinic receptor function in cultured embryonic chick heart cells. Paper presented at the American Heart Association Meetings: 1984, and the American Federation for Clinical Research: 1985.

Wilinger, M., Kuzma, G. (1983). Expression of excitable sodium channels in developing mouse cerebellum. Paper presented at the Society for Neuroscience, 13th Annual Meeting: 1983.

Alkon, D., Kuzma, G., Olds, J. (1983). Protein kinase injections reduce voltage-dependent potassium currents. Science, Vol. 219.

Isabel Goldaracena

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+1 (857) 453 4633

Highly committed researcher with extensive experience in antibody characterization, imaging technologies, and cell biology. Extremely fast learner, resourceful and independent. Areas of expertise include assay development/optimization and multiplexing techniques. Extremely motivated to learn, collaborate and tackle new challenges.

Skills include:

Fluorescence microscopy	Mammalian cell culture	Immunohistochemistry	FlowJo
Flow cytometry	UF/DF	DLS	Python
Bioconjugations of Antibodies	Molecular biology techniques	Chromatography methods	Adobe Illustrator

Experience

Ohana Biosciences, Inc.

Research Associate – Sperm Biology Group

Cambridge, MA.
August 2020 - Present

- Characterization, optimization and trouble-shooting of sperm quality assays for the quick and preventive identification of markers of male infertility.
- Designed and implemented multiplex experiments for the assessment of sperm DNA damage with surface markers using flow cytometry and IF microscopy.
- Trained colleagues to use fluorescence microscopy and image analysis.
- Performed independent analysis, design and representation of data structures and datasets of correlations using Python and FlowJo.
- Regularly communicated findings and results via presentations at project team meetings.
- Co-lead ongoing weekly All Company meetings (60 participants total) with two Senior Research Associates.

Wyss Institute for Biologically Inspired Engineering, Harvard University

Research Assistant II– High Throughput Imaging at Dr. Peng Yin Lab

Boston, MA.
February 2019 - July 2020

- Led the optimization and application of an innovative multiplexed signal amplification immunofluorescence technique using DNA-barcoded antibodies that culminated in a publication.
- Responsible for independent bioconjugation and purification of antibodies, tissue imaging using high-throughput fluorescent microscopy, and mammalian cell culture maintenance for immunostaining.
- Led meetings for the Transformative Technology Development HubMAP NIH Consortium.
- Managed on-going collaborations with hospital pathologists, research groups and biotech startups across the US and Europe.

MIT-Harvard Health Science and Technology (HST)

Research Trainee - Dr. Joseph V. Bonventre Lab.

Boston, MA.
January 2018 - July 2018

- Successfully developed and characterized polymeric and hybrid composite nano spheres for sustained release for drug, protein and gene delivery.
- Led cellular, subcellular and tissue imaging efforts using advanced microscopy.
- Implemented nanoscale pathology techniques for identification of sub cellular structures in injured tissues in collaboration with MIT Media Lab.

Boehringer Ingelheim Pharma

Research Intern - Formulation Development Department

Biberach an der Riss, Germany.
March 2017 - July 2017

- Developed an innovative and alternative ultra- /dia- filtration process for highly concentrated protein solutions.
- Responsible for characterization of the protein integrity during extended storage time and found alternative formulation that enabled prolonged (up to one month) antibody stability during storage in liquid solutions.

Education

BS in Biotechnological Engineering

ITESM

- Graduated in the top 10% of my class (Cumulative GPA: 3.7)

Monterrey, Mexico
August 2013 - December 2018

International assignment: Biomedical Sciences

Reutlingen University

- Awards: DAAD (German Academic Exchange Service)

Reutlingen, Germany
August 2016 - December 2016

Leadership

MIT-MEX student association

Massachusetts Institute of Technology

- Member of student association in charge of linking Mexican students at MIT with other research groups.

Cambridge, MA
August 2019 - August 2020

Varsity female soccer team

ITESM

- Team captain for two years during which we won three national and more than ten regional championships.
- Individual awards: Selected by the sport university commission as the best athlete of 2013.

Monterrey, Mexico
August 2013 - May 2017

Vice president of AESLP student association

ITESM

- Organized events raising up to \$5,000 in academic scholarships for lower income students.

Monterrey, Mexico
August 2016 - December 2016

Tutor for the blind and visually impaired

IPACIDEVI

- Provided Math, Chemistry and Biology tutoring for high school students now pursuing their bachelor degrees.

SLP, Mexico
January 2016 - May 2016

Publications and Presentations

- Wang, Y., Zeng, Y., Saka, S. K., Xie, W., **Goldaracena, I.**, Kohman, R. E., ... & Church, G. M. (2020). Multiplexed in situ protein imaging using DNA-barcoded antibodies with extended hybridization chain reactions. *bioRxiv*, 274456.
- HuBMAP Consortium (Harvard TTD: Saka, SK., Kishi, JY., Wang, Y., **Goldaracena, I.**, Yin, P.). (2019). The human body at cellular resolution: the NIH Human Biomolecular Atlas Program. *Nature*, 574(7777), 187.
- **Goldaracena, I.**, Saka, SK., Kishi, JY., Wang, Y., Beliveau, BJ., Lapan, S., West, ER., Zhu, A., Sasaki, HM., Pihan, G., Church, GM., Cepko, C., Yin, P. SABER enables amplified and highly multiplexed imaging. *Harvard Systems Biology Symposium*. Boston, Massachusetts. 2019. Poster Session.
- Ruiz-Esparza, GU., **Goldaracena, I.**, Torres-Calderon, F., Bonventre, J. V., Development of a Molecular Nanosystem for Renal Genome Editing. *Cardio-Renal Research Symposium at Brigham and Women's Hospital*. Boston, Massachusetts. 2018. Conference Presentation.

ISABELLE M. SANSAL, PhD

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isansal@gmail.com

<https://www.linkedin.com/in/isabellesansal/>

SUMMARY

- Strong cross-functional leader with broad experience in drug-discovery processes (antibody, antibody-conjugate and small molecule), encompassing target validation, assay development, HTS, hit-to-lead, lead optimization, mechanism of action studies, biomarker pre-clinical pharmacology and safety/toxicity studies.
 - Highly motivated, results-driven scientist with strong expertise in research programs at the interface between chemistry, biochemistry and cell biology; particularly in the therapeutic area of oncology, reproductive medicine and metabolic diseases.
 - Successful leader with demonstrated ability to effectively mentor and empower scientists and associates toward the accomplishment of targeted goals. Proven track record of building strong scientific teams and in mentoring and leadership of junior scientists.
 - Demonstrated success developing network and establishing strong relationship and managing CROs to support pre-clinical programs.
 - Enthusiastic team player who takes action beyond explicit job responsibilities in order to assist team members in expediting project completion. Listens actively, asks targeted questions and explores multiple solutions.
 - Excels at managing project workflow under strict deadlines within a multidisciplinary environment while maintaining flexibility and motivating colleagues.
 - Excellent communicator with extensive experience in presenting scientific research findings to cross-functional team and senior management.
-

WORK EXPERIENCE

DIRECTOR OF PHARMACOLOGY, OHANA BIOSCIENCES, INC., *Pharmacology*, 2020- Present

PRINCIPAL SCIENTIST, OHANA BIOSCIENCES, INC., *Pharmacology*, 2018- 2020

- Lead a cross-functional team of 6 scientists plus consultants developing novel approach to improve fertility; reduce inherited disease and enable non-hormonal contraception for men.
- Drove in vitro and in vivo preclinical contraceptive program. Oversee and coordinate all aspects of in vitro assay development to discover and characterize antibody therapeutics. Identify external resources for performing mouse IVF and breeding studies to enable our in vivo team to focus on PK/PD/efficacy relationship assessment.
- Directed a multidisciplinary approach to characterization of mechanism of action (MOA) for Ohana's fertility asset by leveraging expertise in sperm biology.
- Rapidly developed network of consultants and strong relationships with CROs to support pre-clinical programs. Identified multiple avenues to evaluate compounds in different species. This work was critical to evolve our understanding of antibody contraceptives and to evaluate the distribution of systemically administered antibody to the male reproductive tract in human.

DIRECTOR OF PHARMACOLOGY, IMMUNEXCITE, INC., *Pharmacology*, 2014- 2017

SENIOR SCIENTIST, IMMUNEXCITE, INC., *Pharmacology*, 2013– 2014

- Lead the preclinical *in vitro* and *in vivo* pharmacology effort to discover and characterize oncology biotherapeutics.

- Drive the conjugation and *in vitro* biology efforts. Oversee and coordinate all aspects of antibody conjugation procedures, purification, bioanalytical characterization and *in vitro* activity assessment. Delivered several candidates in a timely manner for *in vivo* evaluation.
- Conceive and develop pre-clinical strategies, overseeing cell-line-derived and patient-derived tumor xenograft studies in rodents and syngeneic tumor models. Evaluate efficacy of antibody-conjugate as single therapy or administered in combination with immunotherapy (i.e. checkpoint inhibitors).
- Manage and coordinate execution and interpretation of *in vivo* studies to assess PK/PD/efficacy relationship. Apply expertise in immune-oncology and cancer biology to explore mechanism of action (MOA) and assess the role of innate and adaptive immune response and anti-tumor immunity.
- Work closely with the non-clinical development team to design non-GLP safety pharmacology studies. Manage, coordinate and perform assay development and validations, study monitoring, data analysis and interpretation. Author non-clinical reports and review non-clinical pharmacology reports including toxicology studies in rat and non-human primates. Achieved the corporate goal of selecting safe immunotherapeutic candidate by Q4 2016.

LEADERSHIP AND MANAGERIAL ROLES

- Serve as project team lead, manage timelines, milestones and objectives.
- Worked closely with Biochemistry & Chemistry to organize and execute project plan, review data and drive the advancement of potential lead candidates.
- Participate in multiple cross functional, internal teams. Responsible for providing updates and recommendations to research committees & senior management.
- Comfortably engage in critical scientific discussions. Take charge of the group when necessary and recommend solutions. Advocate for change when needed.
- Communicate effectively within group to establish clear priorities and seek alignment on project team needs. Adjust rapidly to changing priorities; actively seek out ways to improve outcomes, processes or measurements.
- Manage an internal team including biochemist and cell biologist and an external team of *in vivo* scientists. Responsible for the training, supervision and yearly evaluation of 4 FTEs.

SENIOR SCIENTIST, SYNDEXA PHARMACEUTICALS, *Drug Discovery*, 2009– 2012

SCIENTIST, SYNDEXA PHARMACEUTICALS, *Drug Discovery*, 2007– 2009

- Led HTS, hit-to-lead and lead optimization programs for the treatment of insulin resistance and diabetes. Conceived, established, optimized and validated cell-based assays for screening of compounds that alleviate endoplasmic reticulum (ER) stress. Managed technology transfers and assay implementation in a CRO company. This work successfully led to the identification of approximately six novel chemical scaffolds, three of which led to hit-to-lead chemistry programs.
- Drove a lead optimization project; assessed timelines, conceptualized and developed array of secondary assays to guide SAR and compounds progression. Delivered two lead series displaying potent modulation of ER stress and unfolded protein response (UPR) pathways.
- Designed, assessed and selected relevant Type II Diabetes animal models and *in vivo* biomarkers for testing UPR modulators in efficacy study. Achieved the corporate goal of identifying a development candidate by Q4 2012.
- Led mechanism of action (MOA) studies. Conceptualized and deploy strategy to characterized key biomarkers of compound activity *in vitro* and *in vivo*. Explored PK/PD relationships in absence of define molecular targets through the careful monitoring of surrogate readouts of target engagement.
- Evaluated, initiated and executed a small-molecule program focused on the modulation of ER stress for the treatment of cancer. Identified a novel compound series that significantly inhibits cancer cell growth.

LEADERSHIP AND MANAGERIAL ROLES

- Research infrastructure and team building: Played an instrumental role in building laboratory infrastructure and in the hiring and training of all new scientists as one of the first scientist to join the biology team of Syndexa Pharmaceuticals.
- Direct supervision: Responsible for the training, supervision and yearly evaluation of three research associates.

POSTDOCTORAL FELLOW / RESEARCH SCIENTIST, DANA FARBER CANCER INSTITUTE, *Department of Medical Oncology, Laboratory of Dr. William R. Sellers, 2000-2007*

- Identified novel components of the PI3K pathway. Purified and identified novel regulatory factors of the PI3K pathway with the use of mass spectrometry and a comprehensive array of biochemical techniques.
- Characterized, analyzed and demonstrated the requirement of this co-regulator complex for the suppression of tumor formation downstream of the PI3K/PTEN pathway.
- Trained, supervised and managed two research assistants.

DOCTORAL RESEARCH, GUSTAVE ROUSSY INSTITUTE, CNRS, France, 1994–1999

- Identified and analyzed molecular connections between cell cycle control and regulation of neural cells differentiation.
- Set up standard biochemical techniques in the laboratory and developed biological tools including antibody and protein engineering and purification for the analysis of the mechanism of action of *NPDC-1*.

TECHNICAL SKILLS

CELLULAR BIOLOGY

- Broad experience in a variety of mammalian established and primary cell culture;
- Transfection and infection (retrovirus and adenovirus): shRNA and siRNA
- FACS analysis
- Foci formation assay, soft agar colony assay, proliferation and cytotoxicity assays, apoptosis assays
- ADCC, CDC, complement assays
- [35S] - Metabolic labeling and pulse chase
- Cell irradiation (gamma or UV)

MOLECULAR BIOLOGY

- DNA subcloning and strategy design, sequencing, PCR, anti-senses methodologies, Real-Time PCR
- Gene expression analysis: RNA isolation, q-RT-PCR, northern blot, micro-array
- Reporter assay (CAT and Luciferase), Gel shift assay (EMSA), Chromatin immunoprecipitation
- Mammalian two-hybrid assay

BIOCHEMISTRY/IMMUNOCHEMISTRY

- Protein localization: tracking of GFP-tagged recombinant proteins and immunohistochemistry; Fluorescence and semi-confocal microscopy
- Production and purification of antibodies – Internalization assay
- Developed ELISA, In-Cell ELISA – analogous platform i.e. MesoScale
- TR-FRET, DELFIA and AlphaLISA technologies
- Lantha-Screen kinase assay
- Protein production, purification and analysis: *in vitro* translation, GST-fusion and interaction assay, chromatography, glycerol gradient, immunoprecipitation, western blot, 2-D gel analysis
- Mass spectrometry: matrix-assisted laser desorption ionization time-of-flight (MALDI-TOF) mass spectrometry Protein identification using NCBI, Matrix Science and ProFound databases

MOUSE TECHNIQUES

- Processing of tissues for protein and RNA
- Evaluation of compounds & antibody levels (PK), cytokine; anti-drug antibody (ADA) levels in plasma and tumors
- Immune cells analysis and infiltration in tumors (Neutrophils, macrophages, T-cell and B-cell) – FACS, VetScan
- *In vivo* Imaging (IVIS)

ADDITIONAL SKILLS

- Fluent in French
- Microsoft Office Suite, Adobe PhotoShop, Endnote, Graph Prism, MSD, Cell Quest Pro, Multigauge, nucleic acid and protein sequence and structure analysis software

EDUCATION

- 1999 **PHD IN BIOCHEMISTRY** with Honors, *Université Pierre et Marie Curie*, Paris, France
1994 **PROTEIN BIOCHEMISTRY DEGREE**, *Pasteur Institute*, Paris, France
1994 **MS IN BIOCHEMISTRY** with Honors, *Université Pierre et Marie Curie*, Paris, France
1993 **BS in Biochemistry** with Honors, *Université Pierre et Marie Curie*, Paris, France

HONORS/AWARDS

- 2001–2004 Department of Defense, post-doctoral fellowship
1999 Award from La Société des Amis des Sciences, French Science Academy
1998 Award from La Fondation pour la Recherche Médicale, France
1994–1997 French research ministry, doctoral fellowship
1993 French ministerial scholarship

PATENTS

- Gabriel Oscar Reznik, John James Kane, James Michael Siedlecki, Zuzana Dostalova, **Isabelle Sansal-Castellano**, Ifat Rubin-Bejerano, Hua Miao. Preparation of Beta-1,6-glucan oligomers as cetuximab antibody conjugates. PCT International. Application, WO 2016196682 A1.
- Ifat Rubin-Bejerano, Gabriel Oscar Reznik, Zuzana Dostalova, **Isabelle Sansal-Castellano**. Compositions and methods for cancer immunotherapy. PCT International. Application, WO 2016118654.
- Gabriel Oscar Reznik, John James Kane, James Michael Siedlecki, Zuzana Dostalova, **Isabelle Sansal-Castellano**, Ifat Rubin-Bejerano, Hua Miao, Eric Furfine. Preparation of Beta-1,6-glucan oligomers as herceptin antibody conjugates. Submitted provisional patent December 2016.
- Gabriel Oscar Reznik, John James Kane, James Michael Siedlecki, Zuzana Dostalova, **Isabelle Sansal-Castellano**, Ifat Rubin-Bejerano, Hua Miao, Eric Furfine. Preparation of Beta-1,6-glucan oligomers as antibody conjugates. Submitted provisional patent December 2016.

ORAL/POSTER PRESENTATIONS

- **Sansal-Castellano, I.**, Carlson, M., Reznik, G., Siedlecki, J., Kane, J., Dostalova, Z., and Miao, H., and Rubin-Bejerano, I. The mAbXcite platform modifies the tumor microenvironment when applied to an immune-oncology anti-CTLA4 antibody. *Journal for ImmunoTherapy of Cancer* 2015, 3(Suppl 2):P414 (2015).
- **Sansal-Castellano, I.**, Carlson, M., Armstrong, T., Reznik, G., Siedlecki, J., Kane, J., Dostalova, Z., and Miao, H., Jaffee, E. and Rubin-Bejerano, I. mAbXcite: A novel immunotherapy platform that initiates a robust anti-cancer T cell response by recruiting and activating neutrophils. *American Association for Cancer Research (AACR) Annual Meeting* (2015).
- Rubin-Bejerano, I., **Sansal-Castellano, I.**, Carlson, M., Reznik, G., Siedlecki, J., Kane, J., Dostalova, Z., and Miao, H. mAbXcite: a novel immunotherapy platform that initiates a robust anti-cancer immune response by recruiting and activating neutrophils. *Journal for ImmunoTherapy of Cancer* 2014, 2(Suppl 3):P262 (2014).
- **Sansal-Castellano, I.**, Hsu, J., Li, Y., Wildt, A. L., and Lehmann, J. M. "Determination of the Unfolded Protein Response associated with obesity, diabetes and ageing". From Unfolded Proteins in the Endoplasmic Reticulum to Disease, *FASEB conference* (2011).

- **Sansal, I.**, Nakamura, N., Ramaswamy, S., and Sellers, W. R. "FoxO1, a critical mediator of tumor suppression downstream of PTEN, interacts with proteins involved in DNA repair". Annual cancer meeting organized by Dr. David Livingston and Dr. Robert Weindberg (2001).
- **Sansal, I.**, Ramaswamy, S., and Sellers, W. R. "Evaluate the mechanism by which FoxO1 mediates tumor suppression downstream of PTEN?" Monthly DFCI tumor suppressor research group meeting attended by laboratories of Dr. D. Livingston, Dr. W.G. Kaelin, Dr. J. DeCaprio, Dr. M. Ewen and Dr. M. Vidal (Multiple research reports from 2000–2007).
- **Sansal, I.**, Levi, H., Ramaswamy, S., and Sellers, W. R. "FoxO1 a mediator of tumor suppression downstream of PTEN". Weekly DFCI breast and prostate Cancer research seminar attended by laboratories of Dr. M. Brown, Dr. K. Polyak, Dr. P. Sicinski, Dr. M. Ewen, Dr. J. Iglehart and Dr. W. Hahn (Multiple research reports from 2000–2007).
- **Sansal, I.**, Yoo Storer N., Ramaswamy, S., and Sellers, W. R. "How does FoxO1 mediate tumor suppression downstream of PTEN?" Bi-annual DFCI Pi3K meeting attended by laboratories of Dr.L. Cantley, Dr. T. Roberts, Dr. P. Silver, Dr. G. Ruvkun and Dr.M. Vidal (Multiple research reports from 2000-2004).
- **Sansal, I.**, Dupont, E., Toru, D., Evrard, C., and Rouget, P. "NPDC-1, a regulator of neural cell proliferation and differentiation, interacts with E2F-1 and modulates its transcriptional activity". B2M meeting, Paris, France (1998).
- Rouget, P., Galiana, E., Dupont, E., **Sansal, I.**, and Evrard, C. "NPDC-1 regulates cell proliferation and differentiation and is able to act as suppressor gene". *J. Neurochem.*, 65: S144 (1995).

PUBLICATIONS

- **Sansal, I.**, Levy, H., Yoo Storer, N., Ramaswamy, S., and Sellers, W. R. Transcriptional repression by FoxO1 induces cell cycle arrest and mediates tumor suppression downstream of PTEN (2006). *Mol Cell Biol* # MCB01712-06.
- **Sansal, I.**, and Sellers, W. R. (2004). The biology and clinical relevance of the PTEN tumor suppressor pathway. *J Clin Oncol* 22, 2954-2963.
- Ramaswamy, S., Nakamura, N., **Sansal, I.**, Bergeron, L., and Sellers, W. R. (2002). A novel mechanism of gene regulation and tumor suppression by the transcription factor FKHR. *Cancer Cell* 2, 81-91.
- **Sansal, I.**, Dupont, E., Toru, D., Evrard, C., and Rouget, P. (2000). NPDC-1, a regulator of neural cell proliferation and differentiation, interacts with E2F-1, reduces its binding to DNA and modulates its transcriptional activity. *Oncogene* 19, 5000-5009.
- Dupont, E., **Sansal, I.**, Evrard, C., and Rouget, P. (1998). Developmental pattern of expression of NPDC-1 and its interaction with E2F-1 suggest a role in the control of proliferation and differentiation of neural cells. *J.Neurosci Res* 51, 257-267.
- Dupont, E., **Sansal, I.**, Toru, D., Evrard, C., and Rouget, P. (1997). Identification of NPDC-1, gene involved in the control of proliferation and differentiation of neural and glial precursors. *C R Seances Soc Biol Fil* 191, 95-104.

JEANNE MIGWI

CAREER SUMMARY

Perceptive and accomplished accountant with proven ability to handle complex responsibilities and a strong aptitude to learn new technologies and processes. Ability to self-direct and successfully achieve goals in a deadline driven environment through strong analytical skills and best practices solutions.

- **Areas of Exposure:** US GAAP, General Ledger, Accounts Payable, Audit Preparation, Fixed Income, FX, Cash & Asset Reconciliation, Financial Statement Analysis & Reporting, Purchasing, Project Management, Grant Accounting
 - Conscientious professional with a high level of ownership and accountability that has resulted in outstanding account servicing and retention.
 - Motivated, goal-oriented team player with ability to meet and exceed goals as well as build a collaborative working relationship with co-workers and clients.
-

PROFESSIONAL EXPERIENCE

C-SPACE, Boston, MA
Staff Accountant (Contractor)

09/2018 – 12/2018

- Facilitated the research of outstanding purchase orders commitments and took the necessary action to disposition (closure) of PO's
- Interacted daily with other departments to gather data used for invoice classification. Performed margin analysis and advised project managers of insufficient funds or over expenditures
- Performed daily cash applications and generated weekly accounts receivable aging reports to be reviewed by the Assistant Controller
- Processed employee reimbursements expenses, intercompany payables and reviewed for compliance with company policies
- Conducted account analysis of asset and liability accounts to ensure proper recording in GL for month end close
- Maintained the set up of all new vendors and contractor engagements

BEHNISCH ARCHITEKTEN, Boston, MA
Project Accountant

03/2017 – 05/2018

- Entered all payables, receivables into the system and denoted job-related expenses for billing purposes
- Reviewed supporting documentation received from sub-contractors and thereafter created customer invoices for submission to clients
- Downloaded payment summary information from the client's website, matched payments to invoices sent to the customer and subsequently issued payments to subcontractors
- Worked closely with project team leaders to track fee payments/schedules that changed due to scope of work additions i.e. additional services and expenses needed to be categorized separately from basic services with NTE's exceptions
- Tracked sub-contractors COI's and requested agents to provide updated certificates to mitigate exposure risks
- Reviewed, coded and posted into QuickBooks employees travel and expense reimbursements for payments
- Calculated payroll and rates updates for both hourly and non-salaried personnel. Processed wages via the payroll online portal and maintained all wages reporting documents for year-end reconciliation
- Performed HR responsibilities that included on-boarding and off-boarding of employees, visa maintenance for non-residents, 401k administration, health care contribution calculations and adjustments

VARIOUS CONTRACTING ENGAGEMENTS - Creative Financial Staffing, LLC

01/2015 – 11/2016

Performed an array of accounting duties while undertaking consulting engagements in Boston within the Professional and Non-Profit Sectors. The Companies worked for included Third Sector New England, Moran Environmental Recovery, Mass Bay Transportation Authority and City Year, Inc.

Staff Accountant/Project Accountant

- Created and reviewed revenue, expense and amendment contracts received from TSNE sponsored organizations and thereafter created purchase orders for scheduled payments per terms of agreement
- Monitored grants and categorical program expenditures to ensure that grants were spent out hence minimizing agency disallowances
- Re-classed misallocated expenses to the correct budget categories and coordinated with the grant manager to send out revised reports
- Reconciled general ledger entries, processed all payables, account receivables, evaluated any items that that were out of scope and cut checks on a weekly basis
- Processed credit card reconciliations on a monthly basis; reviewed supporting documentation and ensured adherence to federal requirements
- Managed the timely closeout of all expired projects through coordination of fiscal resources
- Posted T&E reimbursements for contractors and ensured supporting documentation had prior approvals before entering

- data into Concur Expense Management System
- Assisted in the consolidation and preparation of monthly and year-end GAAP financial statements and reporting packages
- Reconciled general ledger entries and ran queries to ensure that accruals were in line with payments issued and made adjustments accordingly
- Assisted in the consolidation and preparation of monthly and year-end GAAP financial statements and reporting packages
- Prepared fiscal year end entries in order to facilitate a clean audit

Performed non-accounting related work in 2013 and took a medical leave of absence in 2014.

PREMIER PROPERTY SOLUTIONS, Boston, MA

11/2011 – 02/2013

Senior Accountant

- Performed full cycle accounting tasks related to the efficient management of accounts that included vendor set up, invoice coding, journal entries, general ledger/sub ledger maintenance and insurance payments
- Posted daily lockbox and ACH remittance deposits to the appropriate customer accounts ensuring reconciliation of the batch as well as other timely reconciliations & account analysis
- Resolved months of backlogged work on unpaid net 30 and net 45 invoices by initiating the timely sign off on recurring orders from established vendors
- Interfaced with managers and assisted with large capital projects requiring issuance of special assessments, allocation of supplemental fees, budget forecast and actual vs. budget variance analysis
- Balanced over 75 major accounts, maintained AP aging reports, records and files and implemented accounting procedures to eliminate delays in invoice and PO's processing
- Executed tasks with a high level of accuracy in a dynamic environment related to external audit requests, set up of reserve accounts, reconciliation of corporate credit cards, online fund transfers while ensuring that GL and bank discrepancies were detected and resolved

VINCE TRANSPORTERS, Raynham, MA

01/2010 – 11/2011

Accounting Specialist

- Matched, coded and entered freight bills for vouching and payment on a weekly basis
- Followed up on past due invoices from vendor and made arrangements to have payments processed according to the set terms of agreements
- Assisted the operations manager with the budgeting, stock inventory, reconciliation of company financials as well as other ad-hoc duties

JPM CHASE & CO, TREASURY SERVICES, Boston, MA

04/2007 – 08/2009

Fund Accountant Analyst, Corporate Cash

- Booked trades and monitored cash and asset variances between the core systems daily
- Calculated net asset value, daily prices and yields, income activity and corporate action for diverse domestic and international funds
- Performed reviews to ensure the general ledger balances agreed with the supporting documentation
 - Identified issues
 - Initiated the resolution of those issues with all applicable parties
- Collected and analyzed data to detect controls oversights, fraud, or non-compliance with US GAAP, SAS-70, SOX provisions and established company policies
- Managed complex cash and securities holdings reconciliation processes while mitigating risk resulting in a 99% departmental efficiency
- Prepared forecasts to track financial metrics such as income and expenses and performed allocations for payment of custodian, management and audit fees
- Diligently managed the month-end process for multiple investment funds and thereafter prepared a final closing financial packet for clients

EDUCATION

Northeastern University, Boston, MA GPA 3.5, August 2007

Bachelor of Science: Business Management (Management and Marketing)

TECHNICAL SKILLS

Skills: Excel, Outlook, PeopleSoft, QuickBooks, Oracle ERP System, Bloomberg, IDC, Concur Expense Management, Salesforce, Serenic Navigator, Microsoft Dynamics

Jessica A. Lazaro

PROFILE

More than 15 years of marketing and administrative experience in various industries, including 24/7 support of C-level executives and senior management as well as office management, local marketing engagement and event planning. Empowered as an independent thinker with strong analytical and problem-solving skills to proactively identify opportunities and act accordingly.

EXPERIENCE

Ohana Biosciences, Cambridge, Mass.

Executive Assistant & Office Manager

March 2021 - Present

- Providing day-to-day administrative support to the CEO, VP of Research, CSO and others with heavy calendar management and scheduling with key players such as Ohana's Board of Directors, potential investors, and clients.
- Key resource in assisting the CEO and executive team to seamlessly manage full, complex, and ever-changing calendars, including a range of internal and external meetings and engagements, taking proactive measures for success.
- Liaise with Building Management and landlord on all ongoing facilities-related issues, including maintenance, repair, office cleaning and upkeep in a shared space environment.
- Partnering closely with the Lab Manager in all office communications with the Lab Team, managing weekly Covid testing program, keeping storage room organized, supplies stocked, and orders put away.
- Ensuring office and operations security by maintaining the office ID badges, parking passes, security access points within the facility, and office keys.

GCD Consultants LLC, Wayland, Mass.

Senior Executive Assistant

June 2012 – April 2020

- Managed active calendars of three Partners, including extensive travel schedules and daily meeting arrangements as well as expense report preparation ensuring payment and/or reimbursement occurs promptly.
- Administered office activities including accounts payable & receivable, general ledger, purchasing, filing systems, communications with outside vendors, and technical support.
- Facilitated the onboarding of new hires including offer letters, payroll, administering benefit programs, and training.
- Communicated proactively with clients and outside partners to ensure proper details were reflected on proposals and client reports as well as presentations.

Century 21 Gelineau & Associates, Waltham, Mass.

Executive Assistant & Real Estate Agent

October 2009 – June 2012

- Assisted in the oversight and management of ten sales associates while proactively communicating with buyers, sellers, attorneys, and mortgage brokers involved in property sale to ensure all details are addressed guaranteeing a smooth transaction.
- Developed and implemented successful marketing strategies, including direct mail, email, social media outreach and direct client contact to promote Century 21 Gelineau & Associates, individual properties, and myself as a real estate agent.
- Designed, proofed, approved and ordered all marketing materials (i.e. property brochures, business cards, property signs, and postcards), through vendors to ensure deadlines are met while being flexible to unexpected changes.
- Assisted Broker/Owner with administrative needs, including answering main office phone line, preparing outgoing correspondence (i.e. letters, emails, and newsletters), creating PowerPoint presentations, attending meetings, arranging scheduling and logistics as well as billing support.

-Continued-

ARS Restoration Specialists, Newton, Mass.

Sales & Marketing Assistant

June 2008 – October 2009

- Supported six-person sales team along with company President and Marketing Manager with administrative needs, including writing, editing and proofreading internal and external materials (i.e., press releases, fact sheets and client correspondence) to ensure accuracy as well as worked with sales team to interpret concepts and ideas into PowerPoint presentations to selected audiences as well as current and prospective clients.
- Organized and served as daily event contact on events, including annual Casino Night and Insurance Adjuster Seminars for more than 300 attendees, as well as smaller seminars for 20-30 attendees.
- Planned and arranged our participation in industry related trade shows, including securing booth space, booking booth equipment and supplies, and scheduling booth coverage as well as arranged travel for employees, including flights, hotel, meals and transportation.
- Created social media platforms, including a Facebook account to highlight all the positive work being conducted by ARS Restoration within the New England market.

Blitz Media, Needham, Mass.

May 2005 - June 2008

Client Services Coordinator (October 2006 - June 2008)

- Collaborated with each media department within Blitz to create client media presentations, including proposed media plans and campaign analysis.
- Initiated preliminary media planning for top children’s entertainment account, Feld Entertainment, while developing customized media solutions that met clients’ needs.
- Assisted with project management and budgeting, including oversight of vendors and third-party partnerships, ensuring quality work, deadline and budget adherence for retail account, Tweeter Electronics.
- Managed client communication on a day-to-day basis, including status reports for client calls and meetings.

Broadcast Coordinator (May 2005 - October 2006)

- Responsible for managing agencies largest clients, including maintaining relationships with broadcast media and production companies to communicate instructions and ensure delivery of materials accurately, on time, and on budget.
- Provided daily support to the senior media buyers, including the planning, buying and analytic stages of the media buying process.
- Worked directly with broadcast media confirming station orders, maintaining campaigns in-flight and post campaign analysis.
- Communicated effectively via telephone and/or meetings with media representatives, resulting in a thorough understanding of the market and evaluation of media options.

EDUCATION

Bentley University, Waltham, Mass.

May 2004

- Bachelor of Science in Marketing
- Minor in Business Management

SKILLS

Microsoft Office Suite (Word, Excel, PowerPoint, Outlook, MSFT 365), Google Workspace, Adobe, Quicken / Quickbooks, calendar management, travel coordination, expense report preparation and reconciliation, plan and manage companywide meetings and events, highly organized, strong communicator, high level of multi-tasking ability.

***Professional references available upon request*

JOHN PRESTON MILLER

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linkedin.com/in/john-preston-miller

SUMMARY

A conscientious, flexible, and adaptable scientific leader with a proven record of achieving key strategic initiatives and building strong alliances with external partners. Successful contributions all along the discovery and developmental paths for three clinical candidates, from high-throughput screening to exploratory biomarker readouts during clinical studies.

Expertise includes: team leadership, conflict management, scientific and cross-discipline communication and presentations, vendor and academic collaborator coordination, IND-enabling experimental design, execution and documentation, and authorship and due diligence of the S-1 business section. Proficient in Ussing chamber electrophysiology, mammalian airway primary cell culture, molecular biology, phenotypic assay development and optimization, high-throughput robotic screening, protein and mRNA quantitation, protein engineering, QuantiGene Plex multigene transcriptional profiling, qPCR, RNA interference methodologies, *in vitro* transcription and translation, cellular toxicity assays, biochemical assays, mammalian cell and yeast methodologies, and database management.

PROFESSIONAL EXPERIENCE

OHANA BIOSCIENCES INC., Cambridge, MA

2020 – Present

Senior Director of Discovery Biology (2020 – Present)

Biology Director for Disease Reduction and Future Fertility Programs

Reporting to the vice president of research and responsible for scientific and program strategy and resourcing, including managing external collaborations with academic groups. Supervised five PhD-level reports with a team of six.

- Directed the epigenomics team in driving actionable experimental design and execution in advancing the fertility and disease reduction programs.
- Oversaw the computational biology team's efforts to support project and program deliverables through well-vetted and robustly documented bioinformatic analyses.
- Managed external collaboration relationships with academic and commercial partners to supplement internal capabilities and advance program objectives.

PROTEOSTASIS THERAPEUTICS INC., Boston, MA

2010 – 2020

Senior Director of CF Research (2018 – 2020)

Biology Director for Nonclinical Cystic Fibrosis Program Activities

Reported directly to the chief scientific officer and represented the company's public face in communicating the PTI story at scientific conferences with KOLs and with the CF community. Responsible for scientific and program strategy and resourcing, managing contract vendors and external collaborations with academic groups. Supervised three direct PhD-level reports with a team of five reports.

- Oversaw the electrophysiological research efforts across CF programs to deliver actionable, competitive intelligence and partnering opportunity guidance.
- Directed mechanism of action studies for CF program chemical matter, resulting in a peer-reviewed publication on a novel CFTR modulator mechanism.
- Delivered on-time exploratory biomarker analysis of clinical samples for press releases and investor presentations.
- Supervised experiments and updates of pharmacology sections of IND investigator's brochures for PTI-428, PTI-801, and PTI-808.

Director of CF Research (2015 – 2018)

Biology Director for Preclinical Cystic Fibrosis Program Activities

Reported directly to the chief medical officer and chief scientific officer. Supervised the electrophysiological research efforts across CF programs. Senior sponsor responsible for mechanism of action studies for CF program chemical matter. Responsible for scientific and program strategy and resourcing, managing contract vendors and external collaborations with academic groups. Supervised three direct PhD-level reports with a team of eight reports:

- Supervised the experiments and wrote pharmacology section of PTI-428 investigator's brochure for successful IND application.
- Supervised experiments and wrote scientific content and backup book materials for business section of S-1 filing as part of PTI's successful IPO.
- Led the team responsible for the actionable *in vitro* efficacy data that enabled nomination of the successful IND candidates, PTI-801 and PTI-808.
- As corresponding author, wrote a peer-reviewed article on the strategy that identified PTI's novel amplifier class of CFTR modulator.
- Co-authored a peer-reviewed article with a collaborator on the characterization of a rare CF-causing mutation that responds to our novel modulator.

Senior Scientist I, Molecular and Cellular Biology (2013 – 2015)

Biology Lead for Cystic Fibrosis Program

Responsible for supervising the biology team to deliver CFTR electrophysiological measurements to profile lead chemical matter for activity and potency:

- Led the team that generated actionable *in vitro* efficacy data that enabled nomination of the successful IND candidate, PTI-428.
- Coordinated with bioinformatics team to automate database capture and analysis of results to improve efficiency.
- Oversaw scientific and program strategy and resourcing in coordination with project team leader.
- Directed pharmacology section study report composition and experimental planning in preparation for an investigational new drug application.

Scientist III, Proteostasis Network Biology (2011 – 2013)

Biology Lead for Cystic Fibrosis Program

In charge of coordinating the establishment of in-house capabilities for cystic fibrosis functional assays to complement and progress program. Responsible for profiling of proteostasis network regulator compounds identified using transcriptional and proteomic techniques. Supervised three direct reports:

- Successfully introduced and established electrophysiological capabilities at PTI to enable in-house hit-to-lead and lead optimization of CFTR modulator hits.
- As point person for alliances with electrophysiology vendor and academic expert, delivered chemical matter profiling and supplemented internal capacity once established.
- Performed the phenotypic high-throughput screen that identified the novel amplifier class of CFTR modulator.

Scientist II, Proteostasis Network Biology (2010 – 2011)

QuantiGene Plex Multigene Expression Profiling of the Proteostasis Network

Successfully expanded the company's transcriptional profiling technology to incorporate additional protein homeostasis pathways and performed compound and genetic reagent experiments for programs at the company. Responsible for supervising two direct reports.

BUCK INSTITUTE FOR RESEARCH ON AGING, Novato, CA

2005 – 2010

Postdoctoral Research Fellow, Laboratory of Dr. Robert Hughes

HDAC4 Inhibition Suppresses Mutant Huntingtin Toxicity

Characterization of HDAC4 as a loss-of-function suppressor of mutant huntingtin toxicity in cellular models using siRNA and overexpression.

siRNA Screen for Novel Suppressors of Mutant Huntingtin Toxicity

High-throughput screen of siRNA library for suppression of pathology in cell culture models of Huntington's disease. Identified and characterized the R-Ras signaling pathway as a modulator of mutant huntingtin toxicity in cellular models.

siRNA Screen of Proteases to Identify Modulators of Huntingtin Processing and Toxicity

siRNA screen of human proteases for effect of their knock-down on mutant huntingtin proteolytic cleavage and toxicity in cellular models.

UNIVERSITY OF WASHINGTON, Department of Genome Sciences, Seattle, WA

2004 – 2005

Senior Fellow I, Laboratory of Dr. Stanley Fields

WW Domain Interaction Studies Using Protein Microarrays

In vitro domain interaction studies of purified protein domains with yeast proteins in a microarray format.

EDUCATION

UNIVERSITY OF WASHINGTON, Department of Genome Sciences, Seattle, WA (2004)

Doctor of Philosophy, Genetics (Advisor Dr. Stanley Fields)

Interactions Among Integral Membrane Proteins of Yeast

- Cellular protein-protein interactions between integral membrane proteins.

COLORADO STATE UNIVERSITY, Department of Biochemistry and Molecular Biology, Fort Collins, CO (1997)

Bachelor of Science, *cum laude*, Biochemistry

- Undergraduate thesis (Laboratory of Dr. Marvin Paule).
- Protein purification, ribosomal 5S RNA regulation by TFIIIA during transition from vegetative growth to encysted state in *Acanthamoeba castellanii*.

AWARDS AND SCHOLARSHIPS

PROTEOSTASIS THERAPEUTICS INC. (2012)

Best Presentation of the Year Award

PROTEOSTASIS THERAPEUTICS INC. (2012)

Co-Recipient of Spot Award, Delivering High-Quality High-Throughput Screen Ahead of Schedule

PROTEOSTASIS THERAPEUTICS INC. (2011)

Scientist of the Year Award

DEPARTMENT OF BIOCHEMISTRY, COLORADO STATE UNIVERSITY (1997)

Outstanding Undergraduate Researcher

COLORADO STATE UNIVERSITY (1996 – 1997)

Colorado Scholar's Award Scholarship

LABORATORY OF DR. MARVIN PAULE, COLORADO STATE UNIVERSITY (1995 – 1997)

Merit Work-Study Award

COLORADO STATE UNIVERSITY (1994 – 1997)

Inland Container Scholarship

COLLEGE OF NATURAL SCIENCES, COLORADO STATE UNIVERSITY (1993 – 1997)

Dean's Honor Roll

ADMINISTRATIVE AND TEACHING EXPERIENCE

TUFTS CENTER FOR THE STUDY OF DRUG DEVELOPMENT (2013)

Trainee, Leadership for Drug Development Teams Leadership Course, July 9-10

MASSACHUSETTS BIOTECHNOLOGY EDUCATION FOUNDATION (2012)

Trainee, Leadership Training for Scientists Leadership Course, Oct. 17, Nov. 14

BUCK INSTITUTE FOR RESEARCH ON AGING (2008 – 2010)

Organizer, Internal Research Seminars

Department of Genetics, University of Washington (2001-2002)

Coordinator, Graduate Student-Invited Seminar Speakers

INTRODUCTORY BIOLOGY (2000)

Teaching Assistant, Dr. Bonita Brewer

INTRODUCTION TO GENETICS (2000)

Teaching Assistant, Dr. Christine Tachibana

INTRODUCTION TO GENETICS (1999)

Teaching Assistant, Dr. Stephen Jackson

COLORADO STATE UNIVERSITY (1996 – 1997)

President, Undergraduate Biochemistry Club

PRESENTATIONS

1. Poster. "Intestinal Organoid Models as a Path for Personalized Therapy Development in Cystic Fibrosis." Tissue Organoids as Models of Host Physiology and Pathophysiology of Disease Keystone Symposium, 2020, Vancouver, BC, Canada.
2. Poster. "Two Novel Corrector Classes with the Potential to Be Developed for New Combination Therapies." ECFS Basic Science Meeting. European Cystic Fibrosis Society, 2019, Dubrovnik, Croatia.
3. Talk and Poster. "An Amplifier-Enhanced High-Throughput Screen to Identify Small Molecules with Read-Through Activity on Premature Termination Codon Mutations in CFTR." 32nd NACFC Meeting. Cystic Fibrosis Foundation, 2018, Denver, CO.
4. Talk. "Amplifiers Co-Translationally Stabilize CFTR mRNA Through a Mutation-Independent Mechanism." Emily's Entourage Scientific Symposium, 2018, Philadelphia, PA.
5. Talk and Poster. "*In Vitro* Characterization of Clinical Stage Novel Corrector PTI-801 and Potentiator PTI-808 in Primary Airway Cell Models." ECFS Basic Science Meeting. European Cystic Fibrosis Society, 2018, Loutraki, Greece.
6. Talk and Poster. "Amplifiers Co-Translationally Increase CFTR Levels at the ER Membrane by Improving Membrane Targeting of CFTR." ECFS Basic Science Meeting. European Cystic Fibrosis Society, 2017, Albufeira, Portugal.
7. Talk. "CFTR Amplifiers are Mutation-Agnostic Modulators that Increase CFTR Protein Levels and Complement Other CF Therapeutic Modalities." 39th European Cystic Fibrosis Conference, 2016, Basel, Switzerland.
8. Talk. "Novel F508del-CFTR Corrector that Complements Other CFTR Modulators." 39th European Cystic Fibrosis Conference, 2016, Basel, Switzerland.
9. Talk. "Amplifiers: A New Class of CFTR Modulator." Protein Homeostasis in Health and Disease Meeting, 2016, Cold Spring Harbor Laboratory.
10. Talk. "Ion Channels in Drug Discovery Symposium." Charles River Laboratories, 2015, Cambridge, MA.
11. Talk and Poster. 29th NACFC Meeting. Cystic Fibrosis Foundation, 2015, Phoenix, AZ.

PUBLICATIONS

1. Smith, E. Dukovski, D., Shumate, J. Scampavia, L., **Miller, J.P.** and Spicer T.P. (In Press). "A Homogeneous Cell-Based Membrane Potential Assay to Identify Compounds That Promote Readthrough of Premature Termination Codons in the Cystic Fibrosis Transmembrane Conductance Regulator Ion Channel". SLAS Discov.
2. Dukovski D, Vilella A, Bastos C, King R, Finley D, Kelly JW, Morimoto RI, Hartl FU, Munoz B, Lee PS, Zecevic M, **Miller, J.P.** (2020). "Amplifiers co-translationally enhance CFTR biosynthesis via PCBP1-mediated regulation of CFTR mRNA." J Cyst Fibros. 2020 Feb 14;S1569-1993(20)30052-7. doi: 10.1016/j.jcf.2020.02.006.
3. Giuliano, K.A., Wachi, S., Drew, L., Dukovski, D., Green, O., Bastos, C., Cullen, M.D., Hauck, S., Tait, B.D., Munoz, B., Lee, P-S., **Miller, J.P.** (2018). "Use of a High-throughput Phenotypic Screening Strategy to Identify Amplifiers, a Novel Pharmacological Class of Small Molecules That Exhibit Functional Synergy with Potentiators and Correctors." SLAS Discov. Feb;23(2):111-121. doi: 10.1177/2472555217729790. Epub 2017 Sep 12.
4. Molinski, S.V., Ahmadi, S., Ip, W., Ouyang, H., Vilella, A., **Miller, J.P.**, Lee, P.S., Kulleperuma, K., Du, K., Di Paola, M., Eckford, P.D., Laselva, O., Huan, L.J., Wellhauser, L., Li, E., Ray, P.N., Pomès, R., Moraes, T.J., Gonska, T., Ratjen, F., Bear, C.E. (2017) "Orkambi® and amplifier co-therapy improves function from a rare CFTR mutation in gene-edited cells and patient tissue." EMBO Mol Med. Jun 30. pii: e201607137. doi: 10.15252/emmm.201607137.
5. Smith E., Giuliano K.A., Shumate J., Baillargeon P., McEwan B., Cullen M.D., **Miller J.P.**, Drew L., Scampavia L., Spicer T.P. (2017) "A Homogeneous Cell-Based Halide-Sensitive Yellow Fluorescence Protein Assay to Identify Modulators of the Cystic Fibrosis Transmembrane Conductance Regulator Ion Channel." Assay Drug Dev Technol. Dec;15(8):395-406. doi: 10.1089/adt.2017.810. Epub 2017 Nov 27.

6. **Miller, J.P.**, and Tait, B.D. (2014). "Chapter 20: Disease-Modifying Agents for the Treatment of Cystic Fibrosis". Annual Reports in Medicinal Chemistry. Volume 49. Edited by Manoj C. Desai. Burlington: Academic Press. 317-330.
7. **Miller, J.P.**, Yates, B.E., Al-Ramahi, I., Berman, A.E., Sanhueza, M., Kim, E., de Haro, M., DeGiacomo, F., Torcassi, C., Holcomb, J., Gafni, Mooney, S.D., J., Botas, J., Ellerby, L.M., and Hughes, R.E. (2012). "A Genome-Scale RNA-interference Screen Identifies RRAS Signaling as a Pathologic Feature of Huntington's Disease". PLoS Genetics. 8(11):e1003042.
8. Dumitriu, A., Latourelle, J.C., Hadzi, T.C., Pankratz, N., Garza, D., **Miller, J.P.**, Vance, J.M., Foroud, T., Beach, T.G., Myers, R.H. (2012). "Gene expression profiles in Parkinson disease prefrontal cortex implicate FOXO1 and genes under its transcriptional regulation." PLoS Genetics. 8(6):e1002794.
9. **Miller, J.P.** and Hughes, R.E. (2011) "Chapter 3: Protein Interactions and Target Discovery in Huntington's Disease". The Neurobiology of Huntington's Disease. Frontiers in Science. Edited by Donald C. Lo and Robert E. Hughes. CRC Press. 384.
10. Piña, F.J., O'Donnell, A.F., Pagant, S., Piao, H.L., **Miller, J.P.**, Fields, S., Miller, E.A., Cyert, M.S. (2011). "Hph1 and Hph2 are novel components of the Sec63/Sec62 posttranslational translocation complex that aid in vacuolar proton ATPase biogenesis." Eukaryotic Cell. 10(1):63-71.
11. **Miller, J.P.**, Holcomb, J., Al-Ramahi, I., de Haro, M., Gafni, J., Zhang N., Kim, E., Sanhueza, M., Torcassi, C., Kwak, S., Botas, J., Hughes, R.E., and Ellerby, L.M. (2010). "Matrix Metalloproteinases are Modifiers of Huntingtin Proteolysis and Toxicity in Huntington's Disease". Neuron 67 (2): 199-212.
12. Bell, R., Hubbard, A., Chettier, R., Chen, D., **Miller, J.P.**, Kapahi, P., Tarnopolsky, M., Sahasrabudhe, S., Melov, S., and Hughes, R.E. (2009). "A Human Protein Interaction Network Shows Conservation of Aging Processes Between Human and Invertebrate Species". PLoS Genetics 5 (3): e1000414.
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16. Hazbun, T. and **Miller, J.** (2005). "Genome-Wide Analysis of Protein-Protein Interactions by Using a Two-Hybrid Array". Protein-Protein Interactions: A Molecular Cloning Manual, 2nd edition. Cold Spring Harbor Laboratory Press.
17. **Miller, J.** and Stagljar, I. (2004). "Utilizing the Yeast Two-Hybrid System to Identify Interacting Proteins". Methods in Molecular Biology 261: 247-62.
18. Thaminy, S., **Miller, J.**, and Stagljar, I. (2004). "The Split-Ubiquitin Membrane-Based Yeast Two-Hybrid System". Methods in Molecular Biology 261: 297-312.

Jorge Ticas

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SUMMARY

- Highly motivated assay development scientist with over 6 years of experience in industry and a broad/diversify experimental skill set
- Strong expertise in mammalian cell culture, Flow Cytometry, Immunocytochemistry, and cell-based assays
- Recognized for exceptional work ethic with high enthusiasm for professional lab setting
- Enthusiastic team player who acts beyond explicit job responsibilities to assist team members in expediting project completion with the ability to be a strong and effective independent lab member
- Excels at managing workflow under strict deadlines within a multidisciplinary environment .

EXPERIENCE

Senior Research Associate – In vitro pharmacology/ assay development Jul 2019– Present
Ohana Biosciences
Cambridge, MA

- Core member of the in vitro pharmacology team responsible for the development, optimization and troubleshooting biochemical and cell-based assays. This work was critical to validate target and key for contraceptive therapeutic go/no go decisions
- Supported contraceptive antibody discovery efforts through developing and executing flow cytometry, in-cell-ELISA, ICC and cell-based assays
- Developed sperm and mammalian cell based functional readouts to validate potential contraceptive antibody leads.
- Lead longitudinal sample testing study that successfully determined the concentration of antibody from different biologics in human serum and seminal fluid that provided crucial information for contraceptive dosing purposes
- Developed, optimized and performed assays (i.e. ELISA) to assess antibody concentration in various matrixes to support PK/PD studies in mouse and non-human primate.

Development Associate II Nov 2018– Jul2019
Immunogen Inc.
Waltham, MA

- Utilized working knowledge to develop and run potency assays for characterization and GMP release testing of antibody-drug conjugates across development programs to support CMC activities
- Responsible for the development, optimization and troubleshooting of ELISA and SPR assays to support antibody and conjugate process development
- Developed ADCC FcγRIII binding ELISA for release testing

- Troubleshooted and fixed ligand binding ELISA for process characterization testing
- Developed BLI FcRN assay for process characterization testing
- Performing cell-based cytotoxicity assays to support formulation, stability and GMP toxicity studies.
- Generate and analyze of large assay data sets using Graphpad and Excel

Research Associate

Aug 2015 – Nov 2018

Bioscale Inc.

Billerica, MA

- Developed, verified, and validated ELISA and ViBE assays to the industry standard
- Prepared all buffers needed to develop, verify, and validate assays
- Automated sample testing process using various liquid handling instruments to increase the efficiency of process and increase the quantity and quality of data produced
- Supported the assay development team and lab director in generation and analysis of assay data
- Drafted and reviewed Instructions for use and standard operating procedures in preparation to become an GLP compliant laboratory
- Coordinated training of customers in the working capabilities of the ViBE platform

Technical Expertise

- Experience in a variety of mammalian established and primary cell culture
- Transfection
- Flow Cytometry and FlowJo
- ADCC
- BLI FcRN assay
- Protein localization: Fluorescence microscopy
- Developed ELISA, In-Cell ELISA – multiplexing
- Evaluation of antibody levels (PK) and anti-drug antibody (ADA) levels in various matrixes (such as serum, seminal plasma)

Additional Skills

- Microsoft Office Suite, Graph Prism, FlowJo, PLA, Digital and physical lab notebook keeping (such as serum, seminal plasma)

EDUCATION

MS Applied Biotechnology, PSM Option

2016-2019

University of Massachusetts Lowell

Lowell, MA

BS Biotechnology

2011 - 2015

University of Massachusetts Lowell

Lowell, MA

Julianna Lamm

310-795-7479 | juliannalamm@gmail.com | 52 Fayette St. Cambridge, MA 02139

EDUCATION

University of California, Berkeley, Berkeley, CA

May 2020

Major: BA, Molecular and Cellular Biology– Concentration in Biological Chemistry

RELEVANT WORK/VOLUNTEER EXPERIENCE

Ohana Biosciences, Cambridge, MA

June 2020 - Present

Research Associate

- Integral member of four-person team tasked with the identification, categorization, and standardization of unique sperm cell biological characteristics
- Conduct sperm DNA fragmentation and surface characterization assays for the scalable and quick identification of sperm fertility using cell surface biomarkers
- Assess male contraceptive potential of 50+ novel in-house antibodies via flow cytometry, high-throughput live-cell IF imaging, and IF microscopy on LED microscope

Lishko Lab, UC Berkeley, CA

Sept. 2019 - June 2020

Undergraduate Research Assistant

- Built an open-source, python-based Computer Assisted Sperm Analysis (CASA) script to extract sperm motility, count, hyperactivation, and progressivity using only videos of sperm under standard microscope
- Conducted immunohistochemistry assays, Western Blot analysis, and Bradford assays to assess efficacy of transfection and inform later electrophysiology experiments
- Evaluated male contraceptive potential of novel compounds by assessing sperm energetics via flow cytometry
- Performed routine sperm motility analysis, sperm cytometric assays, cell transfections, cell transformations, DNA Cloning, Western Blot analysis, qPCR, and primary and secondary cell culture

Amyris, Emeryville, CA

June. 2019 - Feb. 2020

Bioscience New Product Development Intern

- Developed consumer driven and scientifically backed skin-care products using innovative and sustainable material science techniques
- Gather, Compile, and disseminate information on current legal limits and emerging controversy relevant to chemicals used in personal care and cosmetic industry

UCSF Brückner Lab, San Francisco, CA

Sept. 2018 -Dec. 2018

Undergraduate Lab Assistant

- Identified apoptosis rates in Down's syndrome cell adhesion molecule (DSCAM) drosophila fly-lines using IF stainings
- Skilled in drosophila husbandry and genetics including: setting crosses, maintaining fly lines, fly virgining, and monitoring fly life-cycles, larval fillets

Blade Therapeutics, South San Francisco, CA

Summer 2018

Summer Intern

- Coordinated and executed a research project investigating the mechanistic pro-fibrotic role of interest on epithelial cell pathology
- Participated in drug-discovery sessions involving the identification of potential new targets and hit to lead optimizations for development of novel synthetic anti-fibrotic compounds
- Proficient in RNA isolation, cDNA synthesis, PCR, Western Blotting, cell staining, cell viability assays, cell culture

LEADERSHIP/VOLUNTEER EXPERIENCE

Head Recruitment Counselor, Berkeley, CA

Nov. 2018-Present

UC Berkeley Panhellenic Executive Council

- Lead, and executed recruitment training for 60+ recruitment counselors, managed cross communication between recruitment counselors, 13 Panhellenic chapters, UC Berkeley administration, and the National Panhellenic Conference
- Revised Panhellenic recruitment structure to include greater emphasis on mental health, ADA accessibility, restorative justice trainings, and conflict resolution that impacted a community of over 1,000 women

Elizabeth Glaser Pediatric AIDS Foundation Berkeley, CA

Fall 2016 - 2018

- *Fall 2016- 2018*: Vice President of Outreach: Lead and executed Pediatric AIDS education to wider Berkeley Community, executed fundraising events, and oversaw Greek Relations committees

Madre Teresa Home for individuals with Mental and Physical Disabilities, Cusco, Peru

Summer 2016

- Spanish to English translator for Physical Therapists at an orphanage specializing in care of adults and children with physical and mental disabilities

SUMMARY

Highly versatile and inventive Biotechnologist experienced in the design, development, and testing of novel bioanalytical and bioprocessing technology: Over 8 years industry experience developing microfluidics, bioassays, automated systems, and analytical instrumentation. Possesses a high level of motivation and initiative, and is known for working both independently and within cross-functional teams in fast-paced environments. Actively takes ownership and manages projects to achieve milestones on time and within budget under aggressive timelines. Has demonstrated ability leading and executing rigorous and systematic technical work while also identifying new research and product application opportunities.

TECHNICAL SKILLS

- Expertise in designing, building, and testing microfluidic devices, PDMS, plastic, silicon, glass; highly knowledgeable of microfluidic technology landscape.
- Broad and thorough understanding of molecular and cellular bioanalytical concepts/applications; knowledgeable of different types of biological samples, e.g. blood, semen.
- Extensive skill with device prototyping, including 3D printing, CNC machining, and bonding to fabricate microfluidic devices, optofluidic cells, and fluidic cartridges.
- Expertise developing automated fluidic systems from concept to prototype; significant experience using software (e.g. LabVIEW) to integrate and automate multiple instruments for bioassay and bioprocess applications.
- Highly skilled with CAD software (AutoCAD, Fusion360, Solidworks) for microfluidic design, photomask production, and prototype hardware development.
- Direct hands-on experience with bacteria and mammalian cell culturing, including growth, handling, labeling, and imaging/analysis; very good sterile lab technique and attention to detail.
- Thorough understanding of biomolecular processing, including protein synthesis, purification/separation, and assay development; extensive experience with immunoassays.
- Expertise with optical techniques for developing molecular/immuno-assays and imaging/analysis with microfluidic devices; proficiency with multi-color flow cytometry.
- Proficiency with various types of computational software and programming languages, including Python, MATLAB, Excel for analysis and visualization of large and diverse datasets.
- Proficiency using modeling software (e.g. COMSOL) to develop biomolecular/bioparticle transport models and designs for microfluidic devices (e.g., fluid flow, diffusion, electrophoresis, DEP).

PROFESSIONAL EXPERIENCE

Senior R&D Engineer, Microfluidics & Automation – Ohana Biosciences (Cambridge, MA) Dec. 2019 to Present

Leading scientific and engineering efforts to develop next generation microfluidic and automation platform systems for clinical cell separation and bioprocessing applications.

- Design, model, fabricate, and test microfluidic device for size-based separation of cells; engage with manufacturing partners to transition from prototype to manufactured devices.
- Successfully transitioned proprietary cell bioprocess to a fully automated system; responsible for system design, hardware assembly, software programming, testing & verification.
- Authoring scientific documents including white papers and journal articles.

Senior Research Engineer – Triton Systems (Chelmsford, MA) Mar. 2016 to Dec. 2019

Established new bioanalytical research and technology avenues for the company, and supported a variety of projects requiring design and development of microfluidics, bioassays, and instrumentation.

- Worked with highly interdisciplinary teams to develop a multitude of novel biosensing and microfluidic technology capabilities within the company.
- Conceptualized innovative bioanalytical/microfluidic approaches, formulated into proposals, including manufacturing and regulatory plans; obtained over \$1M of external R&D funding.

Independent Consulting for Bioanalytical Technology Development– Sept. 2015 to Feb. 2016

Consulted with companies to provide expertise with microfluidic and bioanalytical applications development and R&D proposal writing.

Research Scientist – Agiltron Inc. (Woburn, MA) Jan. 2013 to July 2015

- Led the development of a fully automated fluidic system capable of performing nanoparticle-based assays for detection of biomarkers for a DOD-funded program; resulted in multiple patent filings.
- Established new research capabilities for the company through design and development of microfluidic devices to enable selective separation and transport of biomolecules and microbeads.

Graduate Research Assistant – Dept. of Engineering, Univ. of Georgia (Athens, GA) May 2007 to Dec. 2012

- Pioneered the use of nanorod materials for the development of an optical label-free bioassay for improved nucleic acid detection and analysis.
- Developed a novel microfluidic lab-on-a-chip device; innovated device design/fabrication strategies for integration of nanostructures with traditional microfluidic/microelectrode components.

Lab Technician – Dept. of Infectious Diseases, Univ. of Georgia (Athens, GA) April 2005 to Aug. 2006

- Performed sample analysis and testing procedures for detection of infectious diseases using immunoassays and qPCR.
- Prepared and maintained mammalian tissue cultures for infectious disease studies.

EDUCATION

Ph.D.	Biological Engineering	University of Georgia Aug. 2006 to Dec. 2012
B.S.	1st Major - Biochemistry 2nd Major - Cellular Biology	University of Georgia Aug. 2000 to Dec. 2004

PATENTS AND INVENTION DISCLOSURES

1. **J. L. Abell**, W. A. Weimer, S. Wu “Dielectrophoretic (DEP) Pump”, US Provisional Application No. 62/207,800, filed August 20, 2015
2. **J. L. Abell**, M. J. Wilson, W. A. Weimer, and S. Wu “Systems and Methods for Detecting Target Biological Molecules” U.S. Application No. WO2016081060A2, filed May, 2016
3. J. Chen, **J. L. Abell**, and Y. -P. Zhao, “Thin Layer Chromatography-Surface Enhanced Raman Spectroscopy Chips and Methods of Use”, United States 8810789, issued August 2014

PUBLICATIONS AND PRESENTATIONS

- List of over 10 publications and 3 conference presentations available upon request

KATHLEEN SEYB

122 Butler Ave
Wakefield, MA, 01880

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- Scientific and strategic leadership of therapeutic and device programs from target validation through early clinical development
- Demonstrated success developing networks of scientific consultants and key opinion leaders to support research and clinical programs
- Track record of recruiting and mentoring strong scientific teams, fostering culture of collaboration and scientific innovation
- Creative, data-driven scientist with experience in small molecule, peptide, and antibody discovery and development across multiple therapeutic areas

Professional Experience

OHANA BIOSCIENCES, INC, CAMBRIDGE, MA
Vice President, Research

March 2018-April 2021

Key accomplishments

- Led a team of 24 scientists developing novel approaches to improve fertility and reduce disease risk in offspring by leveraging expertise in sperm biology
- Drove progression of lead fertility product from discovery to clinical development in 1.5 years
- Rapidly developed network of key opinion leaders and clinicians to support design and execution of clinical trials in reproductive medicine
- Developed and presented scientific story externally in support of fundraising efforts for Series B and C and business development

RA PHARMACEUTICALS, INC, CAMBRIDGE, MA
Senior Director, Head of Biology
Director, Target Biology
Associate Director, Target Biology

December 2012 – February 2018
January 2017 – February 2018
January 2016 – December 2016
December 2012 – December 2015

Key accomplishments

- Expanded of biology team from 3 to 13 members, promoting an environment supportive of scientific innovation and teamwork
- Inventor of zilucoplan, a novel cyclic peptide inhibitor of complement C5 in Phase 3 clinical development for myasthenia gravis
- Drove development of translational sciences program within biology team, developed scientific program supporting clinical programs in hematological and neuromuscular indications
- Led early evaluation of indications for lead program, developing network of KOLs critical for supporting internal decision-making and clinical planning
- Program leadership of project from target ID to IND-enabling studies
- Program and alliance management of multitarget research collaboration with Merck; leadership of project that met 3 milestones to date and is currently in clinical development at Merck

Key accomplishments

- Project leader for high-throughput screen (HTS) assay development and screening of 27 targets
- Established criteria for successful on-boarding of new targets and progression toward HTS campaigns
- Developed critical path for multiple programs through demonstration of *in vivo* target engagement and efficacy in animal models of disease
- Initiated data mining effort to ascertain novel biological relationships between targets screened based on hits identified
- Supervise 5 B.S - Ph.D. level scientists per year in target validation and development of assays for HTS

DEPARTMENT OF PHARMACOLOGY AND TOXICOLOGY, UNIVERSITY OF KANSAS, LAWRENCE, KS

Post-Doctoral Fellow

July 2005 - July 2006

Development and screening of a high-throughput cell-based assay to identify compounds that inhibit activation of calpain by β -amyloid in a collaborative project between the Laboratory for Drug Discovery in Neurodegeneration and Dr. Mary L. Michaelis at the University of Kansas

DEPARTMENT OF PHARMACOLOGY AND TOXICOLOGY, UNIVERSITY OF KANSAS, LAWRENCE, KS

Graduate Research Assistant

August 2000 - July 2005

Advisor: Mary Lou Michaelis, Ph. D.

Dissertation: Prevention of β -Amyloid Neurotoxicity by Microtubule-Stabilizing Drugs: The Ca²⁺ Connection

Education & Training

Ph. D. in Pharmacology & Toxicology, University of Kansas, Lawrence, KS, 2005

Master of Science in Pharmacology & Toxicology, University of Kansas, Lawrence, KS, 2003

Bachelor of Science in Chemistry, University of Memphis, Memphis, TN, 2000

Awards and Honors

American Foundation for Pharmaceutical Education Pre-Doctoral Fellow, 2002 – 2005

University of Kansas Bishop-Johnson Graduate Scholarship, 2000 – 2005

University of Memphis Chi Beta Phi Award for Excellence in Chemistry, May 2000

University of Memphis Cecil B. Humphreys Presidential Scholarship, 1996 - 2000

Publications & Patents

Publications

Allylene, C., Amin, R.P., Bhatt, B., Bianchi, E., Blain, J.C., Boyer, N., Branaa, D., Embrey, M., Sookhee, N.H., Jette, K., Jounhs, D.G., Kerekes, A.D., Koeplinger, K.A., LaPlaca, D., Li, N., Murphy, B., Orth, P., Ricardo, A., Salowe, S., Seyb, K., Shahripour, A., Stringer, J.R., Sun, Y., Tracy, R., Wu, C., Xoing, Y., Youm, H., Zokian, H.J., Tucker, T. Series of Novel and Highly Potent Cyclic Peptide PCSK9 Inhibitors Derived from an mRNA Display Screen and Optimized via Structure-Based Design. *J. Med. Chem.* 2020. <https://doi.org/10.1021/acs.jmedchem.0c01084>

Wilson H, Medjeral-Thomas N, Gilmore A, Trivedi P, Seyb K, Farzaneh-Far R, Gunnarsson I, Zikert A, Cairns T, Lightstone L, Cook H, Pickering M. Glomerular membrane attack complex is not a reliable marker of ongoing C5 activation in lupus nephritis. *Kidney Int.* 2019 March;95(3):655.

Yang Z, Concannon J, Ng KS, Seyb K, Mortensen LJ, Ranganath S, Gu F, Levy O, Tong Z, Martyn K, Zhao W, Lin CP, Glicksman MA, Karp JM. Tetrandrine identified in a small molecule screen to activate mesenchymal stem cells for enhanced immunomodulation. *Sci Rep.* 2016 Jul 26;6:30263.

Manocha GD, Puig KL, Austin SA, Seyb K, Glicksman MA, Combs CK. Characterization of Novel Src Family Kinase Inhibitors to Attenuate Microgliosis. *PLoS One.* 2015 Jul 10;10(7):e0132604

Randhawa P, Zeng G, Bueno M, Salgarkar A, Lesniak A, Isse K, Seyb K, Perry A, Charles I, Hustus C, Huang M, Smith M, Glicksman MA. Inhibition of large T antigen ATPase activity as a potential strategy to develop anti-polyomavirus JC drugs. *Antiviral Res.* 2014 Dec;112:113-9. doi: 10.1016/j.antiviral.2014.10.004. Epub 2014 Oct 15.

Pytel D, Seyb K, Liu M, Ray SS, Concannon J, Huang M, Cuny GD, Diehl JA, Glicksman MA. Enzymatic Characterization of ER Stress-Dependent Kinase, PERK, and Development of a High-Throughput Assay for Identification of PERK Inhibitors. *J Biomol Screen.* 2014 Aug;19(7):1024-34

Kong Q, Chang LC, Takahashi K, Liu Q, Schulte DA, Lai L, Ibabao B, Lin Y, Stouffer N, Das Mukhopadhyay C, Xing X, Seyb KI, Cuny GD, Glicksman MA, Lin CL. Small-molecule activator of glutamate transporter EAAT2 translation provides neuroprotection. *J Clin Invest.* 2014 Mar;124(3):1255-67

So, P. P-L., Zeldich, E., Seyb, K.I., Huang, M.M., Concannon, J.B., King, G.D., Chen, C-D., Cuny, G.D., Glicksman, M.A., Abraham, C.R. Lowering of Amyloid Beta Peptide Production with a Small Molecule Inhibitor of Amyloid Precursor Protein Determination. *Am J Neurodegener Dis.*, In Print, 2012.

Tang, X., Seyb, K.I., Huang, M., Schuman, E.R., Shi, p., Zhu, H., Glicksman, M. A. A high-throughput screening method for small molecule inhibitors of the aberrant mutant SOD1 and dynein complex interaction. *J Biomol Screen.* 2012 Mar; 17(3): 314-326.

Liu M., Poulouse S., Schuman E., Zaitsev A.D., Dobson B., Auerbach K., Seyb K., Cuny G.D., Glicksman M.A., Stein R.L., Yue Z. Development of a Mechanism-based High-throughput Screen Assay for Leucine-Rich Repeat Kinase 2: Discovery of LRRK2 Inhibitors. *Anal Biochem.* 2010 Sep 15; 404(2): 186-192.

Colton, C.K., Kong, Q., Lai, L., Zhu M.X., Seyb, K.I., Cuny, G.D, Xian, J., Glicksman, M.A., Lin, C.L. Identification of Translational Activators of Glial Glutamate Transporter EAAT2 through Cell-Based High-Throughput Screening: An Approach to Prevent Excitotoxicity. *J Biomol Screen.* 2010 Jul; 15(6): 653-62.

Qiao, L., Chio, S., Case, A., Gainer, T.G., Seyb, K.I., Glicksman, M.A., Lo, D.C., Stein, R.L., and Cuny, G.D. Structure-activity relationship study of EphB3 receptor tyrosine kinase inhibitors. *Bioorg Med Chem Lett.* 2009, 19(21): 6122-6.

Seyb, K.I., Schuman, E.R., Ni, J., Huang, M.M., Michaelis, M.L., and Glicksman, M.A. Identification of Small Molecule Inhibitors of β -amyloid Cytotoxicity through a Cell-based High Throughput Screening Platform. *J Biomol Screen.* (2008) 13(9): 870-8.

Seyb, K.I., Ansar, S., Li, G., Bean, J., Michaelis, M.L. and Dobrowsky, R.T. p35/Cyclin-dependent Kinase 5 is Required for Protection Against beta-Amyloid-induced Cell Death but not Tau Phosphorylation by Ceramide. *J Mol Neurosci* (2007) 31(1): 23-35.

Seyb, K.I., Ansar, S., Bean, J., and Michaelis, M.L. β -amyloid and endoplasmic reticulum stress responses in primary neurons: effects of drugs that interact with the cytoskeleton. *J Mol Neurosci* (2006) 28(2): 111-23.

Michaelis, M.L., Seyb, K.I. and Ansar, S. Cytoskeletal Integrity as a Drug Target. *Current Alzheimer Research*. (2005) 2 (2): 227-229.

Michaelis, M.L., Ansar, S., Chen, Y., Reiff, E., Seyb, K., Himes, E., Audus, K., Georg, G. beta-Amyloid-Induced Neurodegeneration and Protection by Structurally Diverse Microtubule-Stabilizing Agents. (2005) *J Pharmacol Exp Ther*. 312(2):659-668.

Granted Patents

Methods for promoting fertilization 10470798

Modulation of complement activity 10588936, 10435438, 10328115, 10208089, 10106579, 9937222

Compounds that enhance Atoh1 expression 10406163, 9433610, 8859597, 8188131

Katie Vane, SHRM-CP

vane.katie@gmail.com | 818.554.0035 | Somerville, MA

SUMMARY

Creative, driven, and versatile HR professional with 2+ years of experience in a range of roles at a clinical stage biotech. Experienced in supporting full-cycle recruitment across a range of functions and levels during rapid growth in partnership with internal Talent Discovery Consultant and external agencies. Independently led searches in microfluidics, cell biology and assay development, in vivo models, clinical sample management, operations, and admin. Managed and evolved the employee on-boarding program and experience. Supported company culture and engagement initiatives, facilitating launch of core values, distributing engagement surveys, and partnering with leadership team to create company's first cross-functional culture teams. Managed benefits administration and HR operations in a lean, dynamic, and collaborative environment. Looking for opportunities to grow and step into HR Business Partner role.

EDUCATION

SHRM-CP	2020
M.F.A., Creative Writing – Fiction , Hunter CUNY	2011
<ul style="list-style-type: none">GPA 4.0, Hertog Fellowship Recipient	
B.A., English , Vassar College	2008
<ul style="list-style-type: none">GPA 3.89, Phi Beta Kappa, English and General Honors	

SKILLS

ADP, E-Verify, USABLE Life, Lever, Google Suite (Gmail, GCal, Google Docs, Sheets, and Forms), MS Office Suite (Outlook, Word, Excel, and PowerPoint), Asana, Lucidchart, Slack, and Canva

PROFESSIONAL EXPERIENCE

Ohana Biosciences Cambridge, MA
A Flagship Pioneering company founded in 2016, leveraging proprietary sperm biology platform to develop products that improve fertility; reduce inherited disease, developmental disorders and pregnancy complications; and enable non-hormonal contraception for men and women. Concluded first clinical trial for SPERTILITY™ in October 2020.

Senior Manager, People Operations & Talent Discovery
Manager, People Operations & Talent Discovery
Talent Coordinator

January 2021 – Present
January 2020 – December 2020
February 2019 – December 2019

Talent Discovery

- Supported full-cycle recruitment across a range of functions and levels during rapid growth in partnership with internal Talent Discovery Consultant and external agencies.
 - Contributed to 24 hires in 2019 and 15 hires in 2020, including difficult-to-fill positions.
- Partnered with Talent Discovery Consultant to select and launch first ATS and trained employees.
- Created LinkedIn posts and curated Ohana's company page to increase visibility in support of aggressive recruitment goals. Coordinated with VP of Corporate Communications.

Onboarding

- Developed Ohana's onboarding program. Provided new hire onboarding using ADP, E-Verify, and USABLE Life.
- Partnered with VP of People, Talent Discovery Consultant, VP of IT, and People team to continuously evolve the onboarding experience. Presented suggestions to Leadership Team and launched changes including New Hire Assessment surveys.

- Beginning in March 2020, led transformation of all hiring and onboarding to a virtual format in partnership with People Operations Coordinator (direct report). Created brand new materials such as [virtual office](#) and lab tour videos.

Culture & Engagement

- Partnered with VP of People and StoriTel (external consultant) to create and roll out Ohana's core values and culture story.
- Tracked and analyzed employee engagement through bi-annual Pulse Surveys and annual Culture Survey and made recommendations to Leadership Team. Based on results from 2019 Culture Survey, launched employee "Collectives" focused on People, Culture, and Events. Launched DE&I Collective in 2020.
- Beginning in March 2020, partnered with VP of People, VP of IT, and People team to evolve approach to connecting Ohanites across the company, launching touchpoints including weekly Town Halls, bi-annual Wellness Challenge, summer Storytime/STEAM activities for families & more.

Compensation & Performance Management

- Involved in benchmarking roles using Radford and inputting company data into regular Radford surveys.
- Supported year-end performance review, merit increase and bonus process and liaised closely with Finance to ensure smooth transition to payroll. Facilitated collection of annual self-assessments, assembled slides of ratings with graphs and tables for LT calibration, and created and shared comp letters.

Benefits & Immigration

- Supported annual benefits enrollment, including communications about open enrollment. Interfaced with the Flagship Pioneering benefits group as needed.
- Conducted research to support launch of new transportation benefit in 2019 and facilitated changes to benefit elections.
- Facilitated short-term disability and family leave using USABLE Life and Paid Family Medical Leave (PFML). In partnership with People Operations Coordinator and VP, Legal, created PFML FAQ for employees.
- Provided visa application support in partnership with external immigration attorney, assisting STEM OPT continuation and H-1B and EB-1 applications.

Office & Lab

- Partnered with Office Manager, IT, EA/Office Manager and People team to execute seamless office move in Sept. 2020.
- Beginning in Q1 2021, joined bi-weekly COVID Task Force meetings to revise current office and lab protocols per federal, state, and local guidelines.
- Launched and led cross-functional Evolution of Work group to frame strategy and playbook for return to office slated for May/June 2021.

Self-Employed

Freelance Writer

Somerville, MA

October 2018 – January 2019

- Returned to New England to join my partner in the Boston area.

The Sheet Newspaper

Guest Editor

Mammoth Lakes, CA

July 2018 – October 2018

- Moved back to California for the summer to support my father through serious health issue.

Office of Mayor Miro Weinberger

Communications & Projects Coordinator

Burlington, VT

June 2016 – July 2018

- Directed Mayor's public relations projects, acted as City's primary print and television media liaison, organized press events, coordinated interviews, and served as Mayor's spokeswoman.
- Organized monthly meeting of communications personnel from all City departments to determine best practices and align citywide messaging.

- Managed Mayor’s social media and compiled monthly analytics.
- Scheduled and staffed meetings with a wide range of Department Heads and external partners.
- Panelist: Vermont League of Cities & Towns Town Fair, “Effective Public Communication” session, Oct. 2017.
- Received Mayor’s Award for Distinguished Service in July 2018.

The Sheet Newspaper

Mammoth Lakes, CA

Free weekly paper with circulation of ~6,000, serving communities across two counties.

Editor

2015 - 2016

Staff Writer

2012 – 2015

Part-Time Writer

2010 - 2012

- Assigned stories to staff of two full-time and five part-time contributors.
- Worked with advertising director to coordinate ads and content.
- Generated three to five stories per week covering wide range of subjects, including science and technology, arts and entertainment, and local government.
- Proofread and placed stories in InDesign and WordPress.

LANCE J. COLWELL

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PERFORMANCE DRIVEN BIOTECH EXECUTIVE

Chief Operating Officer • “Corporate Athlete” • Commercial Strategy • New Product Launches

Results-oriented leader with demonstrated success in devising and executing strategic business plans, maximizing limited resources, and building strong organizational cultures to exceed P&L targets. Consistently excel in general management and broad functional leadership roles as evidenced by high performance ratings throughout career and regular designation as key talent/promotable.

Proven experience in building companies, launching successful brands and turning around underperforming products/teams across a variety of functions and therapeutic areas including specialty care and rare diseases. Reputation as a passionate, integrity-driven, empowering team leader capable of motivating others and fostering an environment for personal growth and development. Talent for hiring, building, and leading top-performing teams focused on exceeding patient/HCP expectations, achieving corporate goals, and creating healthy organizational cultures. Demonstrated track record in 20 therapeutic areas, 10+ product launches, and multiple pre-clinical to post-launch phase development programs.

Key Accomplishments:

- Achieved one of the best rare disease launches ever (Spinraza) which surpassed external expectations by 350% (\$657M)
- Exceeded P&L contribution targets each year as affiliate head in EU. Last full year results were 106.6% vs. EU avg. of 94.1%
- Increased product revenue 35% Y/Y (triple growth rate of previous year) for a \$2.6 billion portfolio by transforming strategy
- Earned excellent ratings from customers for commercial/medical affairs teams across a range of leadership roles

PROFESSIONAL EXPERIENCE

Ohana Biosciences – Cambridge, MA

Chief Operating Officer (2018 – present)

Overview of responsibilities:

Have led a range of functions including: program and portfolio management, medical affairs, commercial, manufacturing/quality, corporate affairs (public affairs, advocacy and government affairs), business development and human resources. Responsible for enterprise wide planning to define how to effectively ready the organization to scale appropriately as it prepares for commercialization. Leveraged limited resources to build critical organizational capabilities focused on creating shareholder value. Led business development efforts to out license of phase 3 asset. Partner with Human Resources to implement a variety of internal initiatives to foster a healthy culture. Played a key role within the executive team in ensuring regular cross-functional dialogue regarding organizational priorities and tracking progress against corporate goals.

BIOGEN – Cambridge, MA

2004 – 2018

Vice President, US Rare Disease Group (2016 – 2018)

Vice President, Global Commercial Excellence and Operations (2014 – 2016)

Head of Austrian Affiliate (2011 – 2014)

Senior Director Global Medical Affairs (2010 – 2011)

Senior Director Training and Development (2008 – 2010)

Director Marketing (2005 – 2008)

Associate Director Marketing (2004 – 2005)

Selected accomplishments:

- Achieved one of the best rare disease launches ever (Spinraza) which exceeded external expectations by 350% (\$657M).

- Earned very high Net Promoter scores for Sales (“excellent”) & Family Access (“world class”) as rated by Spinraza customers.
- Attained strong culture survey results for Rare Disease team which exceeded internal/external benchmarks for all categories.
- Oversaw successful development of three separate product launch readiness programs for the global sales organizations.
- Delivered significant cost savings multiple times via restructure of commercial and corporate functions.
- Elevated Austrian affiliate performance from last place to top third in EU+ based on most important P&L metrics.
- Exceeded contribution targets each year in EU. Last full year results were 106.6% of plan for Austria vs. the EU avg. of 94.1%.
- Austrian Sales and Medical teams were ranked #1 by customers after two previous years being rated at the middle/bottom.
- Affiliate employee culture survey showed dramatic improvement, exceeding internal/external benchmarks in nearly all areas.
- Redesigned and deployed medical affairs global governance and instituted new strategic planning process.
- Achieved #1 global ranking as best medical affairs department based on customer perceptions in largest markets.
- Decreased Avonex market share erosion by 50% over a 15-month period. Best Avonex performance between 2000 and 2010.
- Awarded highest achievable “Standing Ovation” for leading VP’s/department heads/co-promote partner during Tysabri crisis.
- Led Tysabri launch to healthcare professionals – considered most successful launch in MS market prior to product withdrawal.
- 1 of 9 employees worldwide selected in March 2010 to participate in two-year long executive development program.
- Focused development of individuals resulting in several staff being promoted to greater areas of responsibility.

Overview of responsibilities:

Vice President, US Rare Disease Group (2016 – 2018)

Selected to lead US launch within one month of organization seeing Phase III data for the first time. Successfully prepared organization for one of the fastest approvals (4.5 months from time of data unblinding) and most complex launches in the history of the industry. Responsible for Marketing, Account Executives (Hospital Sales), Family Access Managers, Reimbursement Managers, and Thought Leader Liaisons. Oversaw cross-functional team (medical, patient services, payer access, patient advocacy, public affairs, government affairs etc.) that ensured successful achievement of P&L performance metrics. Developed and implemented a range of innovative solutions to overcome multiple launch challenges and meet the needs of patients/HCPs/hospitals.

Vice President, Global Commercial Excellence & Operations (2014 – 2016)

Appointed initially to lead the Global Sales Force Excellence and Corporate Meeting management functions and after four months was asked to also oversee the Marketing Excellence, Launch Excellence and Digital Customer Engagement teams. Following corporate restructuring my responsibilities were further expanded to include four more global functions (competitive intelligence, market research, commercial information management, and forecasting/analytics) and the regional commercial operations for LATAM and APAC.

Head of Austrian Affiliate (2011 – 2014)

One of two internal employees in 10+ years to be selected to lead a non-English speaking affiliate on a long-term assignment. Charged with turning around an underperforming affiliate and transforming a dysfunctional organizational culture. Responsible for full P&L and all affiliate functions including marketing, sales, access and reimbursement, medical, public affairs, government relations, regulatory/quality, finance, human resources, and distribution.

Senior Director Global Medical Affairs (2010 – 2011)

Recruited for dual-role as chief of staff to global head of medical affairs and to lead four global functions (medical information, training and development, operations, and grants/donations). Led efforts to assess internal/external perceptions of medical affairs and developed plan to address gaps. Cultivated a stronger performance oriented mindset throughout organization and instituted better accountability across departments. Drove initiatives to overhaul organizational structure, improve department culture, optimize planning processes, and strengthen relationships with partner functions and local affiliates.

Senior Director Training & Development (2008 – 2010)

Hand-selected by Commercial SVP to consolidate and integrate the neurology, oncology, and rheumatology training departments into one centralized function. Conducted a situation assessment and formulated a 3-year operational plan. Overhauled department by replacing 80% of staff, established new team vision/mission/training strategies, and devised/implemented operational efficiencies. Attained average 4.7 of 5 overall satisfaction rating for programs.

Associate Director & Director Marketing (2004 – 2008)

Recruited to analyze current market situations, and devise and incorporate strategic / tactical plans to launch new products and turnaround underperforming brands. Built and led marketing departments and brand teams in US and Germany responsible for all key

Biogen Idec neurology products (Tysabri, Avonex & Franchise). Led large cross-functional teams to focus on key performance drivers and develop innovative marketing plans based upon market research, competitive analysis and target market demographics.

PURDUE PHARMA – Stamford, CT

1997 – 2004

Associate Director of Marketing (2003 – 2004)

Group Product Manager (2001 – 2003),

Senior Product Manager (2000 – 2001),

Product Manager (1999 – 2000)

Sales Representative (1997 – 1999)

Selected accomplishments:

- Increased revenue 35% Y/Y (triple growth rate of previous year) by repositioning products through development of new advertising campaign and physician and patient education program designed to mitigate pain medication abuse
- Appointed to lead Global and US launch team for company's most important pipeline product; Provided key corporate leadership in shepherding three pipeline products through Phase 2 and 3 development process.
- Achieved Top 10 ranking out of 450 representatives while winning the Topper & Regional Product Leader awards in 1998
- Received highest achievable annual performance rating, "Highly Effective", throughout entire company tenure

Overview of responsibilities:

- P&L accountability for \$2.6 billion portfolio consisting of analgesic products within the pain franchise and compounds in the development pipeline. Led team overseeing in-line assets and three product launches. Supervised and led commercial assessments for business development opportunities beyond pain management. Identified, analyzed, and recommended business opportunities, product acquisitions, and partnerships to further corporate goals. Partnered with R&D and Regulatory on the design and incorporation of studies for early and late stage product development to ensure products met market place needs.

BAYER CORPORATION – New Haven, CT

1996 – 1997

Medical Sales Representative

- Ranked #1 in district for launch of new diabetes medication; selected as Captain of the Institutional Target team

G.D. SEARLE – Skokie, IL

1994 – 1996

Medical Sales Representative

- Achieved Top 10 ranking out of 700 representatives for annual sales subsequent to initial rank in bottom 20% at start of employment

3M MEDICAL – Marketing Intern - Borken, Germany

1993

EDUCATIONAL BACKGROUND

Bachelor of Science in Marketing, concentration in German • Bentley University – Waltham, MA

LAUREN BOURKE-LAYNE, Ph.D.
Everett, MA
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PROFESSIONAL SUMMARY

- Forward-thinking biomedical research scientist with extensive experience in molecular biology, cardiovascular development and sperm biology, including identification and characterization of novel biomarkers for cardiovascular disease and sperm health.
- Excellent team player and effective collaborator in cross-functional teams, including clinicians, scientists and bioinformaticians, resulting in peer-reviewed scientific publications.
- Self-motivated, exquisitely organized and detail-oriented, creative individual with a track record of easily integrating into matrixed multidisciplinary work environments.

PROFESSIONAL EXPERIENCE

Oct 2019 - Present Ohana Biosciences Inc, Cambridge, USA
Scientist II

Company leveraging sperm biology expertise to enhance fertility, contraception, pregnancy and child health outcomes.

- Led research team focused on sperm biology, infertility and inherited disease.
- Responsible for design, execution, analysis and interpretation of bulk sperm (human and mouse) and single embryo (mouse) next generation sequencing mRNA and small RNA experiments.
- Led and worked collaboratively in a matrixed environment with a cross-functional team, including genomics, molecular biology, computational biology, clinical, and *in vivo* team members.
- Responsible for communicating scientific insights to the broader scientific and leadership teams.

June 2016 – Sept 2019 University of Massachusetts Medical School, Worcester, USA
Postdoctoral Associate

Lab focused on chromatin modifying enzymes and their role in cardiac development

- Research focused on developing mouse models of congenital heart disease, utilizing knock-in, knock-out and Cre mice.
- Responsible for training students in anatomy, molecular and cell biology, histology and imaging techniques.
- Managed and worked with a cross-functional team that included cardiologists, pathologists, molecular biologists and bioinformaticians.
- Generated and updated SOPs for the lab.
- Served as point-person with vendors for equipment purchases and in evaluating new technologies.

Feb - May 2016 QIMR Berghofer Medical Research Institute (QIMRB), Brisbane, Australia
Research Assistant

Lab sequenced families with a history of cancer to identify gene variants that may predispose members to cancer

- Responsible for extracting DNA, Sanger Sequencing and identification of cancer gene variants among family cohorts.
- Evaluated and interpreted sequencing information from publicly available datasets.
- Responsible for maintenance of laboratory databases, reagents, and supplies.

Feb 2013 – Feb 2016 QIMR Berghofer Medical Research Institute (QIMRB), Brisbane, Australia
Postgraduate Researcher

Lab focused on identifying novel chromatin modifying enzymes in the mouse

- Used molecular biology, cell biology, tissue culture and small animal models to identify a novel gene required for maintenance of DNA methylation and normal heart development.
- Contributed to successful scholarship and grant applications, including personal awards of >\$80,000.
- Presented oral and poster presentations at national conferences.
- Established collaborations with national and international research groups.

July 2010 – July 2014 Mater Adult Hospital, Brisbane, Australia
Clinical Scientist

Biochemistry and Molecular Genetics laboratories

- Performed testing of specimens and controls according to laboratory guidelines and National regulatory agencies.
- Evaluated, interpreted, documented and communicated critical test results to physicians.
- Resolved technical/instrumental problems and verified unexpected clinical results.
- Conducted quality control of new/used reagents and supplies.

April 2009 – July 2010 ImmuneXpress (prev. Athlomics)
Student Researcher

Molecular diagnostics company establishing a gene expression kit for blood poisoning (septicemia)

- Responsible for collating clinical data received from wards into a secure company database.
- Assisted clinical scientists in sample preparation, experimentation and data analysis.

EDUCATION

- 2016** **Queensland University of Technology / QIMRB, Brisbane, Australia**
Ph.D. in Epigenetics
Thesis: Investigating the role of a novel epigenetic modifier, Rearranged L-Myc Fusion.
- 2012** **Queensland University of Technology, Brisbane, Australia**
B. Biomedical Science, First Class Honors (GPA 7/7)
Thesis: Investigating the role of chromatin remodelers in the hypoxia response.
- 2011** **Queensland University of Technology, Brisbane, Australia**
B. App. Science (Biotechnology), with distinction / B. Business (Marketing), with distinction

TECHNICAL EXPERIENCE

Molecular Techniques: DNA extraction and purification, PCR, agarose gel electrophoresis, cloning (ligation, transformation), bisulfite sequencing, site directed mutagenesis, DNA sequence analysis.

RNA Techniques: RNA extraction from cells and tissue, quantitative PCR.

Next Gen Sequencing: Experienced in mRNA and small RNA sequencing and library preparation using the Illumina platform.

Bioinformatics: Basic analysis of microarray, RNAseq, ChIPseq/CUT & RUN, and Hi-C datasets, interpretation of publicly available datasets (UCSC, GEO datasets).

Protein Techniques: Protein extraction, quantification and Western blotting of both cell lines and tissue. Co-immunoprecipitation (Co-IP), chromatin immunoprecipitation (ChIP), cleavage under targets and release using nuclease (CUT&RUN), chromosome conformation capture (Hi-C) of mouse tissue.

Cell Culture: Maintenance of adherent and non-adherent cell lines, generation of cell lines from mouse tissue, cell culture in both hypoxic and normoxic conditions, PEI transfection, archiving of cells in liquid nitrogen, FACS analysis.

Histology: Tissue and cell fixation and preparation, cryo- and microtome sectioning, immunohistochemistry, immunofluorescence, optimization of general staining protocols.

Microscopy: Light microscopy, fluorescent microscopy, confocal microscopy.

Animal Handling: Breeding and maintenance of multiple mouse lines, adult and embryo tissue collection for preparation of DNA, RNA, protein and histology, experienced with whole genome, knock-in, knock-out and Cre mouse lines, tail-vein and intraperitoneal injections, oral gavage.

Software: Microsoft Word, Excel and PowerPoint, Adobe Photoshop and Illustrator, GraphPad Prism, MacVector, EndNote, Literature Search (PubMed, MEDLINE, GoogleScholar, ScienceDirect).

SELECTED AWARDS / SCHOLARSHIPS

- | | | |
|--------------------|--|--------------------------------------|
| 2015 | International Travel Award
\$5,000 awarded to top 3 Ph.D. students to present at an international conference | QIMR Berghofer |
| 2014 – 2016 | Academic Excellence top-up Scholarship
\$10,000 p/a competitive scholarship awarded to top 10 Ph.D. students | QIMR Berghofer |
| 2013 – 2016 | QUT Academic Excellence Scholarship
\$6,000 p/a awarded to students with GPA of 7/7 | QUT |
| 2013 – 2016 | Australian PostGraduate Award
\$26,000 p/a awarded to students with exceptional research potential | Australian Federal Government |

SHORT COURSES

- | | | |
|------|-------------------------------------|---|
| 2016 | Responsible Conduct of Research | <i>University of Massachusetts Medical School</i> |
| 2015 | Research Commercialisation | <i>e-Grad School Aust./Aust. Technology Network, Brisbane</i> |
| 2014 | Introduction to R | <i>QFAB Bioinformatics, Brisbane</i> |
| | Leadership and Communication | <i>e-Grad School Aust./Aust. Technology Network, Brisbane</i> |
| 2013 | Next Generation Sequencing Workshop | <i>CSIRO/ EMBL/ EBI, Melbourne</i> |
| | Project Management | <i>e-Grad School Aust./Aust. Technology Network, Brisbane</i> |
| 2012 | Welfare of Experimental Animals | <i>QIMRB/ University of Queensland, Brisbane</i> |

PUBLICATIONS

Milstone ZJ, Saheera S, **Bourke LM**, Shpilka T, Haynes CM, Trivedi CM. Histone deacetylases 1 and 2 silence cryptic transcription to promote mitochondrial function during cardiogenesis. *Sci Adv.* 2020 Apr 10;6(15):eaax5150. doi: 10.1126/sciadv.aax5150.

Johansson PA, Nathan V, **Bourke LM**, Palmer JM, Zhang T, Symmons J, Howlie M, Patch AM, Read J, Holland EA, Schmid H, Warriar S, Glasson W, Höiom V, Wadt K, Jönsson G, Olsson H, Ingvar C, Mann G, Brown KM, Hayward NK, Pritchard AL. Evaluation of the contribution of germline variants in BRCA1 and BRCA2 to uveal and cutaneous melanoma. *Melanoma Res.* 2019 Oct;29(5):483-490. doi: 10.1097/CMR.0000000000000613.

Acharya D, Nera B, Milstone ZJ, **Bourke L**, Yoon Y, Rivera-Pérez JA, Trivedi CM, Fazio TG. TIP55, a splice isoform of the KAT5 acetyltransferase, is essential for developmental gene regulation and organogenesis. *Sci Rep.* 2018 Oct 8;8(1):14908. doi: 10.1038/s41598-018-33213-4.

Del Monte-Nieto G, Ramialison M, Adam AAS, Wu B, Aharonov A, D'Uva G, **Bourke LM**, Pitulescu ME, Chen H, de la Pompa JL, Shou W, Adams RH, Harten SK, Tzahor E, Zhou B, Harvey RP. Control of cardiac jelly dynamics by NOTCH1 and NRG1 defines the building plan for trabeculation. *Nature.* 2018 May;557(7705):439-445. doi: 10.1038/s41586-018-0110-6.

Bourke LM, Del Monte-Nieto G, Outhwaite JE, Bharti V, Pollock PM, Simmons DG, Adam A, Hur SS, Maghzal GJ, Whitelaw E, Stocker R, Suter CM, Harvey RP, Harten SK. Loss of Rearranged L-Myc Fusion (RLF) results in defects in heart development in the mouse. *Differentiation.* 2017 Mar-Apr;94:8-20. doi: 10.1016/j.diff.2016.11.004

Harten SK, Oey H, **Bourke LM**, Bharti V, Isbel L, Daxinger L, Faou P, Robertson N, Matthews JM, Whitelaw E. The recently identified modifier of murine metastable epialleles, Rearranged L-Myc Fusion, is involved in maintaining epigenetic marks at CpG island shores and enhancers. *BMC Biol.* 2015 Mar 26;13:21. doi: 10.1186/s12915-015-0128-2.

Madhavi Kolli, PhD, MPH

LinkedIn • 508-887-3729 • madhavigolli@gmail.com

Authorized to work in the United States

QUALIFICATIONS & SUMMARY

- Detail-oriented biomedical research scientist with extensive experience in protein-protein/protein-small molecule inhibitor interactions
- Team player that cultivates effective collaboration in cross-functional teams resulting in peer-reviewed scientific publications
- Effective communicator with extensive experience in written and oral presentation of scientific research to varied audiences
- Self-motivated, organized individual with an open mind and ability to adapt to new fields and easily integrate into matrixed multidisciplinary work environments teams

PROFESSIONAL EXPERIENCE

Ohana Biosciences, Cambridge, MA, 2019 - Present

Scientist II, Protein Engineering

- Drove the enhancement of in-house capabilities for expression/purification and biochemical/biophysical characterization of antibodies and antigens
- Established SPR capabilities for the company and characterized binding affinities of target antibodies
- Led the development of in-house protein-bead conjugations, and protein-oligo conjugations by click chemistry for cell separation and surface profiling technologies
- Established and directed antibody expression and purification project with CRO
- Responsible for communicating scientific insights to the broader scientific teams

Blue Point Materials Research, Herndon, VA, 2017 - 2019

Consultant, Biological Research

- Developed research strategies for testing novel materials designed to improve patient outcomes in hospital settings
- Co-authored an NIH SBIR Phase I proposal for funding proof-of-concept study to evaluate novel materials
- Presented to venture capital investors and successfully raised \$50K seed money
- Investigated antibacterial and antibiofilm properties of novel materials
- Mentored and managed a research technician

RESEARCH EXPERIENCE

University of Massachusetts Medical School, Worcester, MA

Post-Doctoral Fellow 2010-2015

Research focused on understanding evolution of drug resistance to HIV-1 protease inhibitors

- Led research focused on investigating impact of co-evolution of resistance mutations on HIV-1 Gag processing using protease assays and x-ray crystallography
- Carried out x-ray crystallographic structural studies and FRET-based enzyme kinetic assays on a collaborative project developing novel small molecule inhibitors of HIV-1 protease
- Trained and supervised undergraduate and graduate students

Graduate Student 2003-2009

- Discovered that HIV-1 Gag polyprotein co-evolves with HIV-1 protease under drug therapy as a drug resistance mechanism using statistical analyses
- Structurally demonstrated the impact of co-evolving mutations using x-ray crystallographic

- studies of protease-substrate co-complexes
- Investigated and compared thermodynamic parameters of inhibitors binding to HIV-1 protease variants using isothermal titration calorimetry
- Trained and supervised undergraduate students

EDUCATION

Harvard T.H. Chan School of Public Health, Boston, MA, USA

MPH, Global Health, 2016

University of Massachusetts Medical School, Worcester, MA, USA

Ph.D., Biochemistry and Molecular Pharmacology, 2010

Manipal University, Manipal, Karnataka, India

M.Sc., Biochemistry, 1999

Osmania University, Hyderabad, Andhra Pradesh, India

B.Sc., Genetics, Chemistry and Zoology, 1996

BIOCHEMISTRY SKILLS

- Recombinant protein production and purification from *E. coli* and mammalian cell culture, and separation by SEC and Affinity chromatography (AKTA)
- Biochemical characterization of proteins by UV/Vis spectroscopy, SEC (HPLC – Agilent), SDS-PAGE, Western Blotting, ELISA
- Protein-protein and protein-small molecule interaction studies by Isothermal titration calorimetry (ITC) and Surface Plasmon Resonance (SPR), and X-ray crystallography
- FRET-based enzyme kinetic assays
- Click chemistry tools

MOLECULAR BIOLOGY SKILLS

- Nucleic acid purification, cloning, PCR, construct design, and site-directed mutagenesis
- *In vitro* transcription & translation using radio-labeled isotopes

COMPUTER SKILLS

- PyMOL, Graphpad Prism, Benchling (ELN), ASANA, Microsoft Office
- Online Tools: Clustal Omega, PDB, UniProt, ExPASy

PUBLICATIONS

- **Kolli M**, Özen A, Kurt-Yilmaz N and Schiffer CA. (2014). *HIV-1 protease-substrate co-evolution in nelfinavir resistance*. J Virol.
- Lee SK, Potempa M, **Kolli M**, Özen A, Schiffer CA, Swanstrom R. (2012). *Context surrounding processing sites is crucial in determining cleavage rate of a subset of processing sites in HIV-1 Gag and Gag-Pro-Pol polyprotein precursors by viral protease*. J.Biol.Chem.
- Parry CM, **Kolli M**, Myers RE, Cane PA, Schiffer C and Pillay D. (2011). *Three residues in HIV-1 matrix contribute to protease inhibitor susceptibility and replication capacity*. Antimicrobial Agents and Chemotherapy.
- Bandaranayake RM, **Kolli M**, King NM, Nalivaika EA, Heroux A, Kakizawa J, Sugiura W and Schiffer CA. (2010) *The effect of clade-specific sequence polymorphisms on HIV-1 protease activity and inhibitor resistance pathways*. J Virol.
- Ali A, Bandaranayake RM, Cai Y, King NM, **Kolli M**, Mittal S, Murzycki JF, Nalam MNL, Nalivaika EA, Özen A, Prabu-Jeybalan MM, Thayer K and Schiffer CA. (2010). *Molecular basis for drug resistance in HIV-1 protease*. Viruses. 2(11), 2509-2535.
- **Kolli M**, Stawiski E, Chappay C, Schiffer CA. (2009). *Human immunodeficiency virus type 1 protease-correlated cleavage site mutations enhance inhibitor resistance*. J Virol.
- **Kolli M**, Lastere S and Schiffer CA. (2006). *Coevolution of nelfinavir-resistant HIV-1 protease and the p1-p6 substrate*. Virology.

Malia J. D'Orlando

Cambridge, MA 02140 | mjedorlando1@gmail.com | (781) 484-6853 | [linkedin.com/in/mjedorlando](https://www.linkedin.com/in/mjedorlando)

PROFESSIONAL SUMMARY

Focused project and program manager with comprehensive experience in healthcare, biotechnology, and academic fields. Skilled in coordinating schedules, proposing timelines, enhancing workflows, and adapting to a dynamic work environment. Equipped with a strong background in public health, and knowledge of IRB regulations and processes.

EDUCATION

Boston University, Boston, MA

Graduate Certificate in Public Health (*Anticipated May 2021*)

University of Massachusetts, Lowell, MA

Bachelor of Science, Public Health – Community Health and Health Promotion

SKILLS INCLUDE:

- Microsoft Office
- Google Suite
- Data Management (Benchling)
- Program Management (Asana, G-Suite)
- Data Entry in Healthcare
- Project Coordination
- Time Management
- CITI Human Subjects Research Certification - Biomedical Basic (Record ID#: 40893220)
- LIMS technology (PowerPath, SunQuest, EPIC)
- Interpersonal Communication/Donor Relations

EXPERIENCE

Ohana Biosciences, Inc.

Cambridge, MA

A company pioneering a reproductive health revolution through a unique platform of sperm-based technologies.

Clinical Sample Management Associate

(January 2021- Present)

- Brought on board as the first Clinical Sample Management Associate to manage, innovate, and improve the existing semen Donor Program.
- Recruit and enroll eligible participants in the semen Donor Program according to established, IRB approved protocol for Sperm Cell Biomarker Research.
- Review, edit, and update existing study documents, preparing them for IRB submission.
- Conceptualized the functional requirements for an innovative, customized application to streamline aspects of the Donor Program including enrollment, sample acquisition, and tracking in collaboration with the VP of IT.
- Organize and maintain electronic master file of PHI and donor records for all past and present participants.
- Act as primary liaison between study participants and all laboratory research scientists, ensuring effective communication and coordinated scheduling.
- Work independently to effectively prioritize daily tasks, special requests, and long-term projects.
- Frequently assess needs of research scientists and adapt project plans to accommodate new research ideas.

Brigham and Women's Hospital

Boston, MA

CMD Coordinator II

(June 2020 - January 2021)

CMD Coordinator I

(June 2019 - June 2020)

- Collaborated with a team in specimen receiving at the Center for Advanced Molecular Diagnostics.
- Facilitated communication between lab technicians and ordering clinicians, research protocol teams, etc.
- Remediated problematic samples and/or testing requisitions by communicating effectively with clinicians and other medical staff from hospitals within the Partner's network and outside institutions.
- Utilized digital medical record systems to verify patient information with vigilant attention to detail.
- Communicated with Molecular and Cytogenetic Technologists to guarantee the desired testing was a medical necessity.
- Processed COVID-19 nasopharyngeal swabs for the Molecular lab and coordinated with varying collection sites to troubleshoot issues and adhere by a firm turnaround time.

- Formulated SOPs for the accessioning team after abrupt implementation of a new LIMS, Sunquest, needed for COVID-19 testing.
- Provided support, assistance, and supervision to CMD Coordinator I team members.

University of Massachusetts Lowell – Wellness Center

Health Education & Promotion Assistant

Lowell, MA

(January 2019 - May 2019)

- Assisted the Director of Health Education and Promotion with events and projects designed to improve the overall health knowledge of the student body.
- Focused projects on health concerns relevant among collegians such as, sexual health, mental health, intellectual health, physical health, social health, etc.
- Implemented social media initiatives to provide students with resources needed to advocate for personal health and improve self-efficacy.
- Designed a visually attractive brochure for an Anti-Vaping Campaign on campus highlighting the harmful effects of nicotine dependence in young adults.

Martin PREYER, PhD

Somerville, MA 02144

858-999-4714

preyer.martin@gmail.com

Summary

Visionary scientific leader with deep expertise in antibody engineering and a strong background in cancer biology and immuno-oncology

Driver of innovation with a track record of inventing and advancing bispecific antibody technologies as supported by patents and publications

Proven manager and leader with experience of managing, mentoring, and developing PhD and non-PhD scientists and successfully leading multidisciplinary drug discovery teams

Excellent communicator and effective presenter to internal stakeholders, leadership teams as well as external audiences and investors

Recognized as outstanding collaborator in multi-disciplinary drug discovery teams in biotech/pharma across various therapeutic areas including immuno-oncology, immunology, neurobiology, hemophilia, fibrotic disease and sperm biology

Experience

Senior Director, Protein Engineering, Ohana Biosciences (April 2020-present)

- Project lead on Ohana's male contraceptive research program, which is developing multiple antibodies as non-hormonal contraceptive drugs
- Managing an organization of 13 people comprising three research groups (protein engineering, cell-based assays, microfluidics and separation technologies)
- Leading all biologics drug discovery activities at Ohana
- Advancing antibody engineering to optimize lead candidates and eliminate liabilities (humanization, immunogenicity assessment, PK-PD optimization, stability engineering)
- Managing antibody discovery campaigns with CROs utilizing immunization and display methods against various target classes including integral membrane proteins
- Developing *in vitro* assays for sperm surface profiling, immunocytochemistry, metabolic and chromosomal integrity, and characterizing functional activity of drug candidates
- Antibody drug target identification and validation
- Member of the extended leadership team of Ohana
- Leading the research strategy meeting, which is planning and strategizing all of Ohana's research activities

Director, Head of Protein Sciences, Revitope Oncology (2017-2020)

- Developing protease-activatable bispecific antibodies for immuno-oncology
- Recruited into Revitope by the CSO as key hire #02, I have successfully built the research organization from the ground up
- Led a cross-functional group of 7 people, which performed all research activities at Revitope: molecular biology, antibody expression, purification, biochemical/biophysical characterization of bispecifics, assay development, pharmacology and *in vitro* assays

- Developing quantitative systems pharmacology models in collaboration with Applied Biomath
- Member of the senior leadership team, reporting to the CSO, responsible for developing and executing the research strategy of Revitope
- Responsible for presenting scientific strategy and progress to Revitope's Board of Directors at all board meetings
- Advancing platform technologies, driving innovation and generating IP
- Managed external research through CROs and academic collaborators (protein production, antibody generation, *in vivo* experiments)

Scientist (various levels), Biogen (2013-2017)

- Managed a molecular biology and protein engineering group, which was focused on engineering antibodies and other biologics drugs and generating reagents as antigens and supporting assay development
- I initiated and led the Bispecific Antibody program at Biogen, which resulted in the development of a novel bispecific antibody platform (patented and published)
- Core team member on several research programs in various therapeutic areas (Neurobiology, Fibrosis, Hemophilia) and at various stages from exploratory science through research-to-development transition, development support and post market
- Collaborated with the Antibody Discovery, Structural Biology and Mass-spectrometry groups on numerous protein engineering projects (humanization, affinity maturation, developability engineering, bispecific antibodies)
- Generated antigens and reagents to support antibody discovery by yeast display and by immunization in mouse and rabbit B cell technologies (recombinant protein, DNA, or engineered cells)
- Molecular biology lead on the technology development of mouse B cell antibody repertoire mining and characterization by next-generation sequencing
- Responsible for genetic engineering of various host cells by CRISPR-mediated knock-out or knock-in

Postdoctoral Fellow, The Salk Institute for Biological Studies (2008-2013)

- Discovery of genes involved in regulating the response of BRCA1-deficient breast and ovarian cancer to chemotherapeutic agents, based on lentiviral vector screen
- Mechanism of action studies on the novel chromatin-modifying protein ZMYND8 and its role in DNA replication stress induced by chemotherapeutic drugs or radiation
- Development of a broad array of *in vitro* assays including labeling and immunofluorescent imaging of DNA replication forks, imaging of Holliday junctions by transmission electron microscopy, use of lentiviral vectors for gene expression and knock-down

Postdoctoral Scientist, Boehringer Ingelheim Austria (2007-2008)

- A valuable first industry experience in small molecule pharmacology
- Mechanism of action studies of the irreversible small molecule EGFR/HER2 inhibitor lead candidate Afatinib (Gilotrif®, BIBW2992) in non-small cell lung cancer
- Development of pharmacological assays to study the interplay of oncogene-dependence and cell adhesion signaling pathways

Graduate student/visiting scholar, University of California San Diego (2002-2006)

- Visiting PhD student supported by a doctoral scholarship from the Austrian Academy of Sciences

- Thesis project "Nuclear Import of ABL tyrosine kinase: Regulation and biological role"
- Mechanism of action studies on the BCR-ABL tyrosine kinase inhibitor Imatinib
- Generation of knock-in and conditional knock-out mice
- Studying DNA damage-induced signal transduction and cell death

Education

PhD in Biotechnology (Dr. rer. nat. techn.), University of Natural Resources and Applied Life Sciences, Vienna, Austria, *with distinction* (2007)

Diploma Engineer, Food Science and Biotechnology, University of Natural Resources and Applied Life Sciences, Vienna, Austria, *with distinction* (2002)

Patents

Preyer M, Colthart A, and Mark Cobbold Improved TEAC and ATTAC immunooncology compositions and methods, PCT/US2020/029548

Preyer M, Weinstein P, Cothart A, Wiencek P, Geiger E, and Meier W, Twin immune cell engagers, PCT/US2019/066542

Preyer M, Bispecific Antibody Platform, PCT/US2016/066865

Cameron TO, Crackower MA, Dolinski BM, Hanf KJM, McCurley AT, Pederson NE, **Preyer M**, Qian F, Violette SM, Weinreb PH. Humanized anti-alpha V beta 5 antibodies and uses thereof, PCT/US2015/049746

Preyer M and Colthart A, Half-life stabilization of immunooncology constructs by using improved masking domains, PCT filed

Presentations

Gordon Research Conference on Antibody Biology and Engineering (Lucca, Italy, 2018, Poster)

Helmsley Center for Genomic Medicine, The Salk Institute (La Jolla, 2013)

Abcam Genome Stability Conference (Nassau, Bahamas, 2012, Poster)

Institute for Cancer Research, Medical University Vienna (Vienna, Austria, 2007)

Basic and Translational Research Rounds, Moores UCSD Cancer Center, (La Jolla, 2005)

44th American Society for Cell Biology Meeting, Annual Meeting (Washington DC, 2004)

Publications

Cooke H, Arndt J, Quan C, Shapiro R, Wen D, Foley S, Vecchi M, **Preyer M**. EFab Domain Substitution as a Solution to the Light-Chain Pairing Problem of Bispecific Antibodies. MAbs. 2018 Nov-Dec;10(8):1248-1259. Epub 2018 Sep 20.

Preyer M, Vigneri P, Wang JY. Interplay between kinase domain autophosphorylation and F-actin binding domain in regulating imatinib sensitivity and nuclear import of BCR-ABL. PLoS One. 2011 Feb 11;6(2):e17020. doi: 10.1371/journal.pone.0017020.

Preyer M, Shu CW, Wang JY. Delayed activation of Bax by DNA damage in embryonic stem cells with knock-in mutations of the Abl nuclear localization signals. *Cell Death Differ.* 2007 Jun;14(6):1139-48. Epub 2007 Mar 16.

Schatzl G, Marberger M, Remzi M, Grösser P, Unterlechner J, Haidinger G, Zidek T, **Preyer M**, Micksche M, Gsur A. Polymorphism in ARE-I region of prostate-specific antigen gene associated with low serum testosterone level and high-grade prostate cancer. *Urology.* 2005 Jun;65(6):1141-5.

Schatzl G, Madersbacher S, Haitel A, Gsur A, **Preyer M**, Haidinger G, Gassner C, Ochsner M, Marberger M. Associations of serum testosterone with microvessel density, androgen receptor density and androgen receptor gene polymorphism in prostate cancer. *J Urol.* 2003 Apr;169(4):1312-5.

Gsur A, **Preyer M**, Haidinger G, Zidek T, Madersbacher S, Schatzl G, Marberger M, Vutuc C, Micksche M. Polymorphic CAG repeats in the androgen receptor gene, prostate-specific antigen polymorphism and prostate cancer risk. *Carcinogenesis.* 2002 Oct;23(10):1647-51.

Schatzl G, Madersbacher S, Gsur A, **Preyer M**, Haidinger G, Haitel A, Vutuc C, Micksche M, Marberger M. Association of polymorphisms within androgen receptor, 5alpha-reductase, and PSA genes with prostate volume, clinical parameters, and endocrine status in elderly men. *Prostate.* 2002 Jul 1;52(2):130-8.

Gsur A, **Preyer M**, Haidinger G, Schatzl G, Madersbacher S, Marberger M, Vutuc C, Micksche M. A polymorphism in the UDP-Glucuronosyltransferase 2B15 gene (D85Y) is not associated with prostate cancer risk. *Cancer Epidemiol Biomarkers Prev.* 2002 May;11(5):497-8.

Matthew Maderia

70 Prospect St · Cambridge, MA 02139 · (978) 317-7311 · mmaderia15@gmail.com
www.linkedin.com/in/matthew-maderia

SUMMARY

BS in Biology with 2 years of industry experience. Skilled in protein expression, purification, and cell culture maintenance. Experience in assay development. Active participant in company culture collectives. Incredibly efficient and ambitious member of the research team with an exceptional work ethic and a high level of enthusiasm for biotech research.

EDUCATION

Boston College, BS in Biology, *Chestnut Hill, MA*

Class of 2019

Semester Abroad – *University College of Cork, Ireland*

January 2018 – May 2018

Saint John's Preparatory High School - *Danvers, MA*

Class of 2015

RESEARCH EXPERIENCE

Ohana Biosciences, *Cambridge, MA*

August 2019 - April 2021

Research Associate - Protein Engineering Team

- Integral member of a four person team tasked with expressing (E. coli and mammalian transient transfection), purifying (affinity purification and FPLC), and performing QC Assays (analytical SEC, endotoxin analysis, western blot) for both antibodies/antigens.
- Developed new protocols to meet the needs of specific proteins and projects including *in vitro* and *ex vivo* assays.
- Validated antibodies and potential antigen targets through Western Blot, and various in-house cell-based experiments.
- Developed and performed protease activity assays for enzyme analysis and inhibitor testing.
- Led the transfer of laboratory protein inventory to an ELN for easy tracking, and developed key processes for managing protein organization for the thirty member laboratory team.
- Assisted in characterizing and identifying sperm specific proteins to facilitate further the understanding of sperm cells.

Sanofi, *Framingham, MA*

Summer 2017, May-October 2018

Undergraduate Intern - Rare Disease Research Department

- Independently maintained mammalian cell culture for transient transfection and purification of CFTR for downstream biophysical and structural characterization in a native lipid bilayer, resulting in successful low Å CryoEM images.
- Developed techniques for the isolation and purification of transmembrane proteins from cultured and primary mammalian cells using an amphipathic copolymer
- Executed construct mutagenesis and plasmid preparation for *in vitro* second-site suppressor mutation analysis, and protein purification work, performing all transient transfections and sample collection.

Matthew Maderia

70 Prospect St · Cambridge, MA 02139 · (978) 317-7311 · mmaderia15@gmail.com
www.linkedin.com/in/matthew-maderia

PUBLICATIONS

1. K Simon, K Nagarajan, I Mechin, C Duffy, P Manavalan, S Altmann, A Majewski, J Foley, J Kaczmarek, S Bercury, **M Maderia**, B Hilbert, J Batchelor, R Ziegler, J Bajko, M Kothe, R Scheule, A Nair, G Hurlbut. *The $\Delta F508$ CFTR defect: molecular mechanism of suppressor mutation V510D and the contribution of transmembrane helix unraveling*. *bioRxiv* DOI:10.1101/2020.04.19.049338, 2020
-

Leadership Activities:

BC Outdoor Adventures Trip Leader, Executive Board Member, and TA

Fall 2015 – May 2019

- Certified to lead remote hiking, backpacking, skiing, kayaking trips, etc.
- Co-taught a semester long course to certify new leaders.

BC Student Admissions Program Tour Guide

Fall 2017 – May 2019

- Selected to give tours to prospective students of Boston College.
- Lead shadow days for prospective students interested in applying to BC

Running4Rare Team Member

- Raising awareness/funds on behalf of the rare disease community by running two half marathons on behalf of a patient partner
 - Started an annual Rare Disease Day Event in 2014 which has been passed down and still on-going/growing
-

RELEVANT LABORATORY SKILLS

- Mammalian tissue culture maintenance (adherent and suspension), primary cell protein extraction, protein purification, transient transfections, bacterial transformation and plasmid preparation, SDS-PAGE and Native PAGE, Western blotting, preparative (ÄKTA Pure) and analytical (HPLC-Agilent) SEC, protease activity assays (Spectramax i3x), TEM and cryo-EM grid preparation, BCA Assay, Endotoxin Testing, site-directed mutagenesis, ELISA, fluorophore conjugation.
 - Graphpad Prism, ImageLab, FlowJo, CASA, SnapGene, Fiji, Microsoft Office Suite, GSuite, Benchling Cloud ELN
-

INTERESTS

Trail Running, Hiking, and Skiing

Melissa Paziuk

617-334-4787 | mpaziuk@live.ca | 43 Mill st. Woburn, MA 01801
<https://www.linkedin.com/in/melissa-paziuk-00a458b8>

PROFESSIONAL EXPERIENCE

Senior Research Associate, Ohana Bioscience, Cambridge, May 2019-present

- Execute assisted reproductive technologies (ART) for mouse characterization studies, specifically in vitro fertilization (IVF), intra-uterine insemination (IUI), microinjection, oocyte micromanipulation, sperm analysis and preparation, assessing embryo development, and performing non-surgical embryo transfers
- Implemented and optimized intracytoplasmic sperm injection (ICSI) in mouse model for biological characterization of sperm cell modifications
- Perform mouse model characterization studies for assessment of male contraceptive antibodies and epigenetic inheritance of metabolic syndrome, duties included IP and IV injections, cardiac/submandibular/tail bleeds, tissue collections, running ELISA and western blots, and GraphPad PRISM data analysis
- Responsible for managing in-vivo projects including SOP documentation, organizing timelines and vivarium space, ordering mice and supplies, coordinating care/oversight of study animals, detailed documentation in lab notebooks, and database management

Scientific Associate II, Transgenic Services, Novartis Institute for Biomedical Research, Cambridge, March 2012-May 2019

- Responsible for colony management and coordination of 50-80 strains of genetically manipulated mice, duties included timed matings, plug checks, weaning, tail clipping, ear punching, neonate euthanasia, and optimizing/performing genotyping assays using conventional PCR
- Implemented, managed, and coordinated in-vitro fertilization, embryo and sperm cryopreservation for genetically engineered mouse strains
- Proficient in surgical embryo transfers in mice for genetically engineered mouse models and rederivation of cryopreserved strains, including administering inhalant anesthesia, post-op analgesics, and superovulation of recipient females via IP injections
- Assisted with phenotyping of transgenic strains by collecting weights, cardiac/submandibular/tail bleeds, and terminal tissue collections of mice

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Surgical Research Technician, Gastrointestinal Metabolism Lab, Massachusetts General Hospital, Boston, April 2010-March 2012

- Gained microsurgery skills by performing complex gastrointestinal survival surgeries (Roux-en-Y gastric bypass) and jugular vein and carotid artery catheter placement in rats and mice
- Performed technical capabilities such as cardiac puncture, IV, IM, IP and SQ injections, tissue harvest, oral gavage, weaning, mating, ear notching, and tail clipping, ITT and GTTs in rodents
- Trained scientists and surgical technicians in rodent techniques and surgery
- Created and maintained SOPs, the surgical database, and the mouse breeding colony
- Gained experience extracting DNA and RNA from tissues

Research Technician, Division of Cancer Biology and Genetics, Cancer Research Institute, Queen's University, Kingston, May 2009-April 2010

- Managed over 1000 transgenic mice in breeding colony, duties included genotyping by PCR and Southern Blotting
- Responsible for purchases, receiving and inventory control within laboratory and maintained detailed records of mouse colonies
- Assisted in mouse model characterization through performing cardiac punctures and tail vein injections

EDUCATION:

St. Lawrence College

May 2009

- Canadian Advanced Diploma in Veterinary Technology
(3-year College Undergraduate Degree Equivalency in the US)

CERTIFICATIONS:

- Certified Veterinary Technologist 2010
- Registered Laboratory Animal Technologist 2015

MERLIT MATHEW

66 Quint Ave, Boston MA 02134 | (857)-407-9115 | merlitmatthew@gmail.com | [linkedin.com/in/merlit-matthew](https://www.linkedin.com/in/merlit-matthew)

TECHNICAL SKILLS:

- Transient expression of recombinant proteins in HEK293 and CHO cell lines
- Culturing of mammalian cell lines and protein expression check using Western Blot
- Functional assay development
- Quantitative and qualitative ELISA
- Antibody staining check using Flow cytometry and immunofluorescent imaging
- Recombinant protein expression and purification in *E. Coli*
- Experience with AKTA FPLC systems, including Protein A, IMAC, SEC, and Unicorn software
- Protein QC by SDS-PAGE, HPLC-SEC, and endotoxin testing
- Extensive experience with small and large-scale plasmid isolation

EXPERIENCE:

Ohana Biosciences, Cambridge, MA

Feb'19 -Present

Research Associate II, Protein Engineering *Antibody screening and production*

- Lead protein expression in mammalian and bacterial systems
- Enhance protein expression check using Western Blot and consistently optimize protein purification
- Develop functional assay to test functionality of lead candidates for male contraception
- Manage internal DNA and protein inventory
- Optimize ELISA for antibody screening and perform other screening techniques such as Flow Cytometry and IF
- Independently manage protein production at CRO and lead communication with vendors of lab instruments

Cogen Therapeutics, Cambridge, MA

June'18-Dec'18

Co-Op, Protein Production and Analytics *Production, purification, and analysis of proteins*

- Expressed and purified recombinant proteins and antibodies in mammalian systems at various scales
- Performed routine bacterial transformation and plasmid isolation to support production
- Cultured Expi293 and ExpiCHO suspension cell lines at various scales
- Performed protein expression check using Western Blot and protein QC by SDS-PAGE and HPLC-SEC
- Performed endotoxin quantitation using Endosafe PTS and developed plate-based chromogenic assay
- Developed and maintained internal database of plasmids, cell-lines, and proteins

Northeastern University, Boston, MA

Agar Lab, Research Assistant

Aug'17-April'18

Purification and stabilization of proteins responsible for neurodegenerative diseases

- Purified proteins linked with ALS using HIC and IEX to support *in-vitro* studies
- Cultured mammalian cell lines to study the effects of cross-linkers on proteins linked to ALS and PD
- Performed dose-response studies of candidate molecules on mammalian cells to study target protein stabilization

Slavov Lab, Research Assistant

Oct'16 – July'17

Studied yeast ribosomal composition and maintained mammalian cell lines

- Performed functional studies on ribosomal composition by translational inhibition
- Cultured yeast cells in bioreactors and shake-flasks
- Cultured mammalian cell lines including CHO, HEK293s, HeLa, mESC, and Jurkat cells

EDUCATION:

Northeastern University, Boston, MA

Sept'16-Jan'19

Master of Science in Biotechnology (Biopharmaceutical Analytical Sciences Concentration)

Amity University Rajasthan, India

Aug'12-Aug'16

Bachelor of Technology in Biotechnology

PUBLICATIONS:

Cyclic Thiosulfinates and Cyclic Disulfides Selectively Cross-Link Thiols While Avoiding Modification of Lone Thiols Daniel P. Donnelly, Matthew G. Dowgiallo, Joseph P. Salisbury, Krishna C. Aluri, Suhasini Iyengar, Meenal Chaudhari, **Merlit Mathew**, Isabella Miele, Jared R. Auclair, Steven A. Lopez, Roman Manetsch, and Jeffrey N. Agar *Journal of the American Chemical Society* **2018** 140 (24), 7377-7380 DOI: 10.1021/jacs.8b01136

Nathan Patrick McBride

55 Wildwood Road

Stow, MA 01775

Phone: (774) 279-4125 Email: nathan+opportunity@longwalk.consulting LI: www.linkedin.com/in/itsn8

Senior Executive: Information Technology, Digital Strategy, and Cloud Architecture

A recognized industry thought leader and cloud evangelist with 22 years of experience breathing technological life into growing life science companies. C-Suite leader and strategic partner who listens, aligns, and delivers. Expertise in all aspects of IT including cybersecurity & compliance, digital transformation, application development, CRM & ERP integrations, enterprise-wide implementations of hardware and software solutions, all while keeping the lights on. Author of "[The Life Sciences IT Survival Guide](#)".

Selected achievements:

- Partnered with pre and post-IPO life science companies to provide CIO advisory services and leadership in order to successfully achieve their desired outcomes
- Prepared and executed a Work From Home technology strategy for *Ohana Biosciences* which ensured zero disruption and seamless Business Continuity all while managing a full corporate relocation mid-pandemic
- Created *Ohana Biosciences'*, *Orchard Therapeutics'* and *AMAG Pharmaceutical's Corporate IT functions from the ground up*, aligning corporate strategy to IT ensuring direct support of revenue growth
- Digitally transformed *Ohana, Orchard, and AMAG's IT infrastructure* by moving the companies into the cloud in preparation for Commercial product launches and M&A strategic planning
- Developed R&D Technology strategic plans at both *Ohana* and *Cubist Pharmaceuticals* implementing comprehensive R&D *platform* with Data Analytics, Clinical Data Management, Regulatory Content Management, Laboratory Information Management, Quality Systems, Research Chemical Database Systems, and Electronic Lab Notebooks
- Published in *Harvard Business Review*, *Computerworld*, and *InfoWeek* for Cloud and Cybersecurity expertise. Featured speaker and headliner at numerous North American technology conferences
- Recognized as Finalist for 2017 Boston CIO of the Year for cloud and digital transformations at *AMAG Pharmaceuticals*

Professional Experience

Vice President, IT, Ohana Biosciences - Cambridge, MA - December 2019 - April 2021

Ohana's platform is a unique combination of biology and technology never before applied to reproductive health which has revealed breakthrough discoveries that impact the most important aspects of the reproductive journey: fertility, pregnancy and child health, and contraception. As IT Employee #1, I built the IT function to support anticipated growth, Commercial Launch of SPERTILITY, Clinical Pipeline, Research, CMC, and Manufacturing expansion and continued growth in all areas of the company.

- **Research and Clinical Support**
 - Selected and deployed a broad research ELN platform to support the research prototype platform
 - Developed a platform to work with the NIH on sample sharing databases
 - Hired IT staff to support the construction of a massive computational biology program
 - Set up Clinical Trial sites at several IVF/IUI Centers around the US
 - Developed a Sperm Donation platform that incorporated mobile scanning and payment functionality
- **Corporate Technology**
 - Constructed 1 and 3-year IT strategies to support potential IPO, Commercial Launch, and Clinical Trials - rapidly scaled Ohana's cybersecurity program in 14 months
 - Eliminated costly Managed Services Providers and relocated all services internally
 - Deployed Google Workplace for collaboration along with a strong SaaS suite supporting our cloud-native approach
 - Implemented new workflow and business processes across R&D and G&A functions
 - Assisted HR leadership in developing a "return to work" transition program
 - Led a corporate relocation to a new facility during the pandemic and initiated a Touchless 21 program
 - Constructed a "passwordless" security program and re-classified all data within the enterprise under new data ontology

Vice President, Global IT, Orchard Therapeutics - London, UK/Boston, MA - Apr 2018 - Dec 2019

Orchard's clinical focus is on Autologous Ex-Vivo Gene Therapies for patients around the globe – Currently commercializing Strimvelis and preparing for launches to treat MLD and ADA-SCID. As IT Employee #1, I built the global IT function to support our IPO, Commercial Launches, Clinical Pipeline, Research, CMC, and Manufacturing expansion and global growth from 50 to 250 employees in one year.

- **Compliance & Security**
 - Created and implemented GDPR program to achieve global compliance
 - Assisted in construction of first Validation Master Plan and Computer Systems Validation structure
 - Assisted with auditing and implementation of eDMS, eCTD, and eTMF platforms
 - Constructed secure VDR model for healthy M&A strategies
 - Deployed comprehensive security training program, anti-phishing platform, and corporate ERM
- **Strategy**
 - Constructed 1 and 3-year IT strategies to align with business growth, clinical pipeline expansion, and commercialization preparation
 - Hired staff to support Commercial, Clinical, CMC, and IT launch programs
 - Deployed global Services program to allow for 24/7 IT Support
 - Initiated construction of a decentralized IT model for global business support
- **Governance**
 - Created Strategic Technology Committee for the oversight of all technology spend
 - Implemented Corporate Security & Risk Council to satisfy HIPAA/21CFR11/SOX compliance
 - Matured the company into a baseline PMO methodology
- **Platforms**
 - Managed the implementation of ERP, CRM, EDMS, EQMS, Track/Trace, and several other platforms currently in flight

SVP & CIO, Innovation Architects - AMAG Pharmaceuticals - Waltham, MA - Jan 2008 - Oct 2017

Products include (Feraheme®) for the treatment of Chronic Kidney Disease, (MuGard™) for the treatment of Oral Mucositis, (Makena®) for extending gestation, CordBlood® for private cord blood banking, Intrarosa™ for the treatment of Dyspareunia

- **Digital**
 - Owned development and management of all websites for both internal and external customers with emphasis on B2C consumer sales, SEO/SEM, and rapid marketing initiatives
 - Led group responsible for the development of digital platform strategy for the business including web, social, mobile to achieve positive CLM and IVA initiatives
 - Initiated and led the implementation of a replacement CRM platform to support the digital transformation model and drive customer engagement improvements
- **Cloud**
 - Planned successful implementation of enterprise-wide cloud strategy including email migration (Google Apps), Web File System and Security Portal Implementation, Active Directory deprecation, AWS Development, and Private Cloud creation and Unified Communications (Cisco UCaaS)
 - Migrated entire company to the cloud including all enterprise and compliant platforms - resulted in a significant decrease in spending with a significant increase in innovation and productivity
 - Created an industry driving long term cloud model as a template for Life Science companies
 - Developed and implemented a rapid M&A model for integrating acquired systems into our cloud architecture
- **Security & Compliance**
 - Created novel IT security model eliminating password management and using smartphones as authentication tokens
 - Established comprehensive IT Governance Model within the organization to provide and support frameworks for GDPR, SOX, 21CFR11, ISO, AABB, MA201, DSCSA, GDPR, and FTC
 - Deployed anti-phishing platforms and DLP and Data classification models
 - Implemented ITIL/COBIT framework among IT functional lines (Change Control, Asset Management, Support Process Management, et al)
- **Leadership**
 - Hired as IT Employee #1 to develop a long-term IT strategy and to support the launch of the first commercial drug; introduced several new industry concepts including Lean IT and Cloud
 - Directed the formulation of information management approaches for all functional areas including Commercial and Manufacturing
 - Demonstrated as a senior executive team member, expertise in technical analysis to effectively

present a recommendation to officers or other high-level officials internal or external to the corporation regarding strategic projects

- Provided core leadership for acquisitions and integrations including key leadership in the execution of recent asset and company acquisitions
- Managed a staff of 42 employees located in Waltham, MA, Tucson, AZ, and South San Francisco, CA all together known as the Innovation Architects team
- Developed a unique monthly review model and career matrix for the department that was modeled for the rest of the company
- **Platforms**
 - Deployed and oversaw the management of several major platforms including:
 - ERP Financials 3x (Microsoft GP, Microsoft AX, Oracle Fusion Cloud)
 - CRM for Consumer Sales (D2C) and Commercial Field Sales 3x (Stay in Front, SFDC for Commercial Sales, SFDC for Consumer Sales)
 - Aggregate Spend/State Reporting, Legal Contracts Management, and Purchasing Systems
 - Product Safety, Regulatory Publishing, Document Management, Clinical Biostats, MSL CMS
- **Business**
 - Launched Commercial Sales Force and deployed Data Warehouse & Desktop Analytics - Established a fully Mobile Workforce
 - Management of all facility operations including construction expansions, facility moves, and turn downs
 - Implemented functional project management (SCRUM/AGILE), application development and management, corporate and regulatory compliance and cybersecurity best practices, KPI and metric development
 - Managed budget of 19mm with quarterly reforecast

Senior Director, Business and Scientific Applications - Cubist Pharmaceuticals - Lexington, MA - 2005 - 2008

Niche Anti-Infective drug discovery and marketing

- Led broad team charged with the deployment of platforms for ELN, QC Lab Management, Chemistry, Clinical, Regulatory, Safety
- Assumed management responsibility for all technical services including Help Desk teams and Cybersecurity
- Built from scratch and deployed Legal Contracts Management System, Clinical CDISC Management
- Supported launch of 2nd indication of Cubicin and assisted in the buildout of new QC lab to support in house testing
- Provided growth strategies needed to support company growth of 200 to ~400 employees

Senior Director, IT - Transkaryotic Therapies, Inc. (formerly Shire Pharmaceuticals) - 1999-2005

Niche protein discoveries and technologies

- Senior-most Leader of IT - Participated in Executive Committee decision-making process
- Supported Launch of UK and Sweden Sites and managed global IT resources
- Deployed ERP/MRP Financials, Clinical Data Warehouse, Product Safety, Regulatory Publishing, Document Management, and Help Desk Issue Management
- Implementation and migration to Virtual Data Center infrastructure including physical, co-lo and cloud
- Managed five corporate facility moves to support company growth

Director of Technology - Cushing Academy - Ashburnham, MA, - 1997-1999

9th-12th Grade Private Secondary Boarding School located in Western Massachusetts

- Solely responsible for all IT infrastructure, software and deployments school-wide
- Senior Curriculum Leader - responsible for designing and teaching annual technology curriculum
- Managed entire campus-wide network and data center
- Taught Java and C+ classes

Assistant Manager IT and Teacher - Rye Country Day School - Rye, NY - 1996-1997

Education and Certifications

Certified Lean Six Sigma Black Belt
 Managing Risk in the Information Age, Cambridge, MA
 Sloan School of Management, Cambridge MA
 Pink Elephant ITIL Training, Boston MA
 Boston University Graduate Programs, Cambridge, MA
 Help Desk Institute, Boston MA

Villanova University
 Harvard VPAL
 Executive Management Training
 ITIL Foundations v3
 Pocket MBA CIO Program
 Director of Support Certification

Connecticut College, New London, CT

B.A. Classics 1996

Industry Recognition & Associations

- **2017 Finalist for Boston “CIO of the Year”**
- **2013 Recipient of Okta’s “Security Pioneer of the Year” Award**
- Hold several Cloud customer advisory board seats and am a recognized industry speaker
- Published in [Harvard Business Review online](#) regarding how companies can adopt the cloud
- A frequent contributor to *Biztech* magazine, *ComputerWorld* magazine; *TechTalk*; *The Wall Street Journal* and member of CDW Leadership Forum
- Featured and/or profiled in *NetworkWorld*, *ComputerWorld* and *InformationWeek*
- Delivery of presentations to external customer focus groups on the cloud stack and leading enterprise technologies
- Demonstrated expertise in technical analysis to effectively present a recommendation to officers or other high-level officials internal or external to the corporation regarding strategic projects - frequently invited to present to other companies’ leadership teams
- Recognized Industry speaker - Some recent engagements include:
 - October 2020 - Speaker at GXP World Conference - “Drawing the Line on Cloud Validation of Data”
 - September 2018 - Speaker at DisruptHR RI - “Preparing for the Matriculating Class of 2021”
 - May 2018 - Customer Keynote at Lucidchart Connect Boston & NYC - “The Lucid Method for Business Process Engineering”
 - April 2018 - Speaker at Atlassian MUG - “Project Management using Trello”
 - March 2018 - Speaker at Varonis Customer Panel - “GDPR: Protecting your Data in the Cloud”
 - October 2017 - Speaker and Panelist at I4CP North America - “How to Enable Agility and Collaboration in Your Organization”
 - October 2017 - Speaker and Panelist at InfoSecurity North America - “Healthcare in the Cloud. What is the current prognosis?”
 - September 2017 - Advisory Speaker and Panelist at Smartsheet Engage 2017 - “Are you Ready to Become the Employee of the Future?”
 - May 2017 - Speaker and Panelist MIT Sloan CIO Symposium - “Journey to the Cloud”
 - May 2017 - Speaker at Bio-IT World - “New Middleware Concepts for Enterprise Platforms”
 - April 2017 - Keynote Speaker @ Cloud Security Alliance Congress - “The Long Journey to the Cloud”
 - February 2017 - Speaker @ 2nd Annual Life Sciences Technology Forum - “Implementing a Mobile Application Development Strategy”
 - January 2016 - Speaker and Panelist @ 11th Annual Laboratory Informatics Summit
 - November 2015 - Speaker and Panelist @ Commercial Data World - “Managing Big Data in the Cloud”
 - May 2015 - Speaker and Panelist @ AppsWorld (CA) - “BYOD in Today’s Privacy World”
 - April 2015 - Speaker @ BIO IT World (MA) - “Two Factor Authentication and Privacy”
 - April 2014 - Speaker @ IDG Editorial Summit (MA)
 - November 2013 - Speaker @ Mid-Market CIO Summit (NY) - “No Data Center Here: AMAG Pharmaceuticals’ Scalable Enterprise Cloud Model”
 - November 2013 - Speaker @ Oktane13 Identity Management Conference (SF) - “Moving Identity to the Cloud: Looking Beyond Active Directory”
 - June 2013 - Speaker @ CloudExpo (NY) - “The Evolution of the Agile IT Department”
 - June 2013 - Speaker and Panelist @ CITEWorld (SF) - “BYOS: Bring Your Own Service”
 - April 2013 - Speaker and Panelist @ Life Sciences Technology Forum (AZ) - “Implementing Cloud Computing for your Disaster Recovery Plan”

Nicolas Da Silva, PhD

781-420-2816 | nicolas.dasilva@mac.com | www.linkedin.com/in/nicoboston
Work authorization: US Citizen | Bilingual English and French

Summary of Qualifications

- Hands on collaborative and creative scientist with a strong background in cell and molecular biology, focusing on reproductive and renal physiology, male infertility, mucosal immunology, epithelial biology, blood-cell biology, and biological imaging. Disease areas include male infertility, kidney diseases, inflammation, auto-immunity
- Extensive academia and industry research experience with intense interest and knowledge in functional interactions between organ systems (reproductive tract, kidneys, immune system).
- Scientific and strategic leadership of assay development and target validation.
- Accomplished publisher (43), manuscript and grant writer, and presenter.
- Track record of recruiting and mentoring strong scientific teams

Professional Experience

OHANA BIOSCIENCES, CAMBRIDGE, MA

- **Principal Scientist** **April 2018 – Present**
Ohana was a startup biotech focused on Assisted Reproductive Technologies improvement, offspring health and male contraception.
 - o Led and co-investigated multiple projects focused on sperm biology to advance the field of male fertility.
 - o Led the Sperm Cell Biology Team, expanded the team to 5 members, promoted an environment supportive of scientific creativity and teamwork. Managed scientists with expertise in cell and molecular biology, bioimaging, electrophysiology, sample management.
 - o Drove the development of sperm storage media, developed assays aimed at evaluating human sperm quality (including DNA damage, membrane damage, mitochondrial activity).
 - o Defined and implemented strategies to unravel complex aspects of human sperm biology, including accessibility of surface targets in vivo and in vitro, improve the accessibility of sperm nuclear components, multiplex assays to define biologically relevant subsets of sperm in extremely heterogeneous human samples
 - o Collaborated with members of the Research and Development team including legal, marketing and manufacturing.

MASSACHUSETTS GENERAL HOSPITAL AND HARVARD MEDICAL SCHOOL, Boston, MA

- **Associate Professor, Principal Investigator** **2013 – 2018**
 - o Lead and co-investigate 4 studies focused on renal and reproductive immuno-physiology to advance the fields of male fertility and renal physiology. Research led to 8 articles and 8 presentations.
 - Male Fertility: study the potential roles of immune cells (mostly dendritic cells and macrophages) in the establishment and maintenance of male fertility, and in the development of male infertility using confocal microscopy, transgenic mouse models.
 - Renal physiology: investigate the mechanisms of pH sensing, pH regulation, and water transport in the renal epithelium. Targets are V-ATPase (proton pump), aquaporins (water channels) and associated molecules. Perform flow cytometry-based analyses of epididymal cells
 - Discovered that the mouse epididymis contains several populations of immune cells (dendritic cells, macrophages) which have not been described in the post-testicular environment before. Established that these cells may play important roles in the control of tolerance to sperm antigens (critical for male fertility) and loss of tolerance (which causes infertility). Currently trying to identify the precise mechanisms.
 - Develop experimental protocols to study interactions between sperm, epididymal epithelial cells, immune cells, and tissue structures (blood capillaries, lymphatic vessels).

- Collaborated with investigators (Nahrendorf Lab at MGH) to perform imaging of macrophages in various tissues (including kidney, spleen, and heart).
- Additional role as PI, co-investigator, and member of the Breton lab (MGH).
- Developed and managed research budgets, set scientific strategy for grants, mentored 4 people.

- **Instructor, Principal Investigator**

2007 – 2013

- Established and contributed to 5 NIH-funded basic research projects, including research strategies, timelines, and a budget, to characterize epithelial mechanisms involved in sperm maturation. Research lead to 17 papers, 5 presentations, and 11 national and international conference presentations.
 - 3 projects aimed at elucidating epithelial mechanisms involved in sperm maturation.
 - 2 projects focused on renal function and disease to understand Physiological or pathological processes: male infertility, immunological infertility, acid/base homeostasis.
- Led the comparative proteomic study of kidney intercalated cells and epididymal cell cells after establishing a collaboration with a NIH/NHLBI lab (2017-2013)
- Contributed to the characterization of luminal sensing capabilities of epithelial basal cells. Worked on several projects from 4 groups in the MGH Program in Membrane Biology (2007-2013).
- Secured a Pilot and Feasibility grant from the Center of the Study of Inflammatory Bowel Disease to initiate the characterization of antigen-presenting cells in the epididymis, an uncharacterized mucosal immune system.

- **Research Fellow**

2001 – 2007

- Research determined regulation mechanisms for key genes/proteins involved in trans epithelial transport and membrane trafficking in the kidney and in the male reproductive tract. Lead to 7 papers.
- Developed protocols for the isolation and characterization of subsets of renal and epididymal epithelial cells (laser microdissection, flow cytometry). Performed imaging (immunofluorescence, confocal microscopy).
- Characterized transporters and mechanisms involved in water, ion and solute transport, vesicle trafficking, in renal and epididymal epithelium (including aquaporin water channels, V-ATPase, CFTR).
- Co-wrote 5 NIH and non-NIH grant proposals; trained research fellows and staff members
- Presented results at 9 national and international conferences, including American Society of Nephrology, American Society of Andrology, Society for the Study of Reproduction, American Physiological Society

- **Research Fellow**

2000 – 2001

- Studied molecular control mechanisms for leukocyte anti-adhesion molecule CD43 expression as well as molecular causes of abnormal CD11c expression in hairy-cell leukemia.
- Studied gene expression in hematopoietic cell lines, transcriptional regulation of gene coding for adhesion molecules (CD11 integrins, CD43).
- Performed cell culture (leukemia cell lines), molecular biology (RT-PCR, analysis of DNA-protein interactions, promoter analysis, transfection), microscopy
- Research lead to 3 papers. Obtained a 12-month Postdoctoral Fellowship Award from the French Cancer Society.

LABORATOIRES RHONE POULENC RORER (SANOFI), Montrouge, France

Clinical Research Associate

1999

- Evaluation of the efficacy of docetaxel in treating Kaposi's sarcoma in HIV+ patients (phase II).
- Performed cost analysis of lung cancer in France.

Skills

- **In Vivo:** Animal handling and survival surgery on rodents, microsurgery (efferent duct ligation, luminal microperfusion of male reproductive organs, parabiosis, minipump implantation...)
- **Histology and Microscopy:** Tissue fixation & prep, tissue clearing: Immunofluorescence, confocal microscopy (Nikon, Zeiss, Olympus), image processing (NIS Elements, Volocity, ImageJ), intravital microscopy

- **Cell biology:** transfection, protein isolation, sample prep for proteomics analysis (trained at NIH), protein isolation, western blotting, immunoprecipitation, microdissection (Arcturus laser capture microdissection, MMI CellCut)
- **Molecular biology:** DNA / RNA extraction, RNA amplification, quantitative RT-PCR, analysis of DNA-protein interactions (EMSA), RNA isolation for RNAseq
- **Cell culture:** (cell lines and primary cells): isolation of epithelial cells from kidney, male reproductive tract; isolation of tissue macrophages, dendritic cells and T cells; maintenance of adherent and suspension animal and human cell lines (leukemia and lymphoma cell lines, epithelial cell lines).
- Flow cytometry: flow data analysis (FlowJo)
- Assay development (DNA fragmentation, DNA oxidation, membrane lipid oxidation, mitochondrial activity, computer-assisted sperm analysis)
- Completed the **CITI Course “Human Subject Research – Biomedical Basic”** (January 2019)

Education

UNIVERSITÉ PARIS 7 – DIDEROT AND HOPITAL SAINT-LOUIS, Paris, France	1994-1999
PhD candidate. Focus in Blood Cell Biology.	
Thesis title: Cellular and molecular bases of the differentiation of leukemia cells: induction of differentiation by G-CSF and control of expression of beta-2 integrins and CD43. 4 articles published.	
UNIVERSITÉ BLAISE-PASCAL, Clermont-Ferrand, France	
Master of Science, Molecular and Cellular Physiology	1993
Cell biology training at the German Collection of Microorganisms and Cell Cultures (DSMZ), Braunschweig, Germany. 2 articles published.	
Bachelor of Science, Cell Biology	1992

Selected Presentations (out of 15)

- American Society of Andrology (ASA), New Orleans LA, 2016. *Exploring the Role of Macrophages and Dendritic Cells in the Epididymis*. Invited speaker.
- Keystone Symposia Conference, Dendritic Cells and Macrophages Reunited, Montreal QC, 2015. *United macrophages and dendritic cells in male reproductive function*. Poster presentation.
- International Symposium on Spermatology, Newcastle, Australia, 2014. *Exploring the role of mononuclear phagocytes in the post-testicular environment*. Invited speaker.
- Réseau Québécois en Reproduction (RQR) Symposium, Québec, 2013. *Mononuclear phagocytes in the post-testicular environment*. Invited keynote speaker.
- Gordon Research Conference, Fertilization & Activation of Development, Holderness NH, 2013. *Role of dendritic cells in the epididymis*. Invited speaker.
- University of Pennsylvania, Center for Research on Reproduction and Women’s Health, Philadelphia PA, 2013. *Role of dendritic cells in the epididymis*. Invited speaker.

Selected Publications (out of 43)

Complete list:

<https://www.ncbi.nlm.nih.gov/myncbi/nicolas.da%20silva.1/bibliography/public/>

- Hulsmans M, Clauss S, Xiao L, Aguirre AD, King KR, Hanley A, Hucker WJ, Wülfers EM, Seemann G, Courties G, Iwamoto Y, Sun Y, Savol AJ, Sager HB, Lavine KJ, Fishbein GA, Capen DE, Da Silva N, Miquerol L, Wakimoto H, Seidman CE, Seidman JG, Sadreyev RI, Naxerova K, Mitchell RN, Brown D, Libby P, Weissleder R, Swirski FK, Kohl P, Vinegoni C, Milan DJ, Ellinor PT, Nahrendorf M. Macrophages Facilitate Electrical Conduction in the Heart. *Cell*. 2017;169(3):510-522.
- Da Silva N, Barton CR. Macrophages and dendritic cells in the post-testicular environment. *Cell and tissue research*. 2016; 363(1):97-104.

- Da Silva N, Smith TB. Exploring the role of mononuclear phagocytes in the epididymis. *Asian journal of andrology*. 2015; 17(4):591-6.
- Dutta P, Hoyer FF, Grigoryeva LS, Sager HB, Leuschner F, Courties G, Borodovsky A, Novobrantseva T, Ruda VM, Fitzgerald K, Iwamoto Y, Wojtkiewicz G, Sun Y, Da Silva N, Libby P, Anderson DG, Swirski FK, Weissleder R, Nahrendorf M. Macrophages retain hematopoietic stem cells in the spleen via VCAM-1. *The Journal of experimental medicine*. 2015; 212(4):497-512.
- Smith TB, Cortez-Retamozo V, Grigoryeva LS, Hill E, Pittet MJ, Da Silva N. Mononuclear phagocytes rapidly clear apoptotic epithelial cells in the proximal epididymis. *Andrology*. 2014; 2(5):755-62.
- Heidt T, Courties G, Dutta P, Sager HB, Sebas M, Iwamoto Y, Sun Y, Da Silva N, Panizzi P, van der Laan AM, Swirski FK, Weissleder R, Nahrendorf M. Differential contribution of monocytes to heart macrophages in steady-state and after myocardial infarction. *Circulation research*. 2014; 115(2):284-95.
- Shum WW, Smith TB, Cortez-Retamozo V, Grigoryeva LS, Roy JW, Hill E, Pittet MJ, Breton S, Da Silva N. Epithelial basal cells are distinct from dendritic cells and macrophages in the mouse epididymis. *Biology of reproduction*. 2014; 90(5):90.
- Da Silva N, Cortez-Retamozo V, Reinecker HC, Wildgruber M, Hill E, Brown D, Swirski FK, Pittet MJ, Breton S. A dense network of dendritic cells populates the murine epididymis. *Reproduction*. 2011; 141(5):653-63.
- Miranda KC, Bond DT, McKee M, Skog J, Păunescu TG, Da Silva N, Brown D, Russo LM. Nucleic acids within urinary exosomes/microvesicles are potential biomarkers for renal disease. *Kidney international*. 2010; 78(2):191-9.
- Da Silva N, Pisitkun T, Belleannée C, Miller LR, Nelson R, Knepper MA, Brown D, Breton S. Proteomic analysis of V-ATPase-rich cells harvested from the kidney and epididymis by fluorescence-activated cell sorting. *American journal of physiology. Cell physiology*. 2010; 298(6):C1326-42.
- Shum WW, Da Silva N, Brown D, Breton S. Regulation of luminal acidification in the male reproductive tract via cell-cell crosstalk. *The Journal of experimental biology*. 2009; 212(Pt 11):1753-61.
- Shum WW, Da Silva N, McKee M, Smith PJ, Brown D, Breton S. Transepithelial projections from basal cells are luminal sensors in pseudostratified epithelia. *Cell*. 2008; 135(6):1108-17.

Ramiro Castro-Santamaria MD, MPH,MBA
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SUMMARY

Medical Doctor with specialist training and certification in Urology and Family Medicine. Twelve years of clinical experience with focus on urological diseases and cancer management (prostate, bladder, and kidney cancer), as well as experience in internal and emergency medicine at both primary care and third level hospitals settings.

Nineteen years of pharmaceutical industry experience in national, European, and global clinical and leadership roles in different countries (Spain, UK, Germany, US); in different therapeutic areas (urology, oncology, cardiovascular, respiratory, immune inflammation and fertility), and in different company cultures and environments.

Strong business ethics and sound judgment capabilities. Deep understanding of the global product development process, from early phase to commercialization stages with successful track record of regulatory submissions to FDA, EMEA, PMDA, KFDA and SFDA, global market readiness and commercialization support initiatives. Two product launches and extensive experience maximizing asset value through life cycle management and operational and technological excellence.

Seasoned leader of complex projects and units of strategic value, developing compelling vision and innovative plans, orchestrating change, and proactively managing sizeable human and economic resources to improve capabilities, drive performance and achieve sustainable growth through medical solutions with value to patients, payers and regulators. Experience leading Alliance drug development programs Strong customer focus and competitive business orientation with formal business education and acumen. Member of therapeutic area leadership teams and senior corporate governance and risk management Boards. Multilingual.

EXPERIENCE

Chief Medical Officer Ohana Biosciences	04/2020- to date
Vice President Clinical Sciences, Head of Rheumatology Interim Head Gastrointestinal & Hepatology GSK Global R&D	2019- 04/2020
Vice President & Interim Head of Early Development Leaders GSK Global Research	2018- 2019
Vice President & Head Unit Physician Immuno Inflammation GSK Global R&D	2016- 2019
Chair of GSK Development Leaders GSK Global R&D	2016-2018

Medicines Development Leader MABA, MABA/FF & Vilanterol. GSK Global R&D. Respiratory	2013-2018
Medicines Development Leader Dutasteride monotherapy & Fixed Dose Combination GSK Global R&D Metabolic Pathways and Cardiovascular Unit.	2011-2013
Executive Director Clinical Development. GSK Global Oncology.	2010-2011
Senior Medical Director, GSK Global Oncology	2009-2010
European Urology Medical Director GSK Pharma Europe & R&D	2006-2009
Corporate Medical Advisor Urology & Neurology Boehringer Ingelheim GmbH	2003-2006
Medical Advisor Urology, Gastroenterology & Women's Health Medical Department Pharmacia & Pfizer (Spain).	2002-2003
Consultant Urologist Hospital Vall D' Hebron.) & I.C.U.N (Catalan Institute of Urology and Nephrology) Barcelona (Spain).	2000 -2002

EDUCATION

THE WHARTON SCHOOL, UNIVERSITY OF PENNSYLVANIA Master of Business Administration Major in Entrepreneurial Management	2014-2016
Residency in Urology Hospital del Mar, Barcelona (Spain) Autonomous University of Barcelona	1995-1999
Residency in Family Medicine Hospital Virgen del Camino, Pamplona (Spain) University of Navarra.	1991-1993
Doctorate studies in Internal Medicine University of Navarra (Spain)	1992-1993
Master's in Public Health. National Institute of Health Carlos III. Pamplona (Spain)	1993
Medical Doctor. University of Salamanca (Spain) Clinical Fellow: Department of Psychiatry Medical Visitor. Department of Psychiatry, Oxford University (UK)	1982-1989 1986-1988. 1988

LANGUAGES

- Spanish: 1st mother tongue
- English: proficient
- French: conversation standard
- German: basic conversation

OTHER: American citizen

Robin F. Chan

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[LinkedIn](#) | [GitHub](#) | [Publications](#)

Skills

Languages: R, Python, Bash, SQL

Tools: Gitlab, Conda, Jupyter, RStudio, Nextflow, Docker, AWS

Methods: Prediction & Classification (linear, logistic, elastic net, GBM, neural networks), Dimensionality Reduction & Clustering (PCA, *k*-means, hierarchical, Louvain, UMAP), Computer Vision (CNN)

Experience

Ohana Biosciences, Inc

Scientist, Computational Genomics

Cambridge, MA

May 2020 – Present

- Built and deployed custom Nextflow pipelines on AWS Batch for high-throughput processing of methylation (WGBS/RRBS), scRNA-seq, scATAC-seq, and CITE-seq datasets
- Developed a predictive model using novel feature reduction methods to counter drop-out in single-cell methylation data while improving model performance by ~50%
- Served as genomics subject matter expert to research team by guiding protocol optimization, experimental design, ad-hoc statistical/bioinformatics support, and interpretation of results
- Directed design and analysis goals for discovery projects including 3 external collaborations

Insight Data Science

Health Data Fellow

Boston, MA

Jan 2020 – April 2020

- Consulted for BioTrillion Inc to create “SkinSkanner” web-app that takes in user uploaded photos of concerning skin spots and returns instant feedback if there is a likely match to skin cancer or a benign spot
- Built data augmentation, training, and evaluation frameworks in PyTorch to train convolutional neural networks on 25,000+ images for classification of skin cancer and unsupervised segmentation

Virginia Commonwealth University, Center for Biomarker Research & Precision Medicine

Postdoctoral Researcher (Statistical Genetics)

Richmond, VA

Sept 2017 – Dec 2019

- Led 2 epigenomic studies that used our own R pipelines (RaMWAS, shiftR) to perform deconvolution, cell-type specific association testing, and enrichment analyses of 3,000+ samples to identify new biomarkers for depression and childhood trauma
- Delivered key contributions as part of team of three in developing 2 novel bioinformatic approaches for gene set enrichment testing that greatly reduced biases and Type I errors common in genomic and epigenomic studies
- Managed team of four to execute time-sensitive pilot projects using neuronal cell culture, CRISPR, third-gen DNA/RNA sequencing technologies (Nanopore), and custom R/Python analysis pipelines critical for 7 grant applications with \$75K awarded, establishing multiple novel research arms

Graduate Research Assistant (Neuroscience and Epigenomics)

Aug 2015 – Aug 2017

- Played leading role in 2 international projects that applied machine learning to predict chronic depression and biological aging from 28 million epigenetic markers across 1,000+ subjects resulting in 2 publications and 1 invention disclosure towards improving patient outcomes
- Developed and validated 6 different methods for assaying DNA methylation in human brain at genome-wide scale (i.e., 150 million observations) requiring statistical analysis of high-dimensional data leading to 4 publications and 1 invention disclosure describing new methodologies

Education

PhD Neuroscience, Virginia Commonwealth University

Aug 2015 – Aug 2017

MS Human Genetics, Virginia Commonwealth University

Aug 2011 – Aug 2013

BS Biology, James Madison University

Sept 2005 – May 2009

Siddhartha Shrivastava, Ph.D.

Wayland, MA

E-mail: shrivastava.siddhartha@yahoo.com; Phone: 518-590-4661

Proven leader and well published senior scientific and technical operations professional

Executive Summary

Member of senior leadership responsible for creating and implementing business plans and strategies, achieving company's financial goals and network wide objectives along with increasing network operating performance. Experienced in leading research, early to late-stage process development, commercial launch, cGMP commercial manufacturing (DS/DP) and reprocessing of bio-therapeutic drugs. Seasoned in developing, leading, transforming and sustaining multisite high-performance matrix organizations and teams. Accomplished leader in process development and manufacturability assessment; CMC program management (process development); CMO management for Phase I/II/III clinical trial material and commercial manufacturing; Assets due diligence, Establishing new PD and commercial manufacturing facilities; IND/IMP, BLA/MAA regulatory filings and product life-cycle management; Consent Decree Remediation and GxP Quality Operations.

Core Competencies

Process Development and characterization; CMC Development and management; GxP Quality & Compliance; External Manufacturing (DS & DP); Innovation, new technologies and Planning; Strategic and technical leadership; Financial Planning & Resource Mgmt.; cGMP facility design; Scale up and Technology Transfer; Repatriation; Quality by Design (QbD); Continuous Manufacturing; Disposable Manufacturing Systems; Project Management; IND/IMP, BLA/MAA filings; Product & Technical Lifecycle Mgmt.; Quality Risk Mgmt. & Remediation; Site transformation & APU (autonomous production unit) implementation.

Selected Career Achievements

- Biologics management of Remicade[®], Stelara[®], ATryn[®], Cerezyme[®], Fabrazyme[®], Thyrogen[®], rhASM[®], Praluent[®], Dupilumab[®].
- Have been associated with 30+ developmental, clinical and commercial biologics molecules.
- Managed over 200 SKUs of small molecules, oral doses, ointments and devices. Some of the famed SKUs managed include Allegra[®], Proctosedyl[®], Flomax[®], Elegard[®], Primaquine[®], Duexis[®], Cholestagel[®], Nicoderm[®], Zinquesta[®], Glyburide[®] etc.
- Development and commercialization of New Drug Entities covering process development, commercialization strategy, global technology transfer & repatriation, worldwide regulatory submission (INDs/BLAs), process validation and successful Pre-Approval Inspections (PAI) by FDA and other regulatory agencies.
- Lead CMC sections of IND and BLA for 8 products; lead/co-lead process approvals for 5 commercial products.
- Successfully launched 7 products so far (biologics and small molecules).

- Product lifecycle management and improvement for 3 biologics resulting in 70% decrease in deviations/ batch and reducing the average lot release time to less than 25 days from 135 days. These improvements led the savings of \$11 million+/year.
- Redesigned and generated the next generation (continuous/semi-continuous) intensified cell culture and DS purification processes for 3 commercial biologics- ATryn®/Cerezyme®/Fabrazyme®, leading to increased yields by 20-30% with reduced cycle time, CAPEX and OPEX requirements translating into increased revenues of ~ \$ 350 Million /year.
- Technical lead on facility design, construction and qualification of 70,000 sqft multiproduct fully disposable biologics cGMP manufacturing facility and PD labs.
- Successful due diligence and negotiation leading to successful absorption of 2 companies and creating alliance of 2 or more partners for 5 molecules.
- Consolidation of external manufacturing CMO network leading to more leverage, better pricing and favorable terms & conditions. Consolidated to 16 CMOs in NA from originally 29.
- Successfully established the serialization requirements for more than 250 products, produced by third parties, in less than 18 months' time frame.
- Successfully mentored multiple OpEx and Lean initiatives imparting network wide transformations leading to increased efficiency, safety and \$Millions in cost savings.
- Demonstrated research expertise with more than 3200 citations. Till date published 16 research articles, 3 sole author books and 2 book chapters.
- Seasoned in employee development and sustaining multisite highly matrix organizations and teams with lowest attrition rate while ensuring efficient prioritization of goals to achieve maximum operating effectiveness.

Professional Experience

Vice President and Head- Global Technical Operations (*Apr. 2020 – present*)

Ohana Biosciences, A Flagship Pioneering Company- Cambridge, MA, USA

Summary:

Responsible for end to end management and technical support of diversified and complex biologics, and device portfolio revolutionizing the reproductive health. Hired for fast-track commercialization of lead product candidate.

Major responsibilities include:

- Establishing technical, quality, regulatory and manufacturing infrastructure.
- Overseeing CMC, global regulatory and quality requirements for the mix portfolio of biologics and devices and pipeline products.
- Establishing analytical strategy for the product portfolio suitable for future scale up.
- Establishment and management of supply chain, 3PL and oversight of business function to attract funding and establishing alliances to extend and diversify the portfolio.
- Managing clinical supply, tech transfers, launches, and new product assessment and strategy formation.
- Support and plan ongoing early stage development of biologics and their clinical supply.
- Qualify new CMOs/ CROs/CDMOs, 3PL to support outsourcing strategy.

Senior Director and Head- North America Technical Operations-EMG (*Aug. 2018 – Apr. 2020*)

Sanofi- Industrial Affairs US, Framingham, MA, USA

Sanofi network supported –Global IA network.

Summary:

Responsible for end to end management and technical support of extremely diversified and complex pharma-biologics product portfolio under Sanofi NA External Manufacturing Operations generating sales of ~ 7 billion USD and distributed in more than 85 markets.

Major responsibilities include:

- Implementation of Sanofi external manufacturing strategy in North America bringing harmonization among CMOs, consolidation of partner portfolio leading to more leverage, better pricing and favorable conditions for Sanofi.
- Establishing the analytical strategy for new products within network.
- Feasibility assessment and allocations of resources and budget for projects to increase the capacity or efficiency of the network/sites.
- Oversight of SC, Quality, Regulatory, Business, Technical, and Finance functions making sure of on time delivery in full compliance with Good Manufacturing Practices in alignment with the market forecast or export orders.
- Be accountable of technical service activities and engineering for Third-Parties including technical support, CMC management, process improvements and audits.
- Oversee all transfers, repatriation, launches and product pruning activities.
- Provide technical and packaging support for all products manufactured externally under NA portfolio.
- Coordinate with other business units worldwide on strategies of Sanofi IA and global EM management.
- Qualify new CMOs to support External Manufacturing strategy
- Responsible of due diligence of identification and procurement of new molecules, market rights or target companies or their division to strengthen broader Sanofi strategy and portfolio.

Associate Director and Site Lead- Global Manufacturing Sciences and Technology (Oct. 2015 – Aug. 2018)

Sanofi- Biologics, Framingham, MA, USA

Sanofi network supported - USA (Framingham, Allston, Northborough), Belgium (Geel), Ireland (Waterford), UK (Haverhill), and France (Vitry)

Summary:

Responsible for leading team of technical leaders for life cycle management of current commercial portfolio for rare disease rEnzymes and therapeutic antibodies (TMABs) as well as establishing, managing and leading technical development plan for drug substance and drug product from pre-clinical through commercial development including support for all regulatory interactions and regulatory filings (INS/BLA) for the assigned developmental product portfolio. Key accomplishments:

- Responsible for lifecycle management and improvement of three commercial enzymes- Thyrogen®, Cerezyme® and Fabrazyme® along with tech transfer and production of therapeutic antibodies with help of MSAT organization across six sites in Sanofi network.
- Established robust network wide process monitoring program ensuring continuous validation verification which led the team to field FDA, EMA, Russian, HC, PMDA, Belarus, Korean regulatory inspections with compliments and ZERO technical observations.

- Lead the successful validation and regulatory approval of commercial formulated bulk (FB) reprocessing and its market release; a very rare feat in biologics industry, saving \$121 Million from otherwise discarded lots. Nominated for Sanofi Innovation Award for the same.
- Reformulated the on-floor support to be more technical training for operators and aggressively closed the validation gaps, upgraded the network policies to latest BPOG standards, replaced traditional SS assets with disposable technology, introduced Daily Capacity Management (DCM) resulting into 38% deviation reduction, faster lot release cycle with 97 FTE hour saving leading to estimated savings of \$3-4 Million /year.
- Directed successful tech transfer, validation and Pre-Approval Inspections (PAI) of an antibody process 3 months ahead of schedule and \$2.43 million less than budget.
- Technical lead on establishment of new 130,000 sq. ft. Continuous Manufacturing facility for biologics (facility of the future), a capital project of \$ 200+ Million. Leading facility design, equipment selection, sample plan generation, background support studies.
- Directed full process and release testing optimization to identify gap and created testing strategy for two commercial molecules that reduced tests by 25% thereby increasing the QC capacity, reducing the lot release cycle time and \$Millions in cost savings.
- As a part of senior leadership team defined strategies of operations, site priorities and policies, financial goals, supply/demand chain etc. enabling smooth delivery of collectively 98 commercial bulks/year of 3 lifesaving biologic drugs.
- Core member of Autonomous Production Unit (APU) steering and implementation team for biologics network.

Principal Scientist and Head - Downstream Process Development (Nov. 2014 - Sep. 2015)

Patheon Biologics, St. Louis, MO, USA

Patheon network supported- USA (St. Louis and Princeton), and Brisbane (Australia)

Summary:

Promoted to this role as a Strategic Functional Leader to lead the Downstream Development and Technical Support organization in the biologics network.

- Directed and managed 7 phase III molecules through their full process development or technology transfer to commercial manufacturing, regulatory filing and product launch.
- Evolved team of technical leaders with business mindset and client facing negotiating skills. Sustained the team of 16 PhD and masters level direct reports and 20+ indirect reports across 3 sites in Patheon network as well as multiple client sites as needed.
- Responsibilities include- operations manufacturing technical support, CAPA, change control, GMP facility scheduling and designing, quality investigations, carrying out viral clearance studies and also supporting process validation studies.
- Successfully (lead) established first cGMP biologics manufacturing plant in Australia under budget.
- Actively involved in new technology development and improvement. Established 20,000 sq ft. of multiproduct fully disposable biologics cGMP suit.
- Lead the creation of network validation, Extractable/Leachable and efficient technology transfer strategies.
- Participated as a leader in the network strategy, pricing determination and goals creation.

Senior Scientist / Group Leader- Downstream Process Development (Jan. 2013-Oct. 2014)

Patheon Biologics, St. Louis, MO, USA

Summary:

Recruited into this role to provide overall team leadership and establish formal strategy and technical guidance for Purification Development and Technical Support organization.

- Lead 4 phase III (two are commercial products) projects through team of 7 PhD and master level scientists to clinical and commercial manufacturing; provided technical guidance and oversight as needed
- Lead technology transfer, partial development and full development for recombinant proteins, enzymes, and monoclonal antibodies.
- Lead and supported the development of reports, RFP, TTPs, GMP batch records, Investigations, scheduling, Gap and Risk analysis documentations.
- Lead the development of new patentable technology and 2 operational excellence projects leading to significant cost savings.
- Actively involved in creating the technical agenda for PD DSP and setting up priorities for the group.
- Lead day to day client interaction, project negotiations, feedback gathering and meetings.

Research Scientist (Jun. 2012 – Jan. 2013)

Cornell University (WCMC-TMHRI), NY, USA

Summary:

- Developed protein conjugated bioactive nanomaterial for selective incarceration of cancerous mass.
- Developed truncated proteins based self-forming 3D matrix system for the selective triggering of immune system.
- Synthesis of custom targeting peptides, their characterization using HPLC, & LCMS and conjugation to the delivery vehicle.
- Responsible for maintenance of mammalian cell culture facility and stock preparation.
- Developing proposals for extramural funding and submitting technical documentation.

Post-Doctoral Research Associate (Feb. 2010 – Jun. 2012)

Rensselaer Polytechnic Institute, NY, USA

Summary:

- Successfully developed a simple and sensitive technique for the determination of protein orientation on nanosurfaces employing position specific chemical modification and quantitative proteomics.
- Expressed and purified (GE AKTA purifier) multiple labeled proteins and identified their specific residues, interacting with the interface, upon conjugation with nanosurfaces using liquid NMR technique.
- Characterized the zinc oxide toxicity in different human cell lines (HeCat cells, Hep G2 and NSCs) and discovered that nano ZnO may modulate the cellular differentiation.
- Developed multiple Extramural Grant Proposals and prepared technical reports.
- Mentored 4 graduate and 6 undergraduate students along with overall lab maintenance.

Academic qualification

- **Ph.D.** -Biochemistry
- **M.Sc.** -Biochemistry
- **B.Sc.** -Biochemistry
- **Post Graduate Diploma** - Industrial program in intellectual property rights
- **Post Graduate Diploma** - Professional diploma in clinical research

Selected Awards / Honors

1. **YOUNG SCIENTIST AWARD** by **Organization of Pharmaceutical Producers of India** comprising of *Abbot, Pzifer, Merck, Roche, Sanofi, Eli Lilly, Johnson & Johnson, Martin & Harris and more* for the year 2009. The award was presented by **President of India**.
2. **Sanofi Innovation Award 2017** for successful validation and regulatory approval of commercial formulated bulk (FB) reprocessing and its market release, saving \$121 Million from otherwise discarded lots.
3. **Sanofi Leadership Evolution Award 2018** for displaying high caliber transversal leadership potential.
4. Research contribution, due to its importance in medical sciences, is **included and mentioned in official Science Gazette of Govt. of India "TIMEIS"**.

Selected Publications

(Full list: <http://scholar.google.com/citations?user=wNV293wAAAAJ&hl=en&oi=ao>)

(A) Research Papers (Total Citations: > 3200 as of Oct 2020, source: Google Scholar)

1. Shrivastava S., McCallum S. M., Nuffer J. H., Qian X., Siegel R. W. and Dordick J. S. "Identifying Specific Protein Residues that guide surface interactions and orientation on Silica Nanoparticles" 2013, *Langmuir* 29 (34), 10841-10849.
2. Shrivastava S., "Metalloproteins in biomedical application", 2013, *Encyclopedia of Mettaloproteins*; Vladimir Uversky, Robert H. Kretsinger, Eugene A. Permyakov (Eds); Springer, New York. 1472-1474.
3. Shrivastava S., Nuffer J. H., Siegel R. W. and Dordick J. S., "Postion-specific chemical modification and quantitative proteomics disclose protein orientation adsorbed on silica nanoparticles", 2012, *Nano Letters* 12(3): 1583-1587. (Published as research highlight by journal **SCIENCE** and **National Science Foundation (NSF)**)
4. Gagner J. E., Shrivastava S., Qian X., Dordick J. S., and Siegel R. W., "Engineering Nanomaterials for Biomedical Applications Requires Understanding the Nano-Bio Interface – A Perspective", 2012, *The Journal of Physical Chemistry Letters* 3, 3149-3158. **(Cover Article for the issue)**
5. Singh S. K., Singh M., Nayak M., Kumari S., Shrivastava S., Grccio J. and Dash D. "Thrombus inducing property of atomically thin graphene oxide sheets", 2011, *ACS Nano*, 5(6): 4987-4996.
6. Shrivastava S., Singh S.K., Mukhopadhyay A., Sinha A.S.K., Mandal R.K. and Dash, D. "Negative regulation of fibrin polymerization and clot formation by nanoparticles of silver", 2011, *Colloids and Surfaces B: Biointerfaces*, 82(1): 241-246.
7. Shrivastava S. and Dash D. "Label-free colorimetric estimation of proteins using nanoparticles of silver", 2010, *Nano-Micro Letters*, 2: 164-168.
8. Shrivastava S., Bera T., Singh S.K., Singh G., Ramachandrarao P. & Dash D. "Characterization of novel anti-platelet properties of silver nanoparticles." 2009, *ACS Nano*, 3(6): 1357-1364. (Published as research highlight by journals **NATURE** and **SCIENCE**)
9. Singh S.K., Shrivastava S., Sinha A.S.K., Jagannadham M., and Dash D. "Biocompatible Silver nanoparticles conjugates and stabilizes protein", 2009, *Journal of Bionanosciences*, 3: 88-97.

10. Shrivastava S., Bera T., Roy A., Singh G., Ramachandrarao P. & Dash D. "Characterization of enhanced antibacterial effects of novel silver nanoparticles." 2007, *Nanotechnology*, 18: 225103. **(Published as research highlight by nanotechweb.org)**

(B) Books

1. Shrivastava S., *"Introductory Nano-biotechnology"*, New Central Book Agency, India, 2013.
2. Shrivastava S., *"Signaling mechanism in blood platelets and effect of nanosilver"*, Lambert Academic Publishing, Germany, 2011.
3. Shrivastava S., *"Molecular techniques in Biochemistry and Biotechnology"*, New Central Book Agency, India, 2009.

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Stephanie Eichler

stephaniebeth82@gmail.com | 617-512-4070 | Worcester, MA

Education

Certificate – Event Planning/Meeting Management **9/07 – 9/09**
Northeastern University Boston, MA

Bachelor of Science – Hospitality Management **9/00 – 5/04**
Boston University Boston, MA

- Major: Hospitality Management and Administration
 - Minor: Business Management with a concentration on Finance and Accounting
 - Relevant Coursework: Accounting, Finance, Marketing, Human Resources, MIS
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Executive Summary

Meticulous, task-driven Assistant with 6+ years of administrative experience in the bio-tech and hospitality industries. Equipped with exceptional ability to facilitate all aspects of internal and external communications, support the day-to-day administrative, financial, and operational functions by working with C-level executives. Operates well with minimal supervision to meet demanding objectives.

Professional Experience

Ohana Biosciences **9/19 - 4/21**
Senior Administrative Assistant Cambridge, MA

Administrative

- General administrative duties for 4 C-level executives as well as other members of the Leadership team.
 - Managed and prioritized schedules to ensure that leadership's time is focused on critical, strategic issues
 - Coordinated communications, track and follow up on requests for BOD, scientific advisory board, potential investors and other high-level meetings
 - Performed with a sense of urgency as meetings arose and communicated with other administrators to accommodate
 - Helped execute and maintain contracts, CDAs, and other documents for vendors, consultants and other key contributors of the company.
- Established and maintained effective and cooperative professional business relationships with all levels of management, employees and outside clients
- Maintaining the strategic time management to ensure executive leadership possessed continuous awareness and knowledge of all critical meetings and responsibilities.
- Performed ad hoc tasks and projects as needed for the entire Leadership team
- Collaborated with other EAs, internal and external, to schedule complex meetings involving investors and other key opinion leaders
- Provided coaching and mentoring to new administrators

Project Management/Special Projects

- Collaborated with Director of Quality to build an eQMS system in order to track of SOPs, employee resumes, training documentation, following requirement of FDA as Ohana moved towards launch
- Worked closely with Chief Medical Officer and outside vendor on organizing and executing Medical Affairs Projects (Training Module for future MSLs and Scientific Communication Platforms)

- Constant communication with vendor in regards to invoice, additional materials and ensuring all timelines were met
- Organized both in person and virtual company participation in JPM, ASRM and ESHRE
- Worked with medical affairs partners to outline relevant sessions and facilitate the attendance
- Facilitated debrief and dissemination of the Congress to the company, through summaries, slide decks and all-company meetings
- Built and organized database for VP, Legal to track status of contracts, NDAs, SOWs, for all current and former vendors.

Talent Discovery

- Collaborated with Senior Talent Discovery Partner, Talent Discovery & People Operations Manager and external agencies on a variety of searches.
- Conducted phone screens and participated in interview panel for multiple positions speaking about the culture and value of the company
- Utilized our hiring platform Lever to screen candidate applications and move them through the hiring process.
- Ensured a hospitable candidate experience from job posting through to onboarding.
- Assisted in onboarding 15 team members in 2020

Office Management & Cultural Engagement

- Managed office needs, including company lunches, kitchen & office supplies
- Planned and executed both in-person and virtual company events - quarterly leadership meetings, quarterly all-company meetings, monthly town halls, social events
- Supported Office Manager for 2 office moves, February 2020 and September 2020, as well as an office shut down in April 2021
- Actively participated in employee “Collectives” focused on People, Culture, and Events and starting in 2021, lead the Events and Meeting collective bi-weekly meetings

Legal Sea Foods

10/14 – 3/19
Boston, MA

Private Dining & Hospitality Manager

- Annual Sales Volume: \$2.2M individually/\$8M company-wide
- Booked 1000+ events per year ranging from small intimate dinners to full restaurant buy outs
- Oversaw 13 restaurants divided between 4 concepts (LSF, Sea Bar, C Bar, Legal On the Mystic)
- Responsible for capturing leads, planning menu details, creating phenomenal guest experience
- Worked closely with managers and associates of all locations for training and executing events
- Sourced outside vendors for enhancements to guests’ experiences
- Participated in local event planning associations & organizations: Cvent, MPI, BCVB
- Created and implemented catering menu to drive sales outside of the restaurant

Legal Sea Foods

5/11-10/14

Associate General Manager

Framingham/Boston/Peabody, MA

- Annual Sales Volume: \$5-\$8M
- Responsible for up to 100 employees
- Managed 3 departmental managers and assisted with their development
- Performed weekly inventory and financial analysis of beverage and wine sales and controls
- Managed all human resource functions for restaurant and employees
- Monitored payroll, A/P, and A/R

TGI Friday’s

5/03 – 5/11

Associate General Manager

Framingham/Millbury/Everett, MA

- Annual Sales Volume: \$4 - \$5M
- Hired, trained, and supervised all employees; front and back of house
- Oversaw guest satisfaction and daily operations
- Other Positions Held: Hospitality Intern, Front of the House Manager, Beverage Manager, Regional Training Assistant, Manager, New Store Opener, Back of the House Manager

Technical Skills

Microsoft Office Suite, Google Office Suite, CaterEase, Micros, SIVA, SmartDraw, OpenTable , SmartSheet, AirTable, Asana, Slack, Lever, LucidChart, Canva, Box, Prendio

209 Harvard St. Apt 1
Cambridge, Ma. 02139

StephanieSaldi@gmail.com

Stephanie Ficks

781-241-3859

WORK EXPERIENCE

Ohana Biosciences

September 2019- Present

Senior Research Associate II

- Sperm specific assay development & optimization for established/novel assays.
- Collaborate across research groups and levels develop, improve and enhance flow cytometry techniques, data acquisition, analysis and experimental design.
- Manage, operate and maintain flow cytometry equipment, training, and best practices.
- Support antibody discovery efforts in the form of conducting and designing screening experiments for 300+ targets by flow cytometry, high-throughput live-cell IF imaging, and IF microscopy on an LED microscope, analyzing data and presenting findings through group presentations.
- Perform microfluidic device testing of different in-house beta instruments.

Institute for Protein Innovation

December 2018- September 2019

Senior Research Associate

- Screened 100s of novel antibodies via flow cytometry for characterization and optimization
- Utilized bacterial transformations and mini/midi/maxi prep for use in mammalian and viral transfections
- Prepared samples for sequencing and analysis.
- Conducted various other cell based assays as needed such as antibody competitions, western blots, and immunoprecipitations.
- Supported cell sorting of mammalian and yeast as an antibody expression system.
- Responsible for assay development and cell culture maintenance associated with antibody screening, and protein production.
- Developed an automation pathway utilizing Thermofisher Momentum software, Biomek NX and Lynx liquid handlers for high-throughput antibody screening.

The Broad Institute

November 2015- December 2018

Research Technologist II

- Worked closely with users to train on instruments (see Field Experience Section for specific instruments), design and carry out sorting experiments, and to ensure that their cell sorting goals were achieved to the extent possible.
- Validated assay performance characteristics, wrote protocols, created excel worksheets that can do calculations based on the number of samples and volume used.
- Performed specimen collection/analysis, and/or experiments/assays from start to finish.
- Optimized and designed assay conditions for new projects; read literature to determine the best way to perform assays.
- Interpreted results and generated reports; troubleshooting, if necessary.
- Maintained equipment and assisted with quality control procedures in the laboratory on a daily basis.
- Recorded time, tracked the workflow, maintained all experimental details and generated billing for each project.

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Cambridge, Ma. 02139

StephanieSaldi@gmail.com

Stephanie Ficks

781-241-3859

Nexcelom Bioscience

August 2014- November 2015

Support Scientist/Technical Product Specialist

- Provided daily scientific application support to domestic FAS team (9), Sales Representatives (20), European and Asian Distributors (15)
- Oversaw Cellometer user support ticket database, Service RMAs, and Evaluation/Rental program
- Acted as direct line of communication and VOC to internal Engineering, Marketing and R+D teams regarding product improvements, software bugs, and evolving needs
- Conducted assay training/development for Cellometer applications from basic concentration and viability measurements to cell-based assays.

Nexcelom Bioscience

May 2013- July2014

Research Associate

- Designed and developed a reagent as a product for sale.
- Self-sufficiently designed, executed and analyzed experimental protocols.
- Coordinated with the marketing and quality control departments to produce customer-facing materials, including white papers, databases, and instruction manuals.
- Perform manufacturing and quality control analyses of reagents for sale to the public.

PUBLICATIONS

1. Saldi, S., Driscoll, D., Kuksin, D., Chan, LYY. Image-Based Cytometric Analysis of Fluorescent Viability and Vitality Staining Methods for Ale and Lager Fermentation Yeast. *J. Am. Soc. Brew. Chem.* 72(4):253-260, 2014
2. Chan, L. L.-Y., Kuksin, D., Laverty, D. J., Saldi, S., and Qiu, J. Morphological observation and analysis using automated image cytometry for the comparison of trypan blue and fluorescence-based viability detection method. *Cytotechnology* DOI:10.1007/s10616-014-9704-5, 2014

EDUCATION

Merrimack College, North Andover, MA

May 2013

B.S.: **Biology**, concentration in **Molecular and Biotechnology**/ B.A.: **Italian Studies (Double Major)**

GPA: 3.9

Awards: Summa Cum Laude, Dean's List, Merrimack College Austin Scholarship, Presidential scholar

Activities: Biology Club, Secretary; MSPCA Nevins Farm, volunteer; intramural soccer team.

American University of Rome, Rome, Italy

Spring 2012

FIELD EXPERIENCE

Maintaining and operating a MoFlo Astrios sorter, Beckman Coulter Cytotflex, the Propel Yeti, Sony SA3800 and SP6800 Spectral analyzers, Intellicyt iQue analyzer, BD FACSMelody sorter and Sony SH800 Cell Sorter.

Extensive training and application of fluorescent dyes; bacterial transformations; agarose gel electrophoresis; PCR; western blots; mini/midi/maxipreps. Experience using FlowJo, Summit, CytExpert, FCS Express, Genesnap, SnagIt, Zoom, Asana, Okta, GSuite/Gdrive, Box, Prendio, Microsoft Word, Excel and PowerPoint.

Stephen J. DeCamp, PhD

Somerville, MA

906-399-3286

stephen.j.decamp@gmail.com

Website Portfolio: www.stephenjdecamp.com

SUMMARY

- Innovative, cross-functional, and interdisciplinary scientist with strong communication skills.
 - Track record of rapidly adapting to new fields and generating high impact advances.
 - Interface of physics, biology, and materials science.
 - Balances high-level strategy with in-the-weeds details.
 - Open mind for creative solutions and a team building attitude.
-

RESEARCH & WORK EXPERIENCE

Ohana Biosciences, Inc.

Cambridge, MA

Surface Chemistry and Microfluidic Scientist II

March 2021 – Present

- Developed microfluidic technology for sperm cell selection and separation for clinical applications of assisted reproductive technologies (ART) impacting fertility and offspring health.
- Initiated R&D projects for ligand-based surface functionalization for cell selection.
- Prioritized research strategy goals and produced timeline and resource requirements for next generation microfluidic technology.
- Co-lead Diversity and Inclusion initiatives for Ohana including STEM outreach opportunities.
- Engaged in outlining breakthrough advances in sperm cell biology for applications in IVF and IUI through Ohana's industry journal club group.

Harvard T.H. Chan School of Public Health

Boston, MA

Research Associate

September 2019 – February 2021

Postdoctoral Research Fellow

September 2016 – August 2019

- Initiated and led a project interfacing materials science, physics, and biology.
- Rapidly learned techniques in cellular biology to achieve project goals.
- Assembled and led a multi-disciplinary team.
- Developed assays for cell metabolism and tissue mechanics studies.
- Leveraged microscopy, materials engineering, biomarkers, and Matlab-based analysis.
- Coded custom data analysis and image analysis pipelines for biophysical applications.
- Founded and led a Boston-based meetup group (Boston Soft Matter Socials) that fostered synergy between researchers with diverse backgrounds ranging from physics, math, engineering, and biology.
- Principal investigator on multiple projects and grants.

Brandeis University

Waltham, MA

Graduate Research Associate

September 2010 – August 2016

- Pioneered advances in bioengineered materials resulting in dozens of high-impact publications.
- Implemented custom instrumentation and hardware for optics, rheology, and 3D bioprinting.
- Fabricated novel microfluidics for high-impact biomaterials science experiments.
- Innovated assays and analytical protocols now used ubiquitously throughout the field.
- Coded algorithms for statistical analysis, micro-rheology, and object tracking.
- Instructed experts and non-experts on proper experimental and analysis procedures.

- Supervised numerous undergraduate research projects.

Michigan State University
Undergraduate Research Assistant

East Lansing, MI
August 2006 – May 2010

- Integrated instrumentation and methods from physics and molecular biology.
- Conducted experiments in real-time protein folding studies.
- Built and maintained laser confocal microscopes.
- Coded instrument controls using LabView software.
- Fabricated silica-based microfluidics using cleanroom techniques such as hard-contact photolithography, polysilicon deposition, and high-aspect ratio silicon wafer etching with D-RIE methods for microfluidic fabrication.

EDUCATION & TRAINING

Harvard School of Public Health, Postdoctoral Fellow (Trainee) September 2016 – August 2019
 Molecular and Integrative Physical Sciences Program
 Supervisor: Dr. Jeffrey J. Fredberg

Brandeis University, PhD. in Physics September 2010 – August 2016
 Attachment: Quantitative biology
 Supervisor: Dr. Zvonimir Dogic
 Dissertation Title: *Dynamics of Active Nematic Liquid Crystals*

Michigan State University, B.S. in Physics and Astrophysics August 2006 – May 2010
 Supervisor: Dr. Lisa Lapidus
 Thesis Title: *Circular Dichroism Measurements in a Microfluidic Serpentine Mixer*

SKILLS

Wetlab Biology: Experience in assay development for cell energy metabolism studies. Glycolysis and mitochondria characterization. Fluorescence biosensors. Mammalian cell culture. FACS flow cytometry. Transfection. Sample fixation. Protein purification. HPLC. Plasmid DNA work. Epithelial bioengineering. Human sperm cell processing. Density gradient centrifugation. Cell staining.

Optics/Microscopy: Experience in multiple modes of microscopy including: fluorescence, laser confocal, phase, CD spectroscopy, TIRF, and polarization light microscopy. – Experience in designing and building optical systems for applications in bio-materials imaging and subsequent image analysis.

Computational: Skilled in image analysis for fluorescence quantification, cell tracking, cell morphology and cell segmentation analysis, object detection, flow analysis (PIV), and traction force analysis. Extensive experience in data analysis, statistical analysis, and data plotting/visualization. Matlab. ImageJ. Mathematica. Ilastik Machine Learning. Leica LASX. MicroManager. LabView. FlowJo. AutoCAD. Fusion 360.

Microfluidics: Experience with microfluidics for cell separation and bio-material applications. Fabrication techniques including photolithography, spin-coating, clean-room work, rapid PDMS microfluidic prototyping, and magnetic microbead based separation.

Materials Science: 3D printing biomaterials. Material characterizations such as rheology and micro rheology. Emulsions and vesicle preparations. Microbead functionalization and passivation.

Spectrophotometers. Monolayer stress and traction force microscopy for characterizing culture tissue material properties.

Administrative: Experience with project leadership and personnel mentorship. Project timeline and resource requirement needs. Excellence in scientific communication and presentation in both written and spoken formats. Skilled in Microsoft Office Suite (Word, Excel, PowerPoint). Adobe Illustrator. Benchling electronic lab notebook. Grant writing. Publication preparation.

SELECTED PUBLICATIONS

My research has resulted in publication in many high impact journals such as *Nature*, *Nature Materials*, and *Science* and have been cited over 1700 times since 2015. Full list available upon request or on [my website](#).

DeCamp, S. J., Tsuda, V. M. K., Ferruzzi, J., Koehler, S. A., Giblin, J. T., Roblyer, D., Zaman, M. H., Weiss, S. T., DeMarzio, M., Park, C. Y., Ogassavara, N. C., Mitchel, J., Butler, J. P. & Fredberg, J. J. Epithelial layer unjamming shifts energy metabolism toward glycolysis. *Scientific Reports* 10, 18302 (2020).

Mitchel, J. A., Das, A., O'Sullivan, M. J., Stancil, I. T., **DeCamp, S. J.**, Koehler, S., Ocaña, O. H., Butler, J. P., Fredberg, J. J., Nieto, M. A., Bi, D. & Park, J.-A. In primary airway epithelial cells, the unjamming transition is distinct from the epithelial-to-mesenchymal transition. *Nature Communications* 11, 5053 (2020).

Atia, L., Bi, D., Sharma, Y., Mitchel, J. A., Gweon, B., A. Koehler, S., **DeCamp, S. J.**, Lan, B., Kim, J. H., Hirsch, R., Pegoraro, A. F., Lee, K. H., Starr, J. R., Weitz, D. A., Martin, A. C., Park, J.-A., Butler, J. P. & Fredberg, J. J. Geometric constraints during epithelial jamming. *Nature Physics* 14, 613–620 (2018).

Wu, K.-T., Hishamunda, J. B., Chen, D. T. N., **DeCamp, S. J.**, Chang, Y.-W., Fernández-Nieves, A., Fraden, S. & Dogic, Z. Transition from turbulent to coherent flows in confined three-dimensional active fluids. *Science* 355, 1979 (2017).

DeCamp, S. J., Redner, G. S., Baskaran, A., Hagan, M. F. & Dogic, Z. Oriental order of motile defects in active nematics. *Nature Materials* 14, 1110–1115 (2015).

Keber, F. C., Loiseau, E., Sanchez, T., **DeCamp, S. J.**, Giomi, L., Bowick, M. J., Marchetti, M. C., Dogic, Z. & Bausch, A. R. Topology and dynamics of active nematic vesicles. *Science* 345, 1135–1139 (2014).

Sanchez, T., Chen, D. T. N., **DeCamp, S. J.**, Heymann, M. & Dogic, Z. Spontaneous motion in hierarchically assembled active matter. *Nature* 491, 431–434 (2012).

DeCamp, S. J., Naganathan, A. N., Waldauer, S. A., Bakajin, O. & Lapidus, L. J. Direct Observation of Downhill Folding of λ -Repressor in a Microfluidic Mixer. *Biophysical Journal* 97, 1772–1777 (2009).

SELECTED PRESENTATIONS

Physical Sciences Oncology Network Junior Investigator Meeting – Bethesda, MD
Squishy Physics Seminar – **Invited Speaker** – Harvard University, Cambridge, MA
ATS Annual Meeting – Dallas, TX
APS March Meeting – Boston, MA

August 2019
July 2019
May 2019
March 2019

Harvard School of Public Health – Environmental Health Department Retreat, Boston, MA	December 2018
8 th World Congress of Biomechanics – Dublin, Ireland	July 2018
APS March Meeting – Baltimore, MD	March 2016
Soft Condensed Matter Seminar – Tufts University, Medford, MA	October 2015
Gordon Research Seminar (GRS) Soft Matter – Colby-Sawyer College, NH	August 2015
APS March Meeting – San Antonio, TX	March 2015
ACS Active Colloids Meeting – University of Pennsylvania, Philadelphia, PA	June 2014
23 rd Berko Symposium – Berko Prize Award – Brandeis University, Waltham MA	May 2014
APS March Meeting – Denver, CO	March 2014
15 th Annual Greater Boston Area Statistical Mechanics Meeting (GBASM)	October 2013
Gordon Research Conference (GRC) Liquid Crystals – U. of New England, ME	June 2013
52 nd New England Complex Fluids – Brandeis University, Waltham MA	September 2012
NIH NIBIB Training Grantees Meeting – NIH Campus, Bethesda, MD (poster)	June 2012
Active Jammed Systems – New York University, New York, NY (poster)	May 2012

SCIENCE OUTREACH

Boston Soft Matter Socials – Co-founder and organizer	2016-2019
Organized Biological Soft Matter Meeting Nov 17, 2017 @MIT	2017
Stratton Elementary School Science Festival – Arlington, MA	2014- 2015
Acton Discovery Museum – tabletop demos – Acton, MA	2011-2014
Lawrence Science Program – Intensive MCAS Science Bootcamp – classroom lessons	2014
Geek is Glam – Girl Scout Camp Event – stage demos – Worcester, MA	2013
Boston Children’s Museum – Tinker Tent – Electricity and Circuits Demo	2013
Boston Common Halloween at Frog Pond – Boston, MA	2013
PBS/NOVA – Making Stuff – tabletop demos – Boston Museum of Science	2011

PERSONNEL MANAGEMENT & MENTORSHIP

Lehman Foundation Research Mentor Supervised 2 student research projects and mentored career development activities	2018-2019
Harvard University Science Education Undergraduate Mentoring Workshop Series Earned a certificate in undergraduate research mentorship from esteemed Harvard program	2018
HHMI Quantitative Biology Research Community Mentor Mentored 6 students in a laboratory-based experiential learning program	2015
Active Sample Bootcamps for the Brandeis NSF MRSEC Trained dozens of external researchers in active sample preparation	2012-2015
Undergraduate Research Mentor in the Dogic Lab at Brandeis University Supervised 3 undergraduates resulting in 1 publication	2012-2015
Teaching Assistant for Introduction to Physics Lab at Brandeis University Instructed a physics lab designed for pre-med students to learn concepts in physics.	2010-2011

Steven “Nick” Wlodychak

5 Brown Terrace, 2F Jamaica Plain MA 02130 – (661)-993-3513 – swlodychak@gmail.com

**6 years of extensive NGS, epigenetic and genetic engineering experience with eager and outgoing disposition. Background in chromatin biology and methylation.
Looking for the next challenging project.**

EDUCATION - UC Merced, B.S. Bioengineering, May 2015

EXPERIENCE

Senior Research Associate, Epigenomics - Ohana Biosciences **Sept. 2019 - Present**

- Sperm specific assay development & optimization for established/novel assays.
- Independent DOE. (RT-PCR, ROS profiling, single-cell, TF and methylation profiling)
- Epigenetic specific workflow from sperm treatment, nucleic acid extraction, library preparation.
- Generation of pipeline for DIP libraries for assays currently in development.
- Developed click-chemistry assay for single-nucleotide resolution & detection of rare modified bases.
- Generation of sperm specific pipelines for RRBS and sc-bisulfite libraries using PBAT.
- Presenting data to leadership of progress and results.
- Planning and leading of various project meetings, including all-company town hall.
- Co-led production of public communications projects for company.

Research Associate, Genomics - Omega Therapeutics **June 2018 - July 2019**

- CRISPR/Fusions workflow - lentiviral/formulations transfection, DNA/RNA isolation, library preparation, NGS and data analysis.
- Variety of DOEs (siRNA knockdown, nuclease/epigenetic guide efficiency)
- Developed and established assay for Hi-C & ChIP-Seq/ChIP-qPCR (H3K4me3, H3K27ac, TFs, etc.)
- Developed and established assay for amplicon bisulfite sequencing
- Primer design for all regions of interest, write/optimize new SOPs
- Operation, maintenance, and troubleshooting of Illumina MiSeq.
- Theoretical understanding of epigenetics, effector nucleases, chromatin remodeling.
- Documented and presented data to superiors on experiments performed.

Sequencing Technician - La Jolla Institute for Immunology **August 2016 - May 2018**

- NGS workflow and consultation from nucleic acid isolation, library preparation, and data analysis
- Support and training for PIs, in custom library design, sample preparation, and troubleshooting (e.g SmartSeq, TrueSeq, Nextera, Swift, ChIP, ATAC, Nugen, etc.)
- Operation, maintenance, and troubleshooting of Illumina HiSeq 2500 and MiSeq.
- Supplementary equipment usage of Agilent TapeStation, Bioanalyzer, Fragment Analyzer, RT-PCR (Biorad, Roche), Plate readers/fluorometers (Envision, Qubit), liquid handler Bravo/Biomex FXP.
- Theoretical understanding of molecular and chemical processes involved in NGS workflow.

Research Associate (Consultant) - Illumina **Sept. 2015 - Nov. 2015**

- Assisted with early stage development of targeted enrichment onco-genomics project.
- Analysis/quantization using both plate readers and Bioanalyzer,
- Independent operation of HiSeq 3000/4000, NextSeq, and Miseq.
- Experience related to following SOPs and experiment design for both DNA and RNA samples.
- Utilized various molecular biology techniques (e.g. PCR, probe hybridizations)
- Gave presentations to the group based on experiments performed.

Bioprinter Capstone Design – UC Merced**December 2014 – June 2015**

- Design and build of an open-sourced 3D stem cell bio-printer with a solenoid valve based extrusion system to mitigate the problems of conventional printers destroying cell membranes.
- Designed detailed circuit diagrams and created a solenoid mounting using AutoCAD. Functions with Cura and personally written G-code. Completed proof of concept and functional prototype.
- Achieved 93% cell viability while maintaining a low cost and efficient product.

Lund Microbiology Lab - Lund University, Sweden**July 2012 – December 2012**

- Formulated protocol to isolate a Lactobacillus species using previously published research.
- Created a specialized media, sugar metabolism test, and then plated individual colonies.
- Isolated DNA which was then matched against previously recorded genomes using a BLAST search.

SPECIAL PROJECTS

Click-Ligation Chemistry (Ohana)**January 2021 – Present**

- Alternative ligation strategy utilizing a azide terminating NTP to bind selectively to an alkyl terminating primer to specifically enrich for rare nucleotide marks at single base resolution.
- Optimized in-cell fragmentation technique, Az-NTP incorporation and click reaction conditions.
- Exploration of other rare marks using alternative BER enzymes.
- Still in early-stage development.

Primer Bank Development and Sequencing Overview (Omega) August 2018 – July 2019

- Development of a comprehensive primer registry for all industry primers (ChIP, amplicon sequencing, bisulfite sequencing, endonuclease digestion, etc.)
- Creation of standardized work-flow for intelligent primer design increasing robustness and throughput of sequencing and ChIP assays.
- Stringent selection method establishes T_m values, amplicon size, GC content, and high specificity.
- Independent nomination/evaluation of hundreds of primer sets; define internal company standards.
- Implementation of strategic plan for expansion of internal sequencing capabilities (specifically GRO-Seq and PRO-Seq used for nascent RNA expression changes).

Tn5 Transposase for ATAC and Bisulfite Sequencing (LJI)**May 2017 – May 2018**

- Cloned vector into competent cells which were then grown and isolated with antibiotic selection.
- Purified and validated protein using chitin columns and western blots.
- Assembled with UMI/methylated adaptors for use in single-cell ATAC and Bisulfite-Seq respectively
- Designed buffers and primers for home-brew library prep.
- 98% mapping against Nextera or similar.

OTHER WET-LAB SKILLS AND RELEVANT EXPERIENCE

- Media/buffer preparation, sterile technique, pipetting, titration, SDS-PAGE
- Gel electrophoresis, protein/DNA/RNA purification, molecular cloning, PCR/RT-PCR
- Antibody optimization, ELISA, immunology processes, reporter assays
- Mammalian cell culture / metabolism, Cas9 transfections, lentiviral particle generation, siRNAs

MEMBERSHIPS AND OTHER AFFILIATIONS

- Engineers for a Sustainable World (ESW) – Various sustainability projects at UC Merced
- Children's Miracle Network - 160 hours community service
- Sigma Chi Fraternity - Scholarship Officer and Public Relations Officer

Sumanprava Giri, Ph.D.

sumanprava@gmail.com | 51 Garfield St Unit B, Quincy, MA 02169 | 217-979-9441

SUMMARY

- A Cell Biologist and Next Generation Sequencing (NGS) Scientist with 10+ years of successfully interrogating cellular processes using a combination of cell and molecular biology, single-cell genomics and deep sequencing tool kits.
- Innovative and skilled assay developer with extensive experience of working with challenging model systems and ultra low-input biological samples.
- Highly effective leadership, management and communication skills evidenced by leading of the genomics and single-cell biology team in the current position, mentorship of multiple junior scientists, and, by effective collaborations both within the company and with external industry and academic partners.

EDUCATION

University of Illinois, Urbana-Champaign (UIUC), Urbana, IL 2015

- Ph.D. in Cell and Developmental Biology
- Thesis: Role of ORCA and ORC in chromatin organization and DNA replication
- NIH F31 Pre-Doctoral Research Fellowship (2014–2016)
- NSF CMMB-IGERT Pre-Doctoral Traineeship (2011-2013)

Anna University, Chennai, India 2010

- B.Tech in Biotechnology

RELEVANT EXPERIENCE

Ohana Biosciences, Cambridge, MA Sept. 2019 – Present

Senior Scientist – Genomics Team Lead

- Led efforts to establish a genomics and single-cell technology platform to better understand sperm biology and single cell heterogeneity.
- Established single-cell and bulk epigenomics capabilities in house: developed protocols to probe DNA methylation (RRBS and WGBS) and chromatin conformation (ATAC-seq) in human and mouse sperm.
- Established single-cell and bulk transcriptomics profiling protocols for mRNA and small ncRNA in sperm and embryos.
- Led optimization efforts to develop sperm surface profiling by onboarding CITE seq like approaches (on the BD Rhapsody platform)
- Onboarded technologies to accurately understand and quantify de novo mutations in sperm like duplex sequencing.
- Developed protocols to probe DNA damage profiles in sperm by 8oxodG sequencing
- Led collaborations with both academia and industry to better understand single cell heterogeneity and de novo mutation biology.

Inari Agriculture Inc., Cambridge, MA June 2018 – Sept. 2019

Scientist II – Molecular Biology Platform Team Lead

- Led three platforms within Inari: Next Generation Sequencing, High throughput Genotyping and Vector construction.
- Established high throughput genotyping capabilities by setting up automation and liquid handling capabilities.
- Established a RNA Seq toolkit comprising of Total, mRNA and 3' RNA Seq to better understand transcriptomic perturbations.
- Onboarded new NGS technologies including single cells genomics and long read technologies like PacBio and Nanopore based sequencing.
- Led efforts to set up robust vector construction platform using Golden Gate and Gibson based workflows.
- Led a team of 10 scientists and RA to maintain an efficient platform.

Inari Agriculture Inc., Cambridge, MA

Scientist I - Next Generation Sequencing and Assay Development Team Lead April 2017– June 2018

- Established Next Generation sequencing capabilities by setting up RNA and Amplicon sequencing pipelines to interrogate levels and effects of gene editing. Set up MiSeq handling protocols to have Next Generation Sequencing facility in house.
- Established ATAC Seq, Bisulphite sequencing and ChIP-sequencing to probe various plant chromatin landscapes.
- Established novel assays for investigating gene editing.
- Helped set up a high throughput small molecule screen to find novel regulators of DNA damage repair pathways.
- Established high throughput nucleic acid extraction and genotyping protocols.
- Currently setting up automation of NGS and nucleic acid extraction pipelines.

Harvard Medical School /Massachusetts General Hospital (MGH) Cancer Center, Boston, MA
Postdoctoral Research Scientist (Advisor: Lee Zou, Ph.D.) 2016–2017

- Designed and executed a RNA-sequencing screen to study the role of DNA replication and replication stress on transcription. Used qRT-PCR to validate differentially expressed genes.
- Established techniques to study epigenetics in the lab and used this expertise to forge collaborations with other members of the lab. Worked on two collaborative projects using my graduate school expertise in ChIP-sequencing.
- Initiated new lines of investigation in the lab and devised research objectives that served as the foundation for future work in the lab.
- One of the collaborative projects led to a publication in *Mol Cell*.

University of Illinois, Urbana-Champaign (UIUC), Urbana, IL
Ph.D. Candidate (Advisor: Supriya G. Prasanth, Ph.D.) 2010–2015

- Identified the mechanism by which ORC and ORCA regulate heterochromatin organization and replication.
- Identified the cross talk between DNA replication machinery and H3K9 methyltransferases.
- Identified a novel role of Orc5 in chromatin decondensation
- Investigated the role of ORC in DNA damage by investigating its interaction with a DNA damage associated E3 Ligase, RFWD3.
- Published in multiple journals including *Elife*, *J Cell Sci*, *PNAS* and *Nucleus*.

KEY TECHNICAL SKILLS

- **Single-cell Genomics:** Plate format sc DNA methylation and mRNA-seq (SMART Seq2), droplet based scATAC-seq + mRNA on 10X Genomics Chromium, and, nanowell based surface profiling (CITE-Seq) using BD Rhapsody
- **Next Generation Sequencing (Illumina and Nanopore):** Library preparation and deep sequencing of RNA and DNA (Whole Genome and amplicon), Bisulphite sequencing, Chromatin Immunoprecipitation and deep sequencing, MiSeq and Fragment Analyzer running and maintenance, single molecule sequencing by Nanopore
- **Molecular Biology:** DNA and RNA isolation from cancer cell lines and primary tissues, molecular cloning, PCR (regular and quantitative real-time), DNA and RNA FISH
- **RNA Biology:** small non-coding and lncRNA library prep and sequencing, RNA stability assays, RNA immunoprecipitation
- **Automation and liquid handling:** Setting up liquid handlers like the Biomek FX^P to carry out NGS library preps.
- **Bioinformatics:** GALAXY workflows, BOWTIE, MACS, Python, R for ChIP-seq and RNA-seq analysis
- **CRISPR and Gene Editing:** DNA and RNP based genome editing, *in vitro* cleavage assays with purified Cas9, on target analysis by amplicon based deep sequencing, T7E1 assays, TiDE analysis, off target detection by GUIDE Seq, SITE Seq and CIRCLE Seq

ADDITIONAL SKILLS

- **Cell culture and engineering:** 2D and 3D Mammalian cell culture (primary and cancerous cell lines) and transfections, Genome editing by CRISPR, RNAi and shRNA mediated knockdowns, generation of reporter cell lines
- **Cell Biology:** Immunofluorescence, Microscopy - live and fixed cell imaging, fluorescent protein biology, RNA and DNA FISH

- **Protein Engineering and expression:** Site directed mutagenesis, Mammalian, baculoviral and bacterial protein expression
- **Biochemistry:** Immunoprecipitation, western blotting, peptide pulldown, in vivo and in vitro methylation assays, glycerol gradient sedimentation, flow cytometry

HONORS AND AWARDS

- **Oyetunji A. Toogun Memorial Award**, Department of Cell and Developmental Biology, University of Illinois at Urbana – Champaign, 2016
- **Ruth L. Kirchstein National Research Service Award for Individual Predoctoral Fellowship (Parent F31)**, National Institutes of Health, 2014 – 2016.
- **Cellular and Molecular Mechanics and Biotechnology (CMMB) – Integrative Graduate Education and Research Traineeship (IGERT)**, National Science Foundation (NSF), 2011-2013
- **WISE research scholarship**, German Academic Exchange Service (DAAD), 2009
- **Summer Research Fellowship**, Indian Academy of Sciences, 2008
- **Department of Biotechnology Biology Scholarship**, Ministry of Science and Technology, India, 2007

PUBLICATIONS

Hsu RYC*, **Giri S***, Wang Y, Lin YC, Liu D, Wopat S, Chakraborty A, Prasanth KV, Prasanth SG. 2020. “The E3 ligase RFWD3 stabilizes ORC in a p53-dependent manner”. *Cell Cycle*. 9(21):2927-2938.

Wang Y., Lin Y. C., **Giri S.**, Wopat S., Chakraborty A., Prasanth K.V., Prasanth S. G. 2018. “PCNA-mediated recruitment of E3 ligase RFWD3 to the replication fork is essential for DNA replication”. *PNAS*. 115(52):13282-13287.

Nguyen H. D., Yadav T., **Giri S.**, Saez B., Graubert T. A., Zou L. 2017. “Functions of Replication Protein A as a sensor of R loops and a regulator of RNase H1.” *Mol Cell*. 65(5):832-847.

Wang Y., Khan A., Marks A.B., Smith O.K., **Giri S.**, Creager R., MacAlpine D.M., Prasanth K.V., Aladjem M.I. and Prasanth S.G. 2016. “Temporal association of ORCA/LRWD1 to late-firing origins during G1 dictates heterochromatin replication and organization.” *Nucleic Acids Research*, pii: gkw1211

Giri S., Chakraborty A., Satyan K.M., Prasanth K.V., and Prasanth S.G. 2016. “Orc5 induces large-scale chromatin decondensation in a Gcn5-dependent manner.” *J Cell Sci*. 129(2): 417-29

Giri S. and Prasanth S.G. 2015. “Association of ORCA/LRWD1 with repressive histone methyltransferases mediates heterochromatin organization.” *Nucleus*. 6(6): 435-41

Giri S., Aggarwal V., Pontis J., Shen Z., Chakraborty A., Khan A., Mizzen C., Prasanth K.V., Ait-Si-Ali S., Ha T., Prasanth S.G. 2015. “The preRC protein ORCA Organizes Heterochromatin by Assembling Histone H3 Lysine 9 Methyltransferases on Chromatin.” *ELife*.

Khan A., **Giri S.**, Wang Y., Chakraborty A., Ghosh A.K., Anantharaman A., Aggarwal V., Sathyan K.M., Ha T., Prasanth K.V., Prasanth S.G. 2015. “BEND3 represses rDNA transcription by stabilizing a NoRC component via USP21 deubiquitinase.” *PNAS*. 112(27): 8338-43

Sun Y., Li D., **Giri S.**, Prasanth S.G, Yoo D. 2014. “Differential host cell gene expression and the regulation of cell cycle progression by non-structural protein 11 of porcine reproductive and respiratory syndrome virus.” *Biomed Res Int*. 2014:430508

Tripathi V., Shen Z., Chakraborty A., **Giri G.**, Freier S.M., Wu X., Zhang Y., Gorospe M., Prasanth S.G., Lal A., Prasanth K.V. 2013. “Long Noncoding RNA MALAT1 Controls Cell Cycle Progression by Regulating the Expression of Oncogenic Transcription Factor Mybl2.” *Plos Genet*. 9(3): e1003368

Shen Z., Chakraborty A., Jain A., **Giri S.**, Ha T., Prasanth K.V., Prasanth S.G. 2012. “Dynamic association of ORCA with prereplicative complex components regulates DNA replication initiation.” *Mol Cell Biol*. 32(15):3107-20

Giri S., Prasanth S.G. 2012. “Replicating and transcribing on twisted roads of chromatin.” *Brief Funct Genomics*. 11(3):188-204

Xiaoyun Guo, Ph.D.

18 Weld Street, Framingham, MA 01702
617-861-3389 (Cell)
guo.xiaoyun.99@gmail.com

QUALIFICATION SUMMARY

- Specialization in genomic data analysis using R, Python, Nextflow and machine learning
- Experience with single cell analysis on single cell RNA-seq and single cell RRBS
- Critical thinking and problem-solving skills with Ph.D. and postdoc training
- Diverse experience: bioinformatics, biology (hands-on experimental), and engineering
- Excellent writing, oral communication, and presentation skills

Work permission: U.S. Citizen

SKILLS

- Data types: single cell RNA-seq, RNA-seq, ChIP-seq, ATAC-seq, DNA-seq, OxiDIP-seq, DNA methylation (RRBS, WGBS), ncRNA-seq, DNA motif, DNA shape
- Machine learning: Scikit-learn, gradient boosting, random forest, SVM, etc.
- Bioinformatic tools: Seurat, Scater, Monocle, edgeR, DESeq2, STAR/RSEM/Cufflinks, Salmon, Kalisto, Bismark, Trim Galore, bowtie/BWA, Samtools, Bedtools, GATK, gkmSVM, GEM, MACS, KMAC, clusterProfiler, fgsea, topGo, biomaRt, IGV, DNashapeR, etc.
- Programming languages: R, Python, Unix shell script, MATLAB
- Flow management: Nextflow
- Platform: Linux, AWS, MAC, Windows

EDUCATION

Boston University

Ph.D., M.S., Electrical and Computer Engineering

Awards: Dean's Fellow (1997-1999); Discover Magazine Award for Technology Innovation (2000)

Boston, MA

Jan 2002

Tsinghua University

B.E., Materials Science and Engineering

Awards: Progress Award

Beijing, China

July 1996

PROFESSIONAL EXPERIENCE

OHANA BIOSCIENCES, CAMBRIDGE, MA

Scientist II, computational biology

Feb 2019 – present

Gene expression analysis on mouse embryo development

- Contributed to experiment design in variable selection, replicates and sequencing depth
- Constructed RNA-seq process pipeline (Trim Galore, Salmon, Kalisto, STAR/RSEM, Nextflow)
- Quality analysis on single cell RNA-seq and low DNA input RNA-seq data (tidyverse, Seurat)
- Conducted differential gene expression and ontology analysis and gene sets enrichment analysis (edgeR, topGo, Seurat, fgsea)
- Analyzed transcription factor motif enrichment in promoter regions of interested genes
- Conducted developmental pseudo time/trajectory analysis and discovered cell stage markers (Monocle3, Seurat)
- Identified (minor) zygotic genome activation using inter-genic transcripts

DNA methylation analysis and molecular clock modeling on human sperm

- Constructed DNA methylation (WGBS and RRBS) data processing pipeline (Trim Galore, Bismark, Samtools)
- Constructed QC pipeline for RRBS and single cell RRBS assay development

- Built molecular age clock model based on sperm DNA methylation using Loess regression and Random forest
- Discovered sperm heterogeneity using molecular age clock on single cell RRBS data

ncRNA analysis on mouse sperm

- Constructed ncRNA-seq data processing pipeline (Flexbar, SPORTS)
- Conducted QC analysis to select assay parameters and sequencing library treatments
- Analyzed and compared ncRNA species/length distribution to identify the epigenomic effects of different animal/sperm treatments

DNA 8Oxo-dG analysis on human sperm

- Constructed OxiDIP-seq data processing pipeline (Nextflow, bowtie2, MACS2)
- Constructed QC pipeline to select 8Oxo-dG antibody and optimize assay parameters
- Discovered 8Oxo-dG hot spots/patterns in sperms

DNA-seq de novo mutation analysis on human testicular cells

- Used modeling to estimate the sequencing depth required by the experiment design
- Constructed DNA-seq mapping and variant calling pipeline for mitochondrial DNA and autosome DNA (BWA, GATK)
- Filtered SNV using available truth sets and confirmed the relationship between SNV counts and donor age

MIT, COMPUTER SCIENCE AND ARTIFICIAL INTELLIGENCE LABORATORY

Bioinformatician (Gifford Lab)

Jan 2015 – Feb 2019

Epigenomic data analysis in motor neuron development

- Analyzed RNA-seq gene expression data using edgeR, STAR/Cufflinks/subread
- Analyzed Nkx2.2, Groucho, and p300 ChIP-seq binding data using GEM peak caller, discovered differential binding sites using edgeR
- Discovered cell-type-specific regulatory elements between embryonic stem cells and motor neurons using ATAC-seq data (using MACS, bedtools, and edgeR)
- Integrated multiple datatypes: gene expression, histone modification and TF binding data, to explore the mechanism of gene regulation

Single Cell RNA-seq analysis in motor neuron development

- Conducted data filtering, dimension reduction, and visualization (Scater/Seurat, PCA/tSNE)
- Conducted pseudo-time analysis, clustering and identified marker genes during motor neuron development using Monocle in Bioconductor/R
- Compared and correlate the expression of marker genes/transcription factors at various stages of motor neuron development

Predict transcription factor (TF) in vivo binding using motif and DNA shape

- Integrated KSM and PWM motifs and DNA shape features (from DNASHapeR) to predict TF binding in 87 ChIP-seq experiments, using a gradient boosting classifier (numpy, pandas, Biopython, scikit-learn in Python, Jupyter)
- Found that DNA shape features provided extra information and improved prediction accuracy

Predict TF binding and effect of non-coding genetic variants

- Constructed gradient boosting model using features from KSM, optimized PWM, and PWM, evaluated feature importance, and performed feature selection using scikit-learn and Python
- Compared TF binding prediction accuracy between KSM, gkmSVM, optimized PWM and PWM
- Predicted the effect of non-coding genetic variants on differential regulatory activities (reference vs. alternative) of massively parallel reporter assay (MPRA)
- Used machine learning methods (scikit-learn, Python) such as Logistic regression, Random forest, SVM, KNN, with cross-validation to prevent overfitting
- We found that KSM is superior to optimized PWM and PWM in prediction accuracy. The results have been included in a paper published in *Genome Research*

AMERICAN JOURNAL EXPERTS

March 2011 – March 2018

Freelance Senior Translator: Translated 150+ Chinese manuscripts for publishing in English academic journals in bioinformatics, biology, medical science, and engineering

MIT, Dept. of BIOLOGY (Krieger Lab)

May 2010 – May 2011

Research Assistant: Genotyped mice with polymerase chain reaction (PCR), developed a new PCR protocol that greatly improved the PCR quality of SR-B1 gene

MIT, Dept. of Electrical Engineering and Computer Science

Aug 2002 – Dec 2007

Postdoctoral Associate: Modelled, designed and fabricated semiconductor devices; analyzed data and built computational models; maintained facilities and trained users

BOSTON UNIVERSITY, Dept. of Electrical and Computer Eng. Sept 1997 – Jan 2002

Graduate Research Assistant: Modelled, designed and characterized semiconductor devices; served as teaching assistant for undergraduate courses

COURSES

- Machine learning (by Stanford University @ Coursera)
- Analysis of single cell RNA-seq data (@ Bioinformatics Training unit by Cambridge University)
- Explore Statistics with R (Edx)
- Intro. to Computer Science and Programming Using Python (Edx MITx-6.00.1x)
- Intro. to Computer Science and Data Science (Edx MITx-6.00.2x)
- Genomic Data Science with Galaxy (by Johns Hopkins University @ Coursera)
- Introduction to Genomic Technologies (by Johns Hopkins University @ Coursera)

PATENTS

1. Rajeev Ram, Tauhid Zaman, **Xiaoyun Guo**, Magnetically active semiconductor waveguides for optoelectronic integration (United States US20040223719 A1) Issued November 11, 2004
2. E. Fred. Schubert, **Xiaoyun Guo**, Photon recycling semiconductor multi-wavelength light-emitting diodes (United States WO2000076005 A1), Issued June 2, 2000

SELECTED PUBLICATIONS

1. Yuchun Guo, Kevin Tian, Haoyang Zeng, **Xiaoyun Guo**, David K Gifford, "A novel k-mer set memory (KSM) motif representation improves regulatory variant prediction", *Genome Research*, 28: 891-900, 2018
2. Nkx2.2-mediated repression of motor neuron identity reveals unifying model of Groucho function, Elena V Abarinov; Michael Closser; Yuchun Guo; **Xiaoyun Guo**; Mary Chalkley; David Gifford; Esteban O Mazzoni; Lori Sussel; Hynes Wichterle, *Cell*, in review
3. Michael Closser, Yuchun Guo, Rachel Kopunova, Tulsi Patel, **Xiaoyun Guo**, Ho Sung Rhee, Yijun Ruan, David K Gifford, Hynes Wichterle, "An expansion of genomic regulatory complexity underlies vertebrate neuronal diversity", *Nature*, in review
4. Tauhid Zaman, **Xiaoyun Guo**, Rajeev J. Ram, "Faraday rotation in an InP waveguide," *Applied Physics Letters*, 90, p.023514, 2007
5. Tauhid Zaman, **Xiaoyun Guo**, and Rajeev J. Ram, "Proposal for a Polarization Independent Integrated Optical Circulator," *IEEE Photonics Technology Letters*, vol. 18, no. 12, pp. 1359-1361, 2006.
6. **Xiaoyun Guo** and E. Fred Schubert. "Current crowding effect in GaN/InGaN light emitting diodes on insulating substrates", *Journal of Applied Physics*, Vol.90, pp.4191-4195, 2001
7. **Xiaoyun Guo** and E. Fred Schubert. "Efficiency of GaN/InGaN light emitting diodes with integrated mesa geometry", *Applied Physics Letters*, Vol.79, pp.1936-1938, 2001
8. More publications at: <https://scholar.google.com/citations?user=EiijKiMAAAAJ&hl=en&oi=ao>

SELECTED PRESENTATIONS

Magneto-Optical Semiconductor Waveguides for Integrated Isolators", SPIE, Photonics West, San Francisco, Mar 2005. (invited talk)

Yong Ren

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Sharon, MA 02067
781-493-2999

yren132@gmail.com
www.linkedin.com/in/yong-ren

SUMMARY:

- 17 years in drug discovery from target identification to early pre-clinical development
- Proven manager of functional groups in a matrix environment
- Skilled in assay development and screening
- Significant experience as cross-functional drug discovery project team leader and member
- Experienced working with external partners, CROs and academic collaborators

PROFESSIONAL EXPERIENCE:

OHANA BIOSCIENCES, Cambridge, MA (March 2020 – present)

➤ Principal Scientist, Pharmacology

- Building internal assay development capabilities for antibody testing and MoA studies.
- Developed functional assays such as calcium flux and ADCC assays for non-hormonal male contraceptives.
- Developed assays to support clinical development of fertility products.

DECIBEL THERAPEUTICS, Boston, MA (February 2017-January 2020)

➤ Associate Director, Pharmacology

- Built and led *in vitro* pharmacology/assay development team of Ph.D. and non-Ph.D. scientists supporting discovery projects and platform efforts.
- Performed IND-enabling *in vitro* studies to demonstrate the efficacy, potency and mechanism of action for Decibel's first small molecule in clinical trial.
- Developed various *in vitro* assays; drove *in vitro* screening of a collection of compounds for their potential otoprotection activities; investigated small molecule and biologic tools to validate potential targets; collaborated with pharmaceutical development team in developing methods to deliver different therapeutics to inner ear.
- Built and optimized virus management and testing workflow for AAVs; performed IND-enabling *in vitro* studies ensuring AAV vector quality while demonstrating their efficacy and potency.

PFIZER INC, Groton, CT (July 2012-January 2017)

➤ Senior Principal Scientist/Lab Head, Hit ID and Lead Profiling

- Served as the Point-of-Contact for Hit ID and Lead Profiling group primarily working with Pfizer Rare Disease Research Unit, participating in setting overall strategy for projects, aligning internal and external resources with research unit priorities.
- Supervised and mentored a group of highly productive Ph.D. and non-Ph.D. scientists, delivering plate-based assay data to cross-site project teams in rare genetic diseases, neuroscience, cardiovascular and metabolism, inflammation and oncology research units.
- Worked on developing and optimizing multiple phenotypic and target-based assays for HTS and subset screens, successfully identifying small molecule lead matters and tool compounds for multiple projects in the genetic neuromuscular, mitochondrial diseases and hematology areas.

- Collaborated with research units, drug safety colleagues and academic key opinion leaders to associate signaling profiles of GPCR ligands to clinical response.

ANCHOR THERAPEUTICS, Cambridge, MA (July 2008-July 2012)

➤ **Senior Scientist – Principal Scientist, *in vitro* pharmacology/screening**

- Led *in vitro* pharmacology/screening group in a start-up company focusing on the discovery of novel lipidated peptides as GPCR ligands. Built and optimized a panel of *in vitro* and *ex vivo* assays, and streamlined work process to maximize efficiency of a small group; incorporated external resource into screening funnel; worked closely with CROs for both pharmacology and ADME/Tox assays.
- Actively participated in strategic and tactical planning as well as business development discussions as a member of the Scientific Leadership Team. Communicated progress by presenting regularly to the Board of Directors, Scientific Advisors Board, and external collaborators.
- Led internal and collaboration discovery projects, successfully identified lead matters for GPCR targets focusing on metabolic and inflammation diseases. Designed, developed and performed *in vitro* GPCR functional and binding assays to demonstrate the efficacy, potency and mechanism of action for these novel ligands.

LUNDBECK RESEARCH USA, Paramus, New Jersey (2004-2008)

➤ **Scientist II - Senior Scientist, Molecular Pharmacology**

- Served as the *in vitro* pharmacology point person on cross-functional small molecule discovery teams from HTS to development candidate nomination; developed and executed ligand-binding and functional assays for various target classes including GPCRs, monoamine transporters, ligand-gated calcium channels.
- Brought scientific leadership to cell biology core; improved quality of cells delivered to molecular pharmacology groups and the global HTS center for Lundbeck; identified and evaluated contract organizations to scale-up cell and membrane productions to meet the needs of both pharmacology and HTS.
- Led exploratory projects for target validation; identified tool compounds through focused small molecule library screens; worked closely with *in vivo* scientists to use these tools in animal models for anxiety and depression.
- Working with compound safety lead in Denmark, developed and executed *in vitro* cytotoxicity assays in the US location leading to significant decrease in turnaround time for compound safety assessment for all project teams.

TUFTS-NEW ENGLAND MEDICAL CENTER, Boston, Massachusetts (1997-2004)

➤ **Research Staff, Molecular Pharmacology (July 1999 – June 2004)**

➤ **Research Fellow, Gastroenterology (July 1997 – June 1999)**

- Studied molecular pharmacology of the most popular drug targets, GPCRs; utilized molecular and cell biology tools to understand ligand-receptor interactions and ligand-independent signaling.
- Collaborated with industry partner to develop constitutively active receptors to expedite hit identification for various GPCR targets including some orphan receptors.
- Led the efforts in identifying, cloning and pharmacologically characterizing the first D2-like dopamine receptor in *Drosophila*, which was used to develop an *in vivo* model for Parkinson disease.
- Trained and mentored graduate students and other post-doctoral trainees in molecular biology techniques and *in vitro* pharmacology assays.

EDUCATION:

Ph.D. in Cellular, Molecular, and Developmental Biology
Boston University Boston, Massachusetts.

B.S. in Biology
Hangzhou University, Hangzhou, Zhejiang, P.R. China

PUBLICATIONS:

1. Viglietta V., Shi F., Hu Q., **Ren Y.**, Keilty J., Wolff H., McCarthy R., Kropp J., Weber P., Soglia J., (2020) *Investigational New Drugs. March 10th*. Phase 1 study to evaluate safety, tolerability and pharmacokinetics of a novel intra-tympanic administered thiosulfate to prevent cisplatin-induced hearing loss in cancer patients.
2. Benredjem B, Gallion J, Pelletier D, Dallaire P, Charbonneau J, Cawkill D, Nagi K, Gosink M, Lukashova V, Jenkinson S, **Ren Y**, Soms C, Murat B, Van Der Westhuizen E, Le Gouill C, Lichtarge O, Schmidt A, Bouvier M, Pineyro G. (2019) *Nat Commun.* 10(1):4075. Exploring use of unsupervised clustering to associate signaling profiles of GPCR ligands to clinical response.
3. Gopalsamy A, Narayanan A, Liu S, Parikh MD, Kyne RE Jr, Fadeyi O, Tones MA, Cherry JJ, Nabhan JF, LaRosa G, Petersen DN, Menard C, Foley TL, Noell S, **Ren Y**, Loria PM, Maglich-Goodwin J, Rong H, Jones LH. (2017) *J Med Chem.* 60(7):3094-3108. Design of Potent mRNA Decapping Scavenger Enzyme (DcpS) Inhibitors with Improved Physicochemical Properties to Investigate the Mechanism of Therapeutic Benefit in Spinal Muscular Atrophy (SMA).
4. Quoyer J, Janz JM, Luo J, **Ren Y**, Armando S, Lukashova V, Benovic JL, Carlson KE, Hunt SW 3rd, Bouvier M. (2013) *PNAS.* 110(52):E5088-97. Pepducin targeting the C-X-C chemokine receptor type 4 acts as a biased agonist favoring activation of the inhibitory G protein.
5. Li G, Zhou H, Jiang Y, Keim H, Topiol SW, Poda SB, **Ren Y**, Chandrasena G, Doller D. (2011) *Bioorg Med Chem Lett.* 21(4):1236-42. Design and synthesis of 4-arylpiperidinyl amide and N-arylpiperidin-3-yl-cyclopropane carboxamide derivatives as novel melatonin receptor ligands.
6. Janz JM, **Ren Y**, et al. (2011) *J Am Chem Soc.*133(40):15878-81. Direct interaction between an allosteric agonist pepducin and the chemokine receptor CXCR4.
7. **Ren Y.**, Tchernychev B. et al. (2010) *PNAS.* 107(51):22255-22259. Discovery of a CXCR4 agonist pepducin that mobilizes bone marrow hematopoietic cells.
8. Al-Fulaij MA., **Ren Y.**, Beinborn M., Kopin A.S. (2008) *Journal of Molecular Neuroscience.* 34:211-213. Pharmacological analysis of human D1 and D2 dopamine receptor missense variants.
9. Al-Fulaij MA., **Ren Y.**, Beinborn M., Kopin A.S. (2007) *The Journal of pharmacology and experimental therapeutics* 321(1):298-307. Identification of amino acid determinants of dopamine 2 receptor synthetic agonist function.
10. Beinborn, M., **Ren, Y.**, Bläker, M., Chen, C., and Kopin, A.S. (2004) *Molecular Pharmacology.* 65:753-760. Ligand function at constitutively active receptor mutants is affected by two distinct yet interacting mechanisms.

11. **Ren, Y.**, Bläker, M., Seshadri, L, McBride, EW., Beinborn, M., and Kopin, AS.(2003) *Journal of Molecular Neuroscience*. 20:115-123 Conserved cholecystokinin receptor transmembrane domain iv amino acids confer high affinity peptide binding.
12. **Ren, Y.**, Hearn, MG., McBride, EW., Reveillaud, I., Beinborn, M., and Kopin, AS. (2002) *PNAS*. 99(22):14554-14559. A drosophila dopamine 2-like receptor: molecular characterization and identification of multiple alternatively spliced variants.
13. Bläker, M., **Ren, Y.**, Seshadri, L, McBride, EW., Beinborn, M., and Kopin, AS.(2000) *Molecular Pharmacology*. 58(2):399-406. CCK-B/Gastrin Receptor transmembrane domain mutations selectively alter synthetic agonist efficacy without affecting the activity of endogenous peptide.
14. Bläker, M., **Ren, Y.**, Gordon, MC., Hsu, JE., Beinborn, M., and Kopin, AS.(1998) *Molecular Pharmacology*. 54(5):857-863. Mutations within the cholecystokinin-b/gastrin receptor ligand 'pocket' interconvert the functions of nonpeptide agonists and antagonists.
15. Hausman, RE., **Ren, Y.**, Ruiz, JF., Shah, BH.(1998) *Biochem Soc Trans*.26(4):S312. Insulin-mediated stimulation of ChAT and c-Jun in the developing retina neurons involves PI 3-kinase.
16. Holdengreber, V., **Ren, Y.**, Ben-Shaul, Y., and Hausman, R.E.(1998) *Experimental Eye Research*. 66(3):307-313. Co-localization of the insulin receptor, jun protein and choline acetyltransferase in embryonic chick retina.
17. **Ren, Y.**, Holdengreber, V., Ben-Shaul, Y., Varanasi, J., and Hausman, R.E.(1997) *Biochemi. Biophys. Res. Commun*. 232(3):788-793. Causal Role for jun Protein in the Stimulation of Choline Acetyltransferase by Insulin in Embryonic Chick Retina.
18. Hausman, R.E., Rao, A.S.M.K., **Ren, Y.**, Sagar, G.D.V., and Shah, B.H.(1993)*Developmental Dynamics* 196:263-266. Retina Cognin, Cell Signaling, and Neuronal Differentiation in the Developing Retina.
19. Sagar, G.D.V., Krishna Rao, A.S.M., **Ren, Y.**, and Hausman, R.E.(1992)*Brain Research*.585:63 The Cell Recognition Molecule, Cognin, Mediates Choline Acetyltransferase Activity in Embryonic Chick Retina.
20. Shi, QX., Zhong, CL., Ye, Z., Yuan, YY., **Ren, Y.**, and Wang, ZJ.(1991) *Sheng Li Hsueh Pao*. 43(5): 480-488. (Chinese) Spermine inhibition of in vitro fertilizing ability of human spermatozoa and its possible mode of action.