

Contact

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Top Skills

Drug Discovery

Life Sciences

Immunology

Michael Shepard

President and CEO at Enosi Life Sciences (Enosi-Life.com)
San Diego, California, United States

Summary

A recipient of the Harvard Medical School Warren Alpert Award and the Lasker Prize for Clinical Medicine, Shepard began his career at Genentech in 1980. After several years of successfully cloning interferons and other potential therapeutics, Shepard initiated a group at Genentech with the aim of understanding mechanisms of sensitivity and resistance to various immune-based therapeutics (TNF- α , IFN- γ). This work resulted in showing that overexpression of HER2 results in resistance to cytotoxicity by TNF/macrophages, and the discovery of the MAb 4D5, which became Herceptin (Hcp), which reversed this resistance. Dr. Shepard led the teams that characterized this MAb's biologic activity, created humanized versions, and brought the antibody into clinical trials. Hcp is the first MAb effective against solid tumors to reach approval. Hcp also proved that tyrosine kinases are targets in cancer. Finally, Hcp initiated the 'era' of personalized medicine with its 'Herceptest' for overexpression of HER2. This work led to Dr. Shepard's recognition as a recipient of Harvard's Alpert Prize in 2007. With this work as background, Dr. Shepard joined Canji in 1992, and brought the first adenovirus gene therapy into clinical trials (for ovarian cancer). Dr. Shepard has founded two biotech companies. NewBiotics: Creating small molecule cancer therapeutics that target cancer targets that are overexpressed following the inactivation of tumor suppressor genes; and Receptor Biologix: Which pioneered the concept of 'pan-HER' inhibition (single drug inhibiting the EGFR, HER2, and HER3). At Halozyme, Dr. Shepard worked with other management (and partners) to obtain three European drug approvals and one US drug approval for EnhanzeTM technology for subcutaneous drug delivery. Dr. Shepard's team at Halozyme also created a platform for discovering tumor specific therapeutics, based upon the physical/chemical properties of the tumor extracellular matrix. The product candidates to emerge from this platform include tumor-specific MABs, and enzyme therapeutics

for immuno-oncology. Shepard received the Lasker Prize in Clinical Medicine in 2019 for his work on Herceptin/trastuzumab.

Experience

Enosi Life Sciences

President and CEO, Enosi-Life.com
April 2019 - Present (5 years 9 months)
San Diego, California, United States

Self-employed

Biopharma Consultant, Biologics21.Net
February 2017 - April 2019 (2 years 3 months)
San Diego, CA.

Halozyme Therapeutics, Inc.

Halozyme Research Fellow and Consultant reporting to the CSO (Mike LaBarre)
January 2015 - February 2017 (2 years 2 months)
San Diego, CA.

Report to CSO, advisory responsibilities for drug discovery and proof of concept of new molecules activated the by tumor micro-environment ; Enhanze* (medical device) for subcutaneous delivery of therapy, esp. monoclonal antibodies; Safety and pharmacology. Highly distinguished in oncology discovery and translational research.

Halozyme

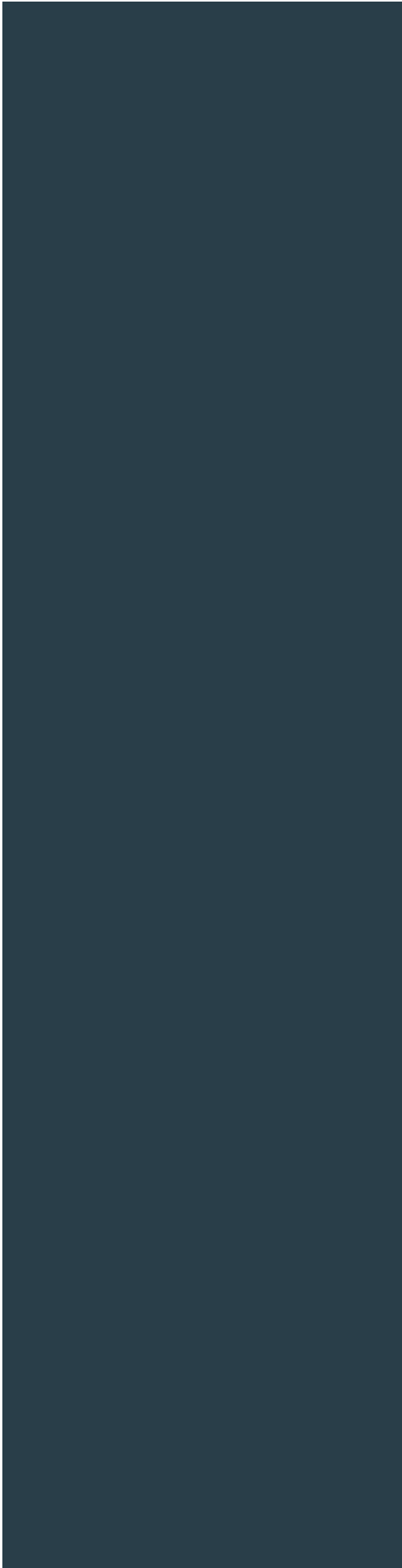
VP Research and CSO
2009 - 2015 (6 years)

Education

Indiana University Bloomington

Doctor of Philosophy (Ph.D.), Cellular and Developmental Biology and Genetics · (1973 - 1980)

University of California, Davis



Bachelor's Degree, Zoology (Cellular and Developmental
Biology) · (1967 - 1973)

Contact

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Top Skills

Pharmacology

Drug Development

In Vitro

Certifications

Nano Tips for Using Microsoft Office with Mike Tholfsen

Navigating Perfectionism as a Manager

Five Ways to Control Your Time

Nano Tips for Better Business Writing with Lorraine Lee

Business Etiquette: Meetings, Meals, and Networking Events

Publications

Cek5, a tyrosine kinase of the Eph subclass, is activated during neural retina differentiation

PH20 is not expressed in murine CNS and oligodendrocyte precursor cells.

Enzymatic depletion of tumor hyaluronan induces antitumor responses in preclinical animal models

Efficacy of a single intravesical treatment with Ad-IFN/Syn 3 is dependent on dose and urine IFN concentration obtained: implications for clinical investigation.

Identification of polyamides that enhance adenovirus-mediated gene expression in the urothelium

Patents

PH20 polypeptide variants, formulations and uses thereof

Methods and compositions for interferon therapy

Robert Connor

Principal Research Scientist at Halozyme Therapeutics, Inc.
Oceanside, California, United States

Summary

Highly motivated research scientist with extensive experience in drug development from initial concept through lead target identification, preclinical development and IND submission. Primary expertise includes developing preclinical models for multiple therapeutic areas including cancer, diabetes and fibrosis. Seeking an opportunity to leverage my extensive background in pharmacology and drug development to guide compounds through advanced preclinical testing to successful IND filing.

- Demonstrated project leadership experience developing a novel gene therapy program (adenovirus-interferon) from bench discovery to IND submission for non-muscle invasive bladder cancer (NMIBC).
- Extensive cancer animal model development in rodents (carcinogen-induced, orthotopic, syngeneic and xenograft) and PK/PD models for multiple programs (oncology, diabetes, fibrosis). Experienced with use of non-invasive imaging techniques/systems.
- Experience designing studies to identify clinically translatable parameters (e.g. dose-response, re-dosing, pre-tox tolerability, immune response characterization).
- Comprehensive in vitro skills include tissue culture, cell line generation, ELISA, SDS-PAGE, Western Blotting, FPLC purification, RNA-seq, IHC, Flow Cytometry and IF/IC.
- Successful at developing collaborative partnerships with academic institutions (MD Anderson Cancer Center Genitourinary Oncology, Univ. of Iowa) to evaluate preclinical gene therapy candidates (adenovirus-interferon) in preclinical and FIH studies.
- Excellent communication skills demonstrated by a track record of scientific accomplishments through publications, patents and presentations. Strong background in virology both in academic research (influenza) and industry (adenovirus).

AREAS OF STRENGTH:

Multi-disciplinary Drug Discovery

Tumor Immunology & Microenvironment

Animal Model Development

Design, Management, Analysis and Reporting of Nonclinical Pharmacology Studies (QA-audited)

Pharmacology Written Summaries for FDA Briefing Documents

Scientific Writing, Reporting and Presentations

Cross-department Coordination and Effective Matrix Team Member

Creativity, Troubleshooting and Critical Thinking Skills

CRO Management - Data Analysis and Quality Control

TECHNIQUES AND SKILLS:

Animal Model Development for disease indications, Animal Dosing,

In Vivo Imaging, Drug Delivery, Tissue Collection and Processing,

IHC, Microscopy, Stable Cell Line and Primary Cell Culture

Development & Optimization, Protein Isolation & Purification, DNA/

RNA Isolation & Purification, WB, ELISA.

Experience

Halozyme, Inc.

8 years

Senior Principal Scientist I

January 2024 - Present (1 year)

San Diego, California

Principal Research Scientist 2

January 2023 - Present (2 years)

San Diego, California, United States

Principal Research Scientist 1

June 2022 - Present (2 years 7 months)

San Diego, California, United States

Senior Research Scientist III

2016 - June 2022 (6 years)

San Diego, California, United States

- Used computed tomography (CT) to characterize physics of high speed/high volume subcutaneous dosing using a swine model. (Connor et al., J. Pharm. Tox Methods. 2020; 106: 106936.)

- Designed and conducted studies using human skin samples to characterize the effects of aging on dermal hyaluronan using IHC, WB and enzymatic analyses. (Connor et al., Dermatol Ther (Heidelb). 2020 10(3): 503-513).
- Designed and conducted preclinical studies in swine for alliance partners prior to FIH dosing. Prepared QA-audited technical reports included in alliance partner IND submissions.
- Lead team member for alliance partnerships with Eli Lilly,, argenx and Alexion collaborations. Team member for Bristol-Myers Squib, Roche, Janssen and AbbVie collaborations. Authored Pharmacy Manuals and Drug Administration Instructions for all FIH studies.
- Provided drug delivery scientific expertise to support BD meetings with potential partners.
- Consistent productivity highlighted by multiple publications and poster presentations at scientific conferences: 2016: PODD, 2017: CRS, 2018: WMIC, 2019: CRS, ISHAS and 2020: CRS, AAPS.

IGNYTA, Inc.

Biologist

2015 - 2016 (1 year)

San Diego, California, United States

- Utilized multiple cancer cell lines to generate MOA data and test potency of current clinical candidate RXDX-105 versus approved RTK inhibitors using cell proliferation assays and Western Blot analyses.
- Created numerous BALB/c-3T3 cell lines expressing BRAF genes with known resistance mutations for testing RXDX-105 activity.

Halozyme Therapeutics, Inc.

7 years

Senior Research Scientist II

2011 - 2014 (3 years)

San Diego, California, United States

New Molecular Entities (Discovery Research) Team Member:

- Identified next generation preservative and thermostable hyaluronidases using genetic library screening / mutagenesis approach to facilitate insulin coformulation (patent #10,865,400). Analyzed large data sets from CRO, identified lead targets and designed in vitro and in vivo assays for NME nomination.
- Expressed and purified numerous hyaluronidase enzymes in CHO-based cell lines and conducted early PK comparability and immunogenicity studies.

- Created numerous production cell lines to express recombinant proteins used for pre-clinical POC studies in tumor-bearing mouse models (e.g., ADA2, LDH, HKII).
- Purified and characterized numerous antibodies and proteins using traditional biochemical and affinity based FPLC purification methods to support preclinical studies and regulatory filings.
- Member of Institutional Animal Care and Use Committee (IACUC) from 2007-2014.

Senior Research Scientist I

2007 - 2011 (4 years)

San Diego, California, United States

Pharmacology Team Member:

- Led collaboration with UCSF (Dr. Frank McCormick's lab) that developed orthotopic liver xenograft tumor model using luciferase-based non-invasive imaging to evaluate preclinical oncolytic non-viral gene candidates delivered via hydrodynamic injection.
- Developed in-house porcine diabetes model and conducted pivotal IND-enabling PK studies evaluating ultra-fast acting insulin formulations.
- Performed pivotal IND-enabling PK studies for PEGPH20.
- Prepared multiple reports and regulatory documents for pre-clinical pharmacology sections for IND submissions (for PH20-ultrafast-acting insulin and PEGPH20 pancreatic cancer programs) and for patent submissions.

Schering Plough Biopharma Corp (formerly Canji Inc.)

Associate Principal Scientist

1997 - 2005 (8 years)

Led project team that advanced nadofaragene firadenovec (adenovirus-interferon; rAd-IFN) gene therapy program from bench discovery to IND submission and clinical evaluation for treatment of non-muscle invasive bladder cancer (NMIBC).

- Identified a novel class of polyamides that potently enhance adenoviral gene transfer to the bladder epithelium (patent #7,355,056). Identified Syn3 as most potent enhancing agent.
- Developed orthotopic bladder cancer model to evaluate adenoviral vectors for anti-tumor activity and identified rAd-IFN/Syn3 as lead development candidate for Schering-Plough.
- Designed and conducted pharmacology studies to support FIH testing of nadofaragene firadenovec (e.g., dose-response, redosing, biodistribution, immune response characterization and tolerability studies).

- Prepared preclinical pharmacological sections of regulatory documents that supported nadofaragene firadenovec IND submission.
- Initiated a collaboration with MD Anderson Genitourinary Oncology to independently evaluate the potential of this therapeutic.
- rAd-IFN program has progressed from discovery research through FIH studies, and having recently met its Phase III endpoint is now awaiting FDA approval.
- Member of Institutional Animal Care and Use Committee (IACUC) from 2001-2005.

Sanford Burnham Prebys Medical Discovery Institute

Postdoctoral Fellow

1993 - 1997 (4 years)

San Diego, California, United States

Postdoctoral fellow – Expression of EPH Kinases in the Visual System

- Characterized expression of EPH receptor tyrosine kinases and their ligands during embryonic development of the avian visual system using ISH, RT-PCR and Western Blot analysis.
- First mapping of the genomic organization of an EPH kinase (EPHB2) using chromosome walking.

Identified three novel avian EPH kinases using degenerative RT-PCR and library screening.

Education

UCLA School of Medicine

Ph.D., Biological Chemistry · (1986 - 1993)

University of California, Santa Barbara

BA, Biochemistry and Molecular Biology

Contact

www.linkedin.com/in/ge-gina-wei-b9696b3 (LinkedIn)

Top Skills

Biochemistry
Assay Development
Protein Purification

Languages

Cantonese (Professional Working)
Chinese (Native or Bilingual)
English (Native or Bilingual)

Certifications

Woman in Leadership Certificate Program
Project Management Certificate

Ge (Gina) Wei

Translational Medicine, discovery and clinical biomarkers, preclinical and discovery research, IND and NDA filings, targeted therapies, Oncology and rare diseases

San Francisco, California, United States

Summary

A seasoned drug development leader with experience in drug discovery and late-stage development, and translational research in oncology and rare diseases. Experienced in carrying drug candidates from discovery research, lead optimization to IND, clinical development to NDA. Proven record in leading translational research, biomarker discovery to support clinical trial strategy and CDx development, and FDA approval for 2 FDA approved drugs, ROZLYTREK (entrectinib, a ROS1/NTRK/ALK Inhibitor) and TRUSELTIQ (Infigratinib, an FGFR inhibitor). Experienced in leading in vitro and in vivo preclinical studies to evaluate the efficacy of drug candidates and MOAs, the combinations strategy, and MOAs of emerging resistance. Experienced in drafting documents to support IND and NDA filing. Capable to conceive, implement and guide R&D programs with excellent communications between laboratory staffs and senior management. Demonstrated success in multi-tasking and coordinating multiple projects, and consistently meeting aggressive time lines. A team player with leadership quality and cooperative spirit.

Specialties: Drug discovery, translational research, Rx/Dx co-development, precision medicine, targeted and immune therapy, small molecules and biologics, PK/PD, biomarker, clinical development, oncology and rare genetic diseases, in vivo and vitro pharmacology, biochemistry and cell biology, glycobiology

Experience

Nurix Therapeutics

Sr. Director, Translational Pharmacology and Biology

May 2022 - Present (2 years 8 months)

San Francisco, California, United States

QED Therapeutics

3 years 2 months

Sr. Director, Translational Medicine
July 2020 - May 2022 (1 year 11 months)
San Francisco Bay Area

Director, Translational Medicine
April 2019 - July 2020 (1 year 4 months)

Bristol-Myers Squibb

Sr. Principal Scientist
March 2018 - February 2019 (1 year)
Redwood City, California

Small molecular drug discovery and tumor intrinsic mechanism of immune evasion

IGNYTA/Roche

4 years 3 months

Sr Principal Scientist, Translational Research
January 2016 - March 2018 (2 years 3 months)

Lead the translational research of Entrectinib (Phase 2b), an investigational anti-cancer drug targeting various types of cancer driven by NTRK/ROS1/ALK fusions .

- Designed and lead both in vivo and in vitro preclinical studies to support patient stratification, biomarker discovery, IND/NDA filing and the clinical/ diagnostic development.
- Conducted preclinical studies to understand the MOA of treatment-emerging drug resistance through the protein array, DNA/RNA sequencing and signal pathway and biomarker analysis.
- The combination strategies found in the preclinical studies were quickly translated to the bedside to help patients in the clinical trials.
- Supervised and trained scientists and research associates.
- Initiated and managed multiple projects with academic collaborators and CROs.
- Developed assays for other discovery and IND-enable projects for pipeline development.

Principal Scientist II
January 2014 - December 2015 (2 years)
Greater San Diego Area

Lead the translational research in Entrectinib, a phase I clinical stage small molecule.

Designed and executed in vitro and in vivo studies for various stages of compounds for epigenetic targets, check-point kinases and other RTKs.

Halozyme Therapeutics, Inc.

6 years 4 months

Group Leader and Principal Scientist

January 2012 - November 2013 (1 year 11 months)

Greater San Diego Area

- Lead the New Molecular Entity (NME) group for pipeline development. NMEs included therapeutic enzymes and mAbs for skin fibrosis, drug delivery platform and oncology.
- Participated in the co-development of FDA-approved product HIQVIA with Baxter Biosciences, a subQ IgG product. Designed key studies and generated reports for BLA filing and helped to answer questions raised by FDA for final approval.
- Involved in the companion diagnostic development and setting up selection criteria to enroll patients in PEGPH20 clinical trials.
- Initiated and managed projects through academic collaborations and CROs
- Developed assays for evolution-mutagenesis library screening. Analyzed large data set from CRO. Defined the hit selection criteria, oversight hit confirmation, designed in vitro and in vivo assays for NME nomination.

Sr. Scientist II

January 2010 - December 2011 (2 years)

- I. Responsible for the functional analysis of rHuPH20, Halozyme's lead therapeutic enzyme.
- II. Lead the CHO cell line development for biologic therapeutics (enzymes and antibodies) manufacturing.
- III. Developed various assays for enzyme potency, HA quantification and high-throughput screening assays.
- IV. Represented the biology group to participate in bioanalytic development, process and product development.

Senior Scientist I

August 2007 - December 2009 (2 years 5 months)

- Responsible for designing and executing key experiments to extend two rHuPH20 patents.

- Lead CHO cell line development to express therapeutic enzymes for GMP production.
- Key member of NME group for discovery research for pipeline development.

The Burnham Institute

Staff Scientist

September 2004 - July 2007 (2 years 11 months)

Neose Technologies

Research Scientist 2

2002 - 2004 (2 years)

The Salk Institute

Postdoctoral Fellow

2000 - 2002 (2 years)

Education

UC Santa Barbara Extension

Woman in Leadership Executive Program · (2022 - 2023)

University of Alabama at Birmingham

Ph.D., Biochemistry and Molecular Genetics · (1999)

Peking University

Master's degree, Biochemistry · (1993)

Peking University

Bachelor's degree, Biochemistry · (1990)

Contact

www.linkedin.com/in/qiping-zhao-05938528 (LinkedIn)

Top Skills

Protein Characterization

AKTA

Protein Expression

Qiping Zhao

Scientist | Cell Line Development | Protein Sciences
San Diego, California, United States

Summary

Highly motivated research scientist with extensive experience in stable cell line engineering, protein production, characterization, and assay development. Highly experienced in the large scale production and purification at the multi-gram level of recombinant proteins in mammalian and bacterial expression systems. Very passionate and skilled in the development of novel biotherapeutic candidates and critical reagents to support preclinical research and bioanalysis.

Experience

Cidara Therapeutics

Scientist

March 2020 - Present (4 years 10 months)

San Diego Metropolitan Area

Protein purifications

Halozyme Therapeutics, Inc.

12 years 1 month

Research Scientist II

March 2019 - January 2020 (11 months)

Greater San Diego Area

Research Scientist I

March 2015 - March 2019 (4 years 1 month)

Greater San Diego Area

Sr. Research Associate II

March 2012 - March 2015 (3 years 1 month)

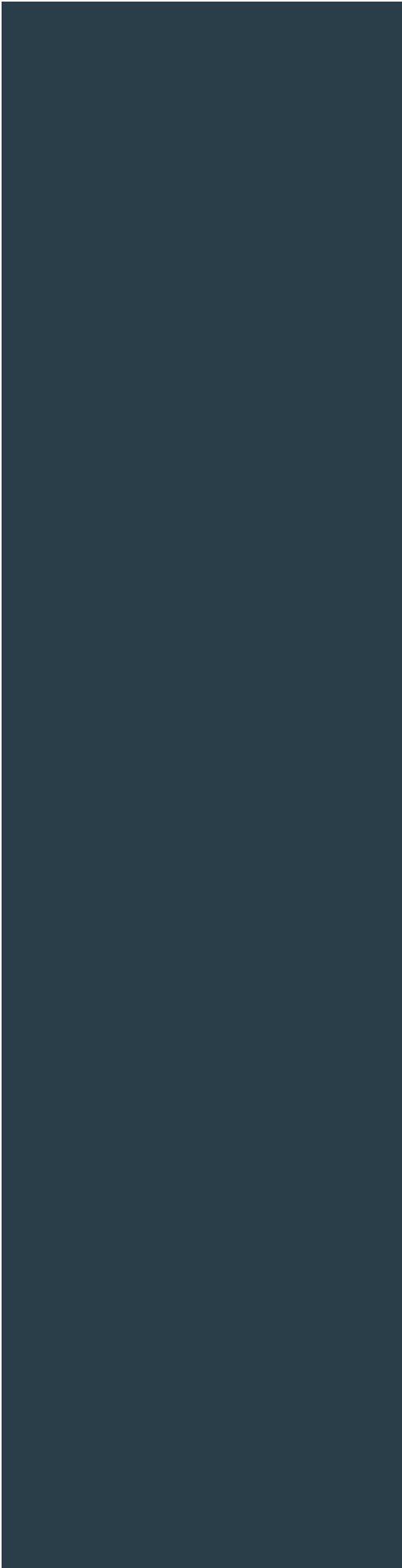
Greater San Diego Area

Sr. Research Associate I

March 2009 - March 2012 (3 years 1 month)

Greater San Diego Area

Research Associate II



January 2008 - March 2009 (1 year 3 months)
Greater San Diego Area
