



Keystone Associates

Resume Portfolio

*Former AVEO Oncology Employees
November 2012*

*Debra M. Noschese
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TABLE OF CONTENTS

Research

Rowena de Jesus, **Senior Research Associate**, Drug Discovery

Andrea Delpero, **Senior Research Associate**

Nanhua Deng, **Associate Scientist**, In Vivo and In Vitro Pharmacology

Samuel Farlow, **Associate Scientist**, Genetic Models and Cancer Biology

Christina Fleet, **Associate Scientist**, Antibody Engineering

Sara Haserlat, **Associate Scientist**, Antibody Engineering

Lu Huang, **Associate Scientist**, Translational Research

Sule Karaman, PhD, **Scientist**, Experimental Toxicology

James Levasseur, **Research Associate I**

Eric Lim, PhD, **Computational Biologist**

Kristan Meetze, PhD, **Associate Director**, Drug Discovery Pharmacology & Preclinical Development

Laura Poling, PhD, **Scientist II**, Drug Discovery

Darren Potz, **Associate Scientist**, In Vivo Pharmacology

Hamid Tissire, **Senior Research Associate**, Antibody Engineering

Arnold Sengooba, **Research Associate II**

Robert Shine, **Research Associate II**, Cancer Biology Model Development Group

Wei Yin, PhD, **Associate Director**, Clinical Pharmacology

Jianhua Zhao, **Senior Research Associate**

Quality Assurance

Kelly Donahue, **Manager**, GMP Quality Assurance

Cynthia McDonough, **Associate Director**, Quality Systems

Other

Tom Meglio, **Research Services Specialist III**, Animal Care

Lauren Nichols, **Senior Technical Services Coordinator**

Leah Persico, **Coordinator**, Investigational Supply Operations

ROWENA M. DE JESUS

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SUMMARY

Senior research associate with extensive experience in molecular biology and biomedical research garnered from academia and the pharmaceutical industry. Proven ability to build upon and refine existing knowledge and technical expertise. Highly-detail oriented with strong communication skills. Core competencies:

- *Technical expertise:* Contributed to validate and characterize novel anti-cancer therapeutics that led to an exclusive licensing partnership of lead drug candidate with another pharmaceutical company.
- *Collaboration/Team-work:* Collaboration with scientists, biochemists, *in vivo* pharmacologists, and bioinformaticians to define translational biomarker signatures.
- *Leadership:* Organized and facilitated trainings with field application specialists to advance the company's drug discovery pipeline gene expression profiling capabilities.

Molecular Biology:

- Extensive experience in molecular biology techniques encompassing DNA, RNA, and protein isolation and down-stream process manipulation through western and southern blotting, biochemical, immunological, and multiplex and signal transduction assays.
- Application of VectorNTI for site directed mutagenesis, PCR, RT-PCR, and molecular cloning of *cynomologous* gene of interest for *in vitro* functional toxicology studies.
- Gene expression profiling using multiple platforms and bioinformatics for biomarker hypothesis testing, modeling, and refinement.

Cell Biology:

- Mammalian cell culture maintenance, propagation, transfection, stable cell line generation, and small-scale antibody production.
- Functional cell based assays, FACS, cell cycle, immunofluorescence, and light and confocal microscopy.

EXPERIENCE

AVEO ONCOLOGY, Cambridge, MA

01/2011-10/2012

Pharmaceutical company specialized in novel anti-cancer therapeutics.

Senior Research Associate, Drug Discovery

Participated in pre-clinical development activities of novel anti-cancer antibody therapeutics targeted against receptor tyrosine kinases:

- Performed *in vitro* functional cell based assays, biochemical assays, signal transduction assays, and molecular biology techniques for target validation, target characterization, and down-stream target modulation.
- Conducted gene expression profiling and bioinformatics studies to support translational program activities and define biomarker gene signatures of drug resistance or response.
- Facilitated and organized training seminars for new technologies to advance drug discovery pipeline activities.
- Developed and optimized assays for samples derived from tumors and serum, expanding program molecular detection capabilities.
- Provided logistical support to collaborations with other pharmaceutical companies resulting in streamlined efficiency of *in vitro* and *in vivo* studies.

TUFTS UNIVERSITY SCHOOL OF MEDICINE, Boston, MA

2002-2011

Senior Research Technician, Department of Biochemistry (2004-2011)

- Authored a manuscript describing the use of transiently transfected mammalian cells to examine the role of viral DNA replication, DNA damage, and the implication on host cell cycle.
- Managed various lab functions, including inventory tracking, ordering and price negotiation, training of graduate students and new-hires, and scientific troubleshooting, minimizing operation downtime significantly.

Research Technician (2002-2004)

- Investigated the role of polyomavirus in mammalian cell growth, signal transduction, and host cell transformation to elucidate mechanisms in molecular oncology.
- Delineated mechanisms by which a viral oncogene perturbs host cell signaling pathways, with an emphasis on transcriptional regulation resulting in second author publications.

GRASSROOT SOCCER, INC., Port Elizabeth, South Africa

Summer 2009

Registered 501(c)3 charitable organization that uses the power of soccer to educate, inspire, and mobilize communities to stop the spread of HIV.

Grassroot Soccer Monitoring and Evaluation Intern

- Designed and implemented an evaluation of a ‘Skillz’ Tournament, provided technical and logistical support to site staff, and presented recommendations based on study findings to improve efficiency and increase uptake of HIV voluntary counseling and testing.

NUTRO PRODUCTS, City of Industry, CA

2001-2002

Leader in natural pet food established in 1926.

Research and Development Analyst, R&D Department

- Performed standard industry techniques to ensure high levels of quality assurance in pet food production, gaining experience on various instruments including Near Infrared Scan Instrument, Oxidative Stability Instrument, and Rancimat.

EDUCATION

TUFTS UNIVERSITY SCHOOL OF MEDICINE, Boston, MA (2010)

Master of Public Health

Thesis: Evaluation of Grassroot Soccer ‘Skillz’ Tournament, Port Elizabeth, South Africa.

UNIVERSITY OF CALIFORNIA, LOS ANGELES, Los Angeles, CA (2001)

Bachelor of Science, Microbiology and Molecular Genetics

Executive Board Member, Student Welfare Commission (1999-2001)

Event Planning and Outreach, Children’s Walk for Life (1999-2001)

HONORS AND AWARDS

- **SPOT Award**, AVEO Oncology Inc. (2012)
Recognized for advancing gene expression profiling capabilities with ABI Vii7 instrument maintenance and training of new users.
- **Tufts PHPD Student Activity Fund Award**, Tufts University School of Medicine (2009)
- **Tufts International Travel Scholarship**, Tufts University School of Medicine (2009)
- **Tufts Conference Award: International Aids Society Conference**, Cape Town, South Africa (2009)
- **Nutro Products Certificate of Excellence Award**, Nutro Products Inc. (2002)
- **Chancellor’s Service Award**, UCLA (2001)

TEACHING EXPERIENCE

- Summer Intern Mentor, **AVEO Oncology** (2011-2012)
- Applied Learning Experience Seminar Lecturer, **Tufts University** (2010)
- Forrest Yoga Instructor, **YMCA/ROYOGA** (2008-Present)
- Citizen School Teacher, “**WOW Apprenticeship**” **Citizen School** (2004)

PRESENTATIONS

- Drug Discovery Meeting, **AVEO Oncology**, Cambridge, MA (2011-2012)
- Poster Session, **AVEO Oncology**, Cambridge, MA (2012)
- Jaharis Signal Transduction Meeting, **Tufts University**, Boston, MA (2007-2011)
- Abstract, **International Association for Physicians in AIDS Care**, New Orleans, LA (2009)
- International AIDS Society Summary Meeting, **Grassroot Soccer Inc.**, Cape Town, South Africa (2009)

SKILLS AND TECHNIQUES

Molecular Biology

- DNA/RNA/Protein isolation
- PCR, Q-PCR, RT-PCR
- DNA Replication Assays
- Gel Electrophoresis
- SDS-PAGE/Western Blot
- Molecular Cloning
- Site directed mutagenesis
- Transfection
- RTK and Intracellular Signaling Arrays
- ELISA
- TAQMAN
- Affymetrix

Functional cell based assays

- Proliferation assays- CTG, MTT, BrdU
- MSD Assays
- Signal Transduction
- Luciferase Assays

Cell Biology

- Flow Cytometry
- Light, fluorescence and confocal microscopy
- Immunofluorescence
- Mammalian Cell Culture

Biochemical

- Immunoprecipitation
- Ligand neutralization
- Tandem Affinity Purification

Software

- Microsoft Office
- GraphPad Prism 5
- EXPRESSO
- ExpressionSuite (ABI)
- ImageStudio (LICOR)
- SPSS
- Vector NTI

PEER-REVIEWED PUBLICATIONS AND ABSTRACTS

1. **de Jesus R** and Schaffhausen B, Polyomavirus Large T (LT) and cell cycle arrest. (In preparation)
2. Banerjee P, **de Jesus R**, Gjoerup OV, Schaffhausen B. Viral Interference with DNA Repair by Targeting of the Single-Stranded DNA Binding Protein RPA. (In preparation)
3. **Rowena de Jesus**. Skillz Tournaments: A Novel Approach to Increase Voluntary Counseling and Testing Access and Uptake among Youth, Port Elizabeth, South Africa. International Association for Physicians in AIDS Care, New Orleans LA (**Abstract**)
4. Whalen KA, **de Jesus R**, Kean JA, Schaffhausen BS. Genetic analysis of the polyomavirus DnaJ domain. J Virol. 2005 Aug;79(15):9982-90
5. Love TM, **de Jesus R**, Kean JA, Sheng Q, Leger A, Schaffhausen B. Activation of CREB/ATF Sites by Polyomavirus Large T Antigen. J. Virol. 2005 Apr;79(7):4180-9

Andrea R. Delpero (Boudrow)

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Adelpero130@gmail.com 978-979-1793
www.linkedin.com/in/andreadelpero

Summary

Determined, intelligent, independent and hardworking researcher with over 9 years of experience in histology, in vivo pharmacology, cell culture and cell-based assay experience within the pharmaceutical industry. Known for excellent time management, communication and trouble shooting skills, true team player, and ability to work well in fast-paced high pressure environment.

Related Experience

Aveo Oncology

Senior Research Associate

Cambridge, MA

2008-2012

- Development of many tumor models in mice, including standard subcutaneous xenografts, orthotopic models including lung, brain bone and colon models, as well as primary human tumor models that were utilized by multiple project teams across the organization.
- Served as in vivo pharmacology team representative for internal antibody-therapy project team which included contributing to lead antibody selection, characterization of lead antibody, as well as biomarker hypothesis evaluation, which contributed to the successful partnering of the program.
- Led pharmacological characterization of lead antibody through multiple dose response efficacy studies, PD studies in multiple settings, full PK characteristics, and over 25 efficacy studies to evaluate biomarker hypothesis to prepare for nomination of the antibody as a development candidate.
- Explored the role of this target in metastasis through efficacy studies using orthotopic models which utilized luminescent imaging via the IVIS Imaging System 200 Series, as well as X-Ray and Bone Density Analysis via the Kodak Digital X-Ray DXS 4000 for quantification of tumor mass and bone destruction.
- Performed PD analysis of studies by multiple means including Western Blot, IHC, and RTK Arrays
- Lead researcher for histology with the drug discovery pharmacology group. Processed, embedded, sectioned, stained, and analyzed samples via Aperio Scanscope XT as well as constructed tumor microarrays across all antibody programs relating to PD and efficacy study analyses.
- Developed multiple immunohistochemical stains for specific projects/targets, one being a critical assay to evaluate the target in clinical samples, resulting in an internal company recognition award.
- Independently prepare study protocols and reports, data analysis, preparation of posters for scientific conferences as well as presentations for internal company meetings.
- Received the maximum amount of recognition awards for providing exceptional research and service.

SmartCells, Inc.

Research Associate II

- In charge of *in vivo* PK/PD experiments and data analysis
- Euglycemic and hyperglycemic clamps in normal and diabetic rats
- IV, SC, IP injections and small surgery in rat models

**Beverly, MA
2007-2008**

Shire HGT (Formerly TKT)

Research Specialist

- Lab animal husbandry , handling, breeding, and colony management
- IV, IP, SC and IBM injections in mice and cannulated rats
- Gavaging, orbital bleeds, and peritoneal and lung lavaging
- PCR genotyping (ear, tail, blood), gel electrophoresis
- DAPI, DMB, Creatinine, BCA , ELISA, IgM, IgG assays
- Gamma counting & dosing with (¹²⁵I Isotope)
- Quantification of Glycolipids by HPLC analysis (tissue & urine)

Histology work:

- Necropsy, Trim, embed, and cut tissue samples
- H&E, Alcian Blue, DAB, multiple fluorescence staining
- Lamp-1, Luxol Fast Blue, Histochem staining
- Cryostat embedding, cutting, and staining

**Cambridge, MA
2003-2007**

Other

Mystic Aquarium and Institute for Exploration

Assistant Aquarist/Trainer for California Sea Lions

**Mystic, CT
Summer 2004**

Animal Clinic of Lynnfield

***Volunteer Vet Technician* (130+ hours)**

**Lynnfield, MA
2003-2004**

New England Aquarium

***Intern: Rescue and Rehab Husbandry* (600+ hours)**

**Boston, MA
2002-2003**

National Marine Fisheries Service

***Volunteer Scientist* (192 Hours)**

**Cape Cod, MA
Summer 2001**

Education

Roger Williams University

- B.S. Marine Biology
- Minors: Environmental Chemistry and Dance
- Dean's List

**Bristol, RI
1999-2003**

Additional Courses:

- Harvard Extension School (Biochemistry)
- Charles River Laboratories 20th Annual Short Course
- Aperio University Short Course

**Cambridge, MA
Newton, MA
San Diego, CA**

Andrea R. Delpero (Boudrow)

Publications/Posters

Meetze K, Tyler S, Clark K, Mazsa E, **Delpero A**, Gyuris J, Vincent S. The anti-tumor Activity of the ERBB3 Inhibitory Antibody AV-203 in Patient Derived Tumor Explant Models. Molecular Targets and Cancer Therapeutics. Proceedings of the International Conference AACR-NCI-EORTC, 2012.

Connolly K, Meetze K, **Boudrow A**, Gyuris J, Han M. The effects of combination of ficlatuzumab with anti-VEGF inhibitors in glioblastoma xenografts. Society for Neuro-oncology, 2012.

Han M, Whalen K, Gifford J, **Boudrow A**, Meetze K, Liu Q, Chen T, Winston W, Weiler S, Gyuris J. Antitumor Activity of Anti-RON Antibodies and Biomarker of Response

Meetze K, **Boudrow A**, Connolly K, Huang R, Rideout, III, Gyuris J, Han M. Anti-tumor activity of SCH 900105 (AV299), an anti-HGF antibody, in non-small cell lung cancer models *Mol Cancer Ther* 2009; 8(12 Suppl):C173

Meetze K, Connolly K, **Boudrow A**, Venkataraman S, Medicherla S, Gyuris J, Han M. Preclinical efficacy and pharmacodynamics of SCH 900105 (AV-299) an anti-HGF antibody in an intracranial glioblastoma model *Mol Cancer Ther* 2009;8(12 Suppl):C181

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SUMMARY

Seeking a research position in vivo and in vitro pharmacology. Extensive experience in the oncology and metabolic disease field, including in-vivo test oncology and diabetic agents using tumor and metabolic models, model development, target identification, validation and downstream drug development. Broad skill set encompassing in vivo pharmacology and cellular, molecular, in-vitro pharmacological and animal modeling techniques. Proven ability to work effectively in individual and team settings.

SKILL & EXPERTISE

IN-VIVO PHARMACOLOGY

Necropsy, animal handling, blood collection, surgery, I.C.V., I.P., I.V., S.C., Gavage drug administrations, brain microinjection, chronic and continuous drug delivery to discrete brain regions or subcutaneous by osmotic minipump, rodent PK and PD study, pathology study (in-situ hybridization), animal physiology, NMR test, Oxymax test, loco-motor test, Xenogen imaging scan, DEXA scan, thermoimaging test, ECG test, GTT, ITT, tumor measurement, body weight and food intake test, genotype and phenotype analysis on transgenic and KO/Tg mice, blood chemistry bio-marker study, dose-response measurement.

IMMUNOHISTOCHEMISTRY

Standard histology procedures, including tissue processing, embedding, sectioning, special staining. IHC optimization, using automachine Leica or Biocompare for IHC, Aperio scan analysis.

CELL BIOLOGY

Cell base luciferase receptor assay, Mammalian cell cultures and isolation of pericytes, endothelia cells, and T cells, transient and stable transfection, cell proliferation and migration assays, flpr (Ca⁺⁺ channel) assay, ligand and receptor binding assay, function assay such as cAMP, GTP^γS, Adenoviral and lentiviral expression assay, FACS.

MOLECULAR BIOLOGY

DNA and RNA purification, DNA cloning, construct different cDNA, and genomic library, the library screening, construct G-Protein couple receptor bias, subtraction libraries, mutagenesis, RT-qPCR, real time PCR, gene expression via transient and stable cell lines, maintain ES cell line. knock in/out targeting construct design and generation, Northern, Southern blot, in-situ hybridization, RNAi technique. Genomic DNA/RNA array, protein RTK array.

PROTEIN BIOCHEMISTRY & IMMUNOLOGY

Antibody development and characterization, tissue lysate, ELISA, Western blot, protein purification, immunocytochemistry and IP assay, protein kinase/phosphatase assay, and enzyme kinetics studies

EXPERIENCE

2008-2012 Aveo Pharmaceuticals, Cambridge, MA

Translational Research Department (In-Vivo /Cancer Biology Group)

Associate Scientist

- Generation of oncology mouse xenograft model and inducible reconstituted human in mouse mammary tumor models, resulting in successful support of oncology drug testing such as TIVO and AVE299 study
- Performed oncology targets validation, including in-vitro molecular cell biology assay, in-vivo test, and IHC/perform oncology biomarker assay (including protein array, gDNA array, cDNA array)
- Performed in vivo oncology pharmacology PK/PD study at late stage such as TIVO and AV299
- Provided cross-functional support for in vivo pharmacology, bioanalytical metabolism and in vivo imaging on the drug repositioning platform.
- Internal and external coordinator for certain aspects of human primary tumor and human in mouse tumor archive

2006-2008 Wyeth Pharmaceuticals, Cambridge, MA

CVMD Department (Cardiovascular and Metabolic Disease Department) In-Vivo Group

Research Scientist II

- Performed in-vitro assay and in-vivo test, PK/PD studies resulting in new drug discovery
- Worked on novel targets and functional assays for metabolic and cardiovascular target validation
- Worked on KO mice for phenotyping analysis
- Worked on novel drug targets– using specially diabetic disease related, induced KO animal models

2003-2006 Novartis Institute for Biomedical Research, Cambridge, MA

Functional Genomic and Proteomics Department, Target Biomarker Discovery Unit

Research Scientist II

- Worked on a GPCR and its ligand for metabolic / cardiovascular target validation
- Identification and expression cloning of a set of human kinases for cell-based assay screen
- Established of cell-based assays for high-throughput screen (PGC-1, AP-1, Agg-1 promoter study)
- Optimized of Lenti-viral shRNA production for HTS in cell base assays.

1993-2003 Millennium Pharmaceuticals, Cambridge, MA

Metabolic Disease Biology Department

RESEARCH ASSOCIATE, SENIOR RESEARCH ASSOCIATE AND RESEARCH INVESTIGATOR

- In vivo pharmacology support for multiple post-HTS drug discovery projects
- Identification and expression cloning of leptin receptor and UCP2, LGR6 and PKD genes
- Identification and cloning of hypothalamic, heart and adipose G-protein coupled receptors
- Assay configuration of GPCRs, OBR, and kinases for high-throughput screening
- Constructing, genotyping, and phenotyping of GPCR KO and transgenic mice

EDUCATION

MASTER OF SCIENCE (M.S.) IN BIOCHEMISTRY

Pharmacy School, Northeastern University, Boston, MA

Doctor of Medicine (M.D.)

Nanjing Medical College, Nanjing, China

AWARDS

2010-2012	Aveo Animal Model Award (2 Times), Thanks Award (8 Times), Sport Achievement Award (2 Times)
2007	Wyeth Drug Development Achievement Award
2001-2002	Millennium Star Award
1994-2002	Millennium Success Share Plan
1996	Special Millennium Thanks Award for Cloning the OB-Receptor
1995	Nothing is Impossible Millennium Star Award

PUBLICATIONS

1. Valerie Clerin, Heather H. Shih, **Nanhua Deng**, Gustave Hebert, Christine Resmini., Kathleen M. Shields. Expression of the cysteine protease legumain in vascular lesions and functional implications in atherogenesis. [Journal Article] *Atherosclerosis* DOI: 10.1016/j.atherosclerosis.2008.01.016
2. Geng L. Segal Y. Peissel B. **Deng N.** Pei Y. Carone F. Rennke HG. Glucksmann-Kuis AM. Schneider MC. Ericsson M. Reeders ST. Zhou J. Identification and localization of polycystin, the PKD gene product. [Journal Article] *Journal of Clinical Investigation*. 98(12):2674-82, 1996 Dec 15. UI: 97136509
3. Tartaglia LA. Dembski M. Weng X. **Deng N.** Culpepper J. Devos R. Richards GJ. Campfield LA. Clark FT. Deeds J. et al. Identification and expression cloning of a leptin receptor, OB-R. [Journal Article] *Cell*. 83(7):1263-71, 1995 Dec 29. UI: 96128129
4. Gu W. Tu Z. Kleyen PW. Kissebah A. Duprat L. Lee J. Chin W. Maruti S. **Deng N.** Fisher SL. Franco LS. Burn P. Yagaloff KA. Nathan J. Heymsfield S. Albu J. Pi-Sunyer FX. Allison DB. Identification and functional analysis of novel human melanocortin-4 receptor variants. [Journal Article] *Diabetes*. 48(3):635-9, 1999 Mar. UI: 99176454
5. Gimeno RE. Dembski M. Weng X. **Deng N.** Shyjan AW. Gimeno CJ. Iris F. Ellis SJ. Woolf EA. Tartaglia LA. Cloning and characterization of an uncoupling protein homolog: a potential molecular mediator of human thermogenesis. [Journal Article] *Diabetes*. 46(5):900-6, 1997 May. UI: 97278985
6. MEDLINE Filderman AE. Bruckner A. Kacinski BM. **Deng N.** Remold HG. Macrophage colony-stimulating factor (CSF-1) enhances invasiveness in CSF-1 receptor-positive carcinoma cell lines. [Journal Article] *Cancer Research*. 52(13):3661-6, 1992 Jul 1. UI: 92315208

SAMUEL J. FARLOW

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PROFILE

Innovative bench scientist with extensive *in vitro* and mouse *in vivo* research experience. Expertise in experimental design, assay development, troubleshooting, and result interpretation developed during employment in both academic and pharmaceutical institutions. Exceptional ability to identify and adapt protocols and methods from scientific literature for current research. Recent work at AVEO Oncology included novel approach and invention of unique process to create mouse models of hepatocellular carcinoma (HCC).

QUALIFICATIONS

- *In Vivo* Pharmacology
- Translational Research
- Mouse Models of HCC via Intrasplenic Injection
- Mouse Models of Breast Cancer via Mammary Fat Pad Clearing and Injection
- Mouse Anesthesia and Survival Surgery
- Mammalian Cell Culture
- Human and Mouse ES Cell Culture
- Virus Production (BL2+, Lentivirus, Retrovirus, Adenovirus, and AAV)
- Cancer Biology
- Drug Discovery
- PO, SC, IP, IM, and IV Injections and Dosing
- Harvest and Propagation of Primary Tumors in Mice For Use in Drug Studies
- Breeding Colony Husbandry and Maintenance
- Primary Cell Isolation and Culture
- Molecular Biology, Protein Biochemistry
- Viral Transduction of Primary Mouse and Human Cells

EXPERIENCE

AVEO ONCOLOGY, Cambridge, MA

2006-2012

Associate Scientist, Genetic Models and Cancer Biology (2009-2012)

Senior Research Associate, Genetic Models and Cancer Biology (2006-2009)

- Invented unique process to generate human HCC tumors in mice using primary human hepatocytes.
 - Assisted in writing and submission of U.S. Provisional Patent Application Serial No. 61/661,030 relating to mouse models of human hepatocellular carcinoma (not yet published).
- Identified, adapted, and implemented tissue reconstitution protocols and methods for hepatocellular and breast carcinoma mouse tumor models.
- Utilized mouse tumor models to support and confirm translational research hypotheses and drug discovery/development.
- Designed and conducted preclinical cancer biology studies, analyzed and interpreted results.
- Established, characterized, and maintained tumor archives that were included in \$25M research collaboration with OSI Pharmaceuticals.
 - Wrote methods for HCC model and trained OSI researchers as part of technology transfer.
 - Generated and delivered over 50 HCC archived tumor lines.
- Genetically engineered mouse ES cell lines utilized in chimeric mouse tumor models as part of AVEO's Human Response Platform.
- Interacted and collaborated extensively with other groups within the company, provided training and guidance on various methods and lab equipment.
- Trained and supervised summer interns with independent and collaborative projects.
- Trained animal care staff on survival surgery, tissue and tumor harvest, cancer model health monitoring, and breeding colony protocols.
- Wrote and submitted abstracts of completed research for scientific conferences.
 - Analyzed and evaluated data to validate hypotheses for poster submissions.
- Instituted safety policies and ensured compliance as Safety Committee Chair, Institutional Biosafety Committee Chair, and Biosafety Officer.

HARVARD MEDICAL SCHOOL,BETH ISRAEL DEACONESS MEDICAL CENTER, Boston, MA

1999-2006

Senior Research Associate, Department of Radiology, Laboratory of Dr. Takeshi Sano

- Developed novel viral-based gene transfer technologies for gene therapy of cancer and IBD, focusing on targeted transgene delivery and increased transduction efficiency.
 - Wrote proposals and secured grant funding from NIH.
 - Published findings in the journal BMC Biotechnology.
- Developed virus-nanoparticle conjugate technologies for MRI monitoring of transduction sites.
- Designed and characterized a streptavidin-peptide fusion protein with tumor targeting and anti-tumor properties, published findings in the journal FEBS Letters.

UNIVERSITY OF CALIFORNIA, San Diego, CA

1993-1999

Research Associate, Department of Cellular and Molecular Medicine and HHMI, Laboratory of Dr. Lawrence Goldstein

- Designed and subcloned constructs for bacterial expression of kinesin microtubule-dependent motor proteins.
- Purified and analyzed expressed proteins utilized in X-ray crystallography and single-molecule fluorescence polarization microscopy studies.
- Identified and characterized novel kinesin proteins, published findings in the journals Protein Science and The Journal of Cell Biology.

UNIVERSITY OF MINNESOTA, Minneapolis, MN

1991-1993

Laboratory Technician, Department of Cell Biology and Neuroanatomy, Laboratory of Dr. Mary Porter

- Identified and cloned eight genes encoding axonemal dynein microtubule-dependent motor proteins in the unicellular flagellar algae *Chlamydomonas*, published findings in the journal Genetics.

E D U C A T I O N**B.S.**, Biology, UNIVERSITY OF MINNESOTA, Minneapolis, MN**P U B L I S H E D A R T I C L E S**

- **SJ Farlow**, A Jerusalmi, T Sano. (2007) Enhanced transduction of colonic cell lines in vitro and the inflamed colon in mice by viral vectors, derived from adeno-associated virus serotype 2, using virus-microbead conjugates bearing lectin. *BMC Biotechnol.* 2007 Nov 28; 7:83.
- **Farlow SJ**, RJ Wang, MW Pandori, T Sano. (2002) A chimera of a gelatinase inhibitor peptide with streptavidin as a bifunctional tumor targeting reagent. *FEBS Lett.* 2002 Apr 10; 516(1-3):197-200.
- R Sakowicz, **S Farlow**, LS Goldstein. (1999) Cloning and expression of kinesins from the thermophilic fungus *Thermomyces lanuginosus*. *Protein Sci.* 1999 Dec; 8(12):2705-10.
- JR Marszalek, JA Weiner, **SJ Farlow**, J Chun, LS Goldstein. (1999) Novel dendritic kinesin sorting identified by different process targeting of two related kinesins: KIF21A and KIF21B. *J Cell Biol.* 1999 May 3; 145(3):469-79.
- ME Porter, JA Knott, SH Myster, **SJ Farlow**. (1996) The dynein gene family in *Chlamydomonas reinhardtii*. *Genetics.* 1996 Oct; 144(2):569-85.

P U B L I S H E D A B S T R A C T S

- **SJ Farlow**, D Potz, T Zi, X Sun, J Lin, I Chiu, M Robinson, J Heyer, Y Zhou. (2009) Variation in Response to Triple VEGFR Inhibitor Tivozanib in Mouse Models of Hepatocellular Carcinoma. 2009 AACR-EORTC-NCI Molecular Targets and Cancer Therapeutics, Boston, MA.

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- Y Zhou, **SJ Farlow**, T Zi, K Jesmer, D Potz, A Bressel, I Chiu, M Robinson, J Heyer. (2009) Mouse Models of Hepatocellular Carcinoma Exhibit Features of VEGF-Driven Angiogenesis. 100th AACR Annual Meeting, Denver, CO.
 - **SJ Farlow**, Y Zhou, A Bressel, T Zi, Q Xiao, A Cooper, J Brodeur, W Rideout, L Lerner, K Kannan , M Bosenberg, I Chiu, S Clark, M Robinson, Joerg Heyer. (2008) In-Vivo Characterization of Pathways Implicated in Lung and Breast Cancer Using Chimera Based Tumor Models. Gordon Research Conference - Cancer Models and Mechanisms, Smithfield, RI.
 - **SJ Farlow**, Y Zhou, A Bressel, T Zi, Q Xiao, A Cooper, J Brodeur, W Rideout, L Lerner, K Kannan , M Bosenberg, I Chiu, S Clark, M Robinson, Joerg Heyer. (2008) In-Vivo Characterization of Pathways Implicated in Lung and Breast Cancer Using Chimera Based Tumor Models. CSHL Meeting - Mechanisms & Models of Cancer, Cold Spring Harbor, NY.
 - A Jerusalmi, **SJ Farlow**, T Sano. (2006) Colon-directed delivery of viral vectors using virus-microbead conjugates for gene therapy of inflammatory bowel disease. 2006 Annual Meeting, American Society of Gene Therapy, Baltimore, MD.
 - A Jerusalmi, MW Pandori, **SJ Farlow**, Y Watanapokisin, T Sano. (2005) Colon-directed delivery of viral vectors using virus-microbead conjugates for gene therapy of inflammatory bowel disease (IBD). 3rd Annual Broad Medical Research Program Investigator Meeting, Los Angeles, CA.
 - **SJ Farlow**, MW Pandori, T Sano. (2004) AAV-microbead conjugates for the enhanced delivery of AAV-based vectors. 2004 Annual Meeting, American Society of Gene Therapy, Minneapolis, MN.
 - R Sakowicz, **SJ Farlow**, LS Goldstein. (1996) Cloning, expression and purification of kinesin superfamily members from the thermophilic fungus *Thermomyces lanuginosis*. 1996 Annual Meeting, The American Society for Cell Biology, San Francisco, CA.

C H R I S T I N A M . F L E E T

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S U M M A R Y

Research scientist with experience in early stage drug discovery in antibody therapeutics with a proven ability to work independently in multiple scientific disciplines including: neuroscience, gene therapy, and oncology. Versatile skill set with expertise in tissue culture, molecular biology, immunohistochemistry, and multiplex assays.

T E C H N I C A L E X P E R I E N C E

- **Molecular Biology** – plasmid purification, cloning, PCR, northern and southern blot, western blot, immunoprecipitation, in vitro kinase assays, sequencing, RNA/DNA/Protein isolation from tissue and cells lines, and FACS
- **Tissue Culture** – transfection, siRNA technology, cell motility assays, cell growth assays, primary cell isolation, viral packaging, and cell infection
- **Multiplex Assays** – multiplex ELISA (MSD), ELISA, and RTK arrays
- **Immunohistochemistry/FFPE** – tissue embedding, sectioning, staining, protocol development, and Aperio
- **RNA in-situ** – RNAscope analysis on FFPE tissue

W O R K E X P E R I E N C E

AVEO PHARMACEUTICALS, Cambridge, MA 2005-2012

Associate Scientist, Drug Discovery (2007-2012)

- Participated in the development of new antibody drug candidate, as a member of a Drug Discovery team responsible for initial proof of concept, screening, and characterization; culminating in a successful IND filing and initiation of phase I clinical trial. Advance antibody study with translational and biomarker efforts to help guide clinical development.

Senior Research Associate, Molecular Technologies (2005-2007)

- Supported multiple projects as a member of the molecular technology team. Employed cloning, siRNA development, lentiviral production, and cell line development to facilitate in-house screening platforms.

BRIGHAM AND WOMENS HOSPITAL, Boston, MA 2003-2005

Senior Research Associate, Karen Cichowski, Division of Genetics

- Studied the function and regulation of the tumor suppressor NF1, a RAS GTPase activating protein. Focused on cloning the 327kDa protein into an expression vector.
- Created ErbB3 expressing cell lines to study gefitinib sensitivity in NSCLC.

GENETIX PHARMACEUTICALS, Cambridge, MA 1999-2003

Senior Research Associate, Robert Pawliuk

- Designed and produced lentiviral vectors for gene delivery to explore gene therapy as a potential treatment for Rheumatoid Arthritis and Sickle Cell Anemia.

MASSACHUSETTS GENERAL HOSPITAL, Charlestown, MA 1991-1994

Laboratory Technologist, Katherine Sims, DNA Diagnostic Lab (1994-1999)

- Performed clinical diagnostic testing for various disease gene mutations.

Laboratory Technologist, Xandra Breakfield, Molecular Neurogenetics (1991-1994)

- In charge of carrying out the majority of tissue culture experiments in a gene therapy laboratory as well as maintaining the day to day organization of the tissue culture room.

E D U C A T I O N

B.A., Biology, SAINT ANSELM COLLEGE, Goffstown, NH

P U B L I C A T I O N S

- Wu M, Jung L, Cooper AB, **Fleet C**, Chen L, Breault L, Clark K, Cai Z, Vincent S, Bottega S, Shen Q, Richardson A, Bosenburg M, Naber SP, DePinho RA, Kuperwasser C, Robinson MO. Dissecting genetic requirements of human breast tumorigenesis in a tissue transgenic model of human breast cancer in mice. *Proc Natl Acad Sci U S A*. 2009 Apr 28;106(17):7022-7. Epub 2009 Apr 15.
- Engelman JA, Janne PA, Mermel C, Pearlberg J, Mukohara T, **Fleet C**, Cichowski K, Johnson BE, Cantley LC. ErbB-3 mediates phosphoinositide 3-kinase activity in gefitinib-sensitive non-small cell lung cancer cell lines. *Proc Natl Acad Sci U S A*. 2005 Mar 8;102(10):3788-93. Epub 2005 Feb 24.
- Geromin D, Bourge JF, Soulie A, Pawliuk R, **Fleet C**, Michel E, Denizot Y, Berthou C, Leboulch P, Sigaux F, Sasportes M. Glycoprotein 170 induces platelet-activating factor receptor membrane expression and confers tumor cell hypersensitivity to NK-dependent cell lysis. *J Immunol*. 2004 Mar 15;172(6):3604-11.
- Gouze E, Pawliuk R, Gouze JN, Pilapil C, **Fleet C**, Palmer GD, Evans CH, Leboulch P, Ghivizzani SC. Lentiviral-mediated gene delivery to synovium: potent intra-articular expression with amplification by inflammation. *Mol Ther*. 2003 Apr;7(4):460-6.
- Eriksson A, Cao RPawliuk, R, Berg SM, Tsang M, Zhou D, **Fleet C**, Tritsaris K, Dissing S, Leboulch P, Cao Y. Placenta growth factor-1 antagonizes VEGF-induced angiogenesis and tumor growth by the formation of functionally inactive PIGF-INEGF heterodimers. *Cancer Cell*. 2002 Feb;1(1):99-108.
- Gouze E, Pawliuk R, Pilapil C, Gouze JN, **Fleet C**, Palmer GD, Evans CH, Leboulch P, Ghivizzani SC. In vivo gene delivery to synovium by lentiviral vectors. *Mol Ther*. 2002 Apr;5(4):397-404.
- Klein C, Friedman J, Bressman S, Vieregge P, Brin MF, Pramstaller PP, De Leon D, Hagenah J, Sieberer M, **Fleet C**, Kiely R, Xin W, Breakefield XO, Ozelius LJ, Sims KB. Genetic testing for early-onset torsion dystonia (DYT1): introduction of a simple screening method, experiences from testing of a large patient cohort, and ethical aspects. *Genetic testing*. 1999 3(4):323-8.
- Lin Q, Cunningham LA, Epstein LG, Pechan PA, Short MP, **Fleet C**, Bohn MC. Human Fetal astrocytes as an ex vivo gene therapy vehicle for delivering biologically active nerve growth factor. *Human Gene Therapy*. 1997 Feb 10;8(3):331-9.
- Scarf J, Boviatsis EJ, **Fleet C**, Breakefield XO, Chiocca EA. Genetically Modified Rat 9L Gliosarcoma Cells Facilitate Detection of Infiltrating Tumor Cells in a Rat Model of Brain Neoplasms. *Transgenics*. 1994 Vol.1, pp.219-224.
- Takamiya Y, Short MP, Moolten FL, **Fleet C**, Mineta T, Breakefield XO, Martuza RL. An experimental model of retrovirus gene therapy for malignant brain tumors. *Journal of Neurosurgery*. 1993 Jul;79(1):104-10.

P O S T E R S

- AV-203, a Humanized ERBB3 Inhibitory Antibody Inhibits Ligand-Dependent and Ligand-Independent ERBB3 Signaling in vitro and in vivo. Vincent S, **Fleet C**, Bottega S, McIntosh D, Winston W, Chen T, Tyler S, Meetze K, Weiler S, Gyuris J. presenter AACR 103rd Annual Meeting, 2012, Chicago, IL.
- Functional Characterization of a Diverse Set of ERBB3 Antibodies Vincent S, Weiler S, **Fleet C**, Bottega S, DiPrima M, Wang F, McIntosh D, Breault L, Tyler S, Meetze K, Winston W, Gyuris J. AACR 102nd Annual Meeting, 2011, Orlando, FL.
- Novel EGFR Antibodies with Increased Activity Towards Mutant EGFRs and Potentially Reduced Toxicity Wang F, McIntosh D, Bottega S, Zhou Y, **Fleet C**, Tyler S, Meetze K, Jiang J, Chen T, Weiler S, Winston W, Heyer J, Clark S, Gyuris J, Vincent S. AACR 102nd Annual Meeting, 2011, Orlando, FL.

Sara M. Haserlat

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Boston, MA 02108
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Summary

Enthusiastic and driven Associate Scientist with seven years of industry experience.

MS in Biochemistry, skilled in molecular biology, cell biology, phage display technology, genetics, diversity-based protein engineering, antibody engineering/affinity maturation, antibody affinity-based screening (using Octet platform) and mammalian cell culture.

Strong interpersonal skills; experience in managing projects and small teams.

Professional Experience

AVEO Oncology
Associate Scientist, Antibody Engineering
Senior Research Associate, Antibody Engineering

Cambridge, MA
07/2011-11/2012
04/2009-07/2011

Advancement of the Drug Discovery Pipeline/ New Technology Development:

- Implementation of Antibody Phage Display technology platform to identify lead and surrogate antibodies for target pipeline projects
 - Use of Phage Display Library panning and ELISA based screening to discover novel Fabs.
 - Expression and purification of Fabs
 - Conversion of unique Fabs into full-length human IgG molecules using heavy and light chain vector cloning, followed by affinity and binding specificity assessment (using Octet system)
- Development and validation of Affinity Maturation process for lead antibodies
 - Incorporation of high-throughput machinery and protocols to scale-up Affinity Maturation process
 - Affinity matured and engineered top IgG variants from Phage Display Platform, to increase affinity and specificity
- Communication of experimental results in large and small Drug Discovery Group settings
 - Presented valuable results and figures to small and large teams to aid in pipeline development

Codon Devices, Inc.
Senior Research Associate, Protein Engineering

Cambridge, MA
08/2008-02/2009

Affinity maturation of therapeutic antibodies:

- Construction of single-chain and full-length antibody (IgG) libraries.
- Selection of antibodies with increased target binding affinity using Secretion-and-Capture (SnC), a proprietary yeast-based display technology.
- Analysis of binding specificity of collected clones.
- Obtained antibodies with 5-10 fold higher affinity relative to the wild type.

Selection of antibody-based therapeutic proteins:

- Collaboration with Merrimack Pharmaceuticals.
- Design and construction of high-complexity libraries.
- Identification of target-binding clones using SnC display.

Team Lead, Gene Engineering 03/2008–08/2008
Senior Research Associate, Gene Engineering 03/2007–03/2008
Research Associate, Gene Engineering 08/2006–03/2007

Gene construction: Lead a team focused on high-throughput development and construction of complex genes for large scale custom projects

- Assembled DNA products using ligation, PCR, sequencing, and error correction techniques.
- Developed new methods for gene construction at the bench and using high-throughput formats, optimized gene construction strategy.
- As Team Lead, tracked and organized all active projects, coordinated with Sales and Logistics, trained new hires, and developed standard operating procedures.

Massachusetts General Hospital, Molecular Genetics Charlestown, MA
Research Technician, Cancer Center for Risk Analysis 06/2002–08/2006
(Laboratory of Dr. Daniel Haber)

Identification of cancer predisposition genes in families with susceptibility to breast cancer

- High through-put mutational detection by automated sequencing to screen for germline mutation of novel genes in families with Li Fraumeni syndrome or familial breast cancer.
- Clinical diagnostic testing for the $CHK2^{1100delC}$ mutation in patients with susceptibility to breast cancer.

Millipore Corporation Danvers, MA
Genomics and Molecular Biology Intern 06/2000–09/2001
Summer 2000

- Evaluated product performance for the Multiscreen PCR (membrane-based, 96-well, purification device).
- Analyzed PCR product recovery using both solution based fluorescence assay, agarose gel electrophoresis, and densitometry.
- Presented data in support of improved protocol.

Summer 2001

- Evaluated and validated product performance of Microcon-PCR centrifugal filtration device.
- Validated protocol and presented recommendations to Product Manager and Marketing Department.

Connecticut College New London, CT
Molecular and General Biology Lab Assistant 09/1999–12/2001
Admissions Tour Guide 09/1999–5/2001
Zoology Advisor Board Member 09/1999–05/2002

Education

Tufts University, Friedman School of Nutrition Science and Policy
M.S. in Nutritional Biochemistry and Metabolism
Specialization in Molecular Biology

Boston, MA
2004–2006

Exercise Physiology Lab Intern

- Exercise stress testing on volunteer test subjects
- RPE scale literature review

Mineral Biology Lab Intern

- Research on current literature linking the Vitamin D receptor to Heat Shock Protein

Connecticut College
B.A. Zoology w/ concentration in Molecular Biology
Dean's Honor

New London, CT
1998–2002
1999, 2000, 2002

Skills

Molecular Biology

RNA isolation, gDNA and cDNA preparation, PCR amplification/purification/optimization, PCR and sequencing primer design, colony PCR, restriction cloning, ligation independent cloning (In-Fusion) site-directed mutagenesis, optimization of filtration products, gel electrophoresis, analysis of DNA samples using gel densitometry (BioRad Molecular Analyst Program), SYBR green fluorescent detection assays, cell fractionation, plasmid preparation, restriction-enzyme digestion, yeast two-hybrid system, automated sequencing, sequence analysis (Sequence Navigator, SeqMan, and Vector NTI programs)

Diversity-Based Protein/Antibody Engineering

Yeast Secretion-and-Capture display technology, library design and construction, yeast transformations, Fluorescent Activated Cell Sorting, flow-cytometry–based analysis of target-binding properties (K_d determination), protein quantitation, protein electrophoresis, protein densitometry, Phage Display technology, Affinity Maturation of phage-based Antibodies, Small/Medium Scale Antibody Purification, Full-length Antibody construction, Antibody Engineering/Germlining/Humanization, Affinity and Specificity measurements via Octet system.

Genetics

Genetic crossing/hybridization, chromosome classification.

Cell Culture

E.coli and *S. cerevisiae* culture growth/maintenance/storage, mammalian cell culture, white blood cell isolation, generation of stable cell lines, transient transfections with 293T.

General Computer Skills

Microsoft Office (Word, Excel, PowerPoint, Access)

Publications

Lynch TJ, Bell DW, Sordella R, Gurubhagavatula S, Okimoto RA, Brannigan BW, Harris PL, **Haserlat SM**, et al. (2004) Activating Mutations in the Epidermal Growth Factor Receptor Underlying Responsiveness of Non-Small-Cell Cancer to Gefitinib, *N Eng J Med* 350 (21), 2129–2139.

Bell DW, Lynch TJ, **Haserlat SM**, et al. (2005) Epidermal Growth Factor Receptor Mutations and Gene Amplification in Non-Small-Cell Lung Cancer: Molecular Analysis of IDEAL/INTACT Gefitinib Trials, *J Clin Oncology* 23(31), 8081–8092.

Bell DW, Kim SH, Godwin AK, Schiripo TA, Harris PL, **Haserlat SM**, Wahrer D, Haiman CA, Daly MB, Niendorf KB, Smith MR, Sgroi DC, Garber JE, Olopade OI, Marchand LL, Henderson BE, Altshuler D, Haber DA, Freedman ML. (2007) Genetic and functional analysis of CHEK2 (CHK2) variants in multiethnic cohorts, *Int. J. Cancer* 121, 2661–2667.

Cohen EEW, Lingen MW, Martin LE, Harris PL, Brannigan BW, **Haserlat SM**, et al. (2005) Response to Some Head and Neck Cancers to Epidermal Growth Factor Receptor Tyrosine Kinase Inhibitors May be Linked to Mutation of ErbB2 rather than EGFR, *Clin Cancer Res* 11(22), 8105–8108.

Kwak EL, Jankowski J, Thayer SP, Lauwers GY, Brannigan BW, Harris PL, Okimoto RA, **Haserlat SM**, Driscoll DR, Ferry D, Muir B, Settleman J, Fuchs CS, Kulke MH, Ryan DP, Clark JW, Sgroi DC, Haber DA, Bell DW. (2006) Epidermal Growth factor Receptor Kinase Domain Mutations in Esophageal and Pancreatic Adenocarcinomas, *Clin Cancer Res* 12(14), 4283–4287.

Kim WJ, Okimoto RA, Purton LE, Goodwin M, **Haserlat SM**, Dayyani F, Sweetser DA, McClatchey AI, Bernard OA, Look AT, Bell BW, Scadden DT, Haber DA. (2008) Mutations in the neutral sphingomyelinase gene SMPD3 implicate the ceramide pathway in human leukemias, *Blood* 111 (9), 4716–4722.

Lu Lucia Huang

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West Roxbury, MA02132

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luhuang38@gmail.com

Extensive expertise in molecular biology, genetics, genome analysis, cell culture and assays, oncology animal models and drug discovery. Motivated researcher with strong people skills, excellent team player.

Technical skills

Cell Biology

Cell based assays (proliferation, apoptosis)
Cell transient transfection using plasmid and siRNA library.
High throughput or large scale viral production
Cell infection using viruses
Stable cell line construction/generation
Cell line maintenance (include normal and cancer cell lines)
FACS Analysis

Molecular biology

- Genomic and cDNA library screening
- Restriction analysis
- primer design and optimization
- Mutagenesis
- Sequence analysis
- DNA, RNA isolation and purification from cells and tumors (manual and automation)
- Quantification of gene expression by RT-PCR (ABI PRISM 7900H Sequencing Detection System)
- Quantification of protein expression by western (LiCor Odyssey and Image Studio Ver2.1)
- Quantification of RNAi knockdowns using QuantiGene® 2.0 Reagent System and real time PCR (ABI 7900HT Fast Real-Time PCR System).
- Mechanism of action study using pooled siRNA and compound rescue approach
- Oligo synthesis using Oligo 1000M DNA synthesizer (Beckman)
- Probe design, radioactive labeling and Southern Hybridization
- Vector construction (including viral, mammalian and plant)
- Gateway cloning, Positional cloning, High throughput cloning

Protein Analysis

- SDS PAGE
- Isolation (from cells and tissues)
- Western
- ELISA

In Vivo Techniques

- Rodent handling and anaesthesia
- Small animal handling (i.e. mice daily care, euthanasia, observation for animal health)
- Tumor implantation, latency, penetration and size monitor, tumor collection.
- Tissue collection (internal organ, muscle, fat, brain)
- Cardio-puncture
- Drug dosing (ip injection)
- PD and efficacy studies using small molecules and antibodies.

Histology

- Tumor/tissue/organ collection for formalin-fixed paraffin embedding and OTC embedding
- Tissue section by Leica RM 2255, Leica CM 1850
- H&E staining and Immunohistochemistry staining

- Imaging analysis by Leica Picture Frame software.

Genome analysis

- Mutation detection using DHPLC technology (Denaturing High Performance Liquid Chromatography)
- Maintenance and propagation of BAC and YAC libraries
- BAC library replication using 'Q' BOT (GENETIX)
- Production of filters containing ordered arrays of YAC and BAC clones using high-density replicating tool (BIOLMEK 1000 Workstation -Beckman)
- Hybridization of BAC and YAC filters, and data analysis and database entry
- Generated BAC contigs using the Bio Image System (MILLIPORE), and using BAC end sequencing construction approach as well as fingerprint analysis (FPC program).
- BAC and YAC Purification and sizing by CHEF gels
- BAC library pooling by TECAN(Genesis RSP 200).
- RFLP analysis

Automation

- TECAN (Genesis RSP 200).
- Autogen 740 (AN [IWATA] COMPANY)
- 'Q' BOT (GENETIX)
- Sciclone ALH 3000 (Zymark)
- BIOMEK 1000, BIOMEK 2000 Workstation (Beckman)
- EVOLUTION P3 (Perkin Elmer)
- Multidrops (Thermo)
- QIAcube (QIAGEN)

Microbiology

- E.coli: plasmid, BAC
- Phage: lambda genomic and cDNA library
- Agrobacteria: growth, transformation
- Yeast: growth and YAC

Gene function studies

- Gene silencing by siRNA and shRNA
- Arabidopsis mutant screening and analysis
- Maize leaf protoplast preparation and cell based assay (transactivation).
- Transposon tagging
- Gene targeting

Computer Software

- Microsoft office
- Internet and email software
- LiCOR (imaging system)
- Openlab (imaging system)
- Leica Picture Frame Imaging
- UNIX basics
- Spot fire
- WAVE system (DHPLC)
- SDS (genotyping).
- Vector NTI (cloning, sequencing)
- PCR LIMS (data compiling)
- Access Database
- Sequencher

Education

Bachelor of Science, Department of Biology, Xihua Normal University, China

Professional Experience

Aveo Oncology INC. Cambridge, MA

June 2008-Oct. 2012

Associate Scientist, Translational Research.

- Generated specific target-driven tumor models for drug discovery. Techniques include cloning, transfection, injection, monitoring tumor latency and penetration, tumor model validation by RT-PCR, IHC & drug treatment.

- Conducted pharmaco-dynamics and efficacy studies in mouse using genetically-engineered tumor models or xenograft models
- Performed in vitro and in vivo new target discovery screening and validation
- Assay development
- Wrote and provided standardized operating procedures for technology transfer

Novartis for Biomedical Research INC. Cambridge, MA

May 2004-June 2008

Scientist I, Oncology/Target and Biomarker

- New target discovery through high throughput shRNA cloning
- Established new platform for automated high throughput-high efficiency shRNA validation
- Target validation using cancer related shRNA libraries
- New technology development
- Managed DNA bank. Database input and management. Provided reagents to piers and collaborators in multiple research sites around world.

GPC-biotech INC, Waltham, MA

Sr. Research Associate.

2002- 2004

Work involved in two major groups in the company:

In Biology Group, projects include mammalian interaction technology development and inhibitor screening

- Determined optimal cell density and growth condition for multiple cell lines in 96 well format
- Inhibitor screening using a cell proliferation assay- SRB (Sulforhodamine B) assay in 96 well format
- Kinase inhibitor cloning, mutagenesis

In Oncology group, projects include technology and candidate validation.

- Evaluated Synthetic Lethal Screening technology using transient transfection followed by colony formation assay (CFA).
- Validated 80 candidates using CFA, cell death detection ELISA assay (CDDR), and siRNA
- Created stable cell line using VSVG virus infection
- Viral vector construction for cDNA library
- Cloned two candidate genes into viral vectors for validation
- Developed and improved assays.
- Wrote standing operation protocols for technology transfer and training.

Cereon Genomics LLC, Cambridge, MA

Sr. Research Associate.

1999-2002

Responsibilities include physical mapping and positional cloning; gene regulation studies, mutation detection, high throughput cloning, transactivation and cell based assays.

- Cloned two Soybean Cyst Nematode (SCN) resistance genes.
- Characterized a transgene regulation in two crop plant species.
- Explored new methods for SNP discovery. Evaluated DHPLC as a tool for SNP detection in plants.
- Established a high throughput cloning system. Cloned 120 genes into expression vectors in 2-3 months. Sixty of the constructs with perfect sequence were used for plant transformation.
- Reporter and activator construction including site directed mutagenesis, and evaluating transcriptional activation using a cell-based assay.

Available upon request:

1. Contributions to publications and patents
2. References

SUMMARY

A scientist with 5 years of industry experience creating projects in the fields of regulatory and experimental toxicology; biopharmaceutical development and safety; immunology, *in silico* allergy, immunogenicity and toxicity prediction; functional assay and animal models; and safety evaluation of GMOs.

WORK EXPERIENCE

Scientist (Experimental Toxicology) 2012

AVEO Oncology, Clinical Pharmacology and Toxicology – Cambridge, Massachusetts

- Responsible for strategy, experimental design, interpretation and management of execution of nonclinical toxicology and safety pharmacology studies for oncology development programs in accordance with ICH and GLP guidelines
- Assist in the preparation of nonclinical safety sections of clinical and regulatory documents such as clinical protocols, investigator brochures, annual reports, INDs, NDA/MAAs and product labels
- Evaluate immunogenicity prediction tools (*in silico* methods and functional assays; T-cell and B-cell assays) to implement an immunogenicity prediction and mitigation approach at AVEO Oncology
- Organize, track and integrate safety data and communicate results to project teams and management, and use in external presentations/publications
- Lead selection of CROs and qualification activities

Research Scientist (Toxicology/Human Product Safety Assessment Group) 2007 – 2012

DuPont, Biotech Affairs and Regulatory – Ankeny, Iowa

- Design and monitor preclinical GLP and exploratory studies to evaluate safety of genetically engineered products
- Develop methods/animal models to predict potential allergenicity of novel recombinant proteins
- Develop bioinformatics methods to predict potential of recombinant proteins to be toxic
- Develop technical safety evaluation reports and publications
- Evaluate new technologies that could be applied to qualitative and quantitative risk assessment of genetically engineered products

Post-doctoral Research Associate (Regulatory Science and Policy) 2006 – 2007

Iowa State University – Ames, Iowa

- Assess risks involved in commercialization of recombinant pharmaceuticals and enzymes

Research Assistant (Molecular Biology, Biotechnology) 2001 – 2006

Interdepartmental Physiology, Iowa State University – Ames, Iowa

- Generate and characterize a recombinant antigen to be used as a vaccine against cholera and traveler's diarrhea and conduct preclinical tests to determine its immunogenicity
- Analyze long-term immunogenic effects of a recombinant antigen to be used as a vaccine against traveler's diarrhea
- Design genes, genetically transform multiple organisms, analyze DNA and protein, perform immunoassays and use animal models for efficacy studies

Research Assistant (Toxicology) 1998 – 2000

Department of Biochemistry, Middle East Technical University – Ankara, Turkey

- Analyze effects of novel retinoids (generated as potential anti-cancer agents) on healthy tissue for determination of toxic levels. Use glutathione-S-transferase activity levels in erythrocytes and DNA ladder formation in lymphocytes as toxicity indicators.

Undergraduate Research Assistant 1996 – 1998

Microbiology Laboratory Course, Middle East Technical University – Ankara, Turkey

EDUCATION

Ph.D. Interdepartmental Physiology	Iowa State University	2006
<i>Dissertation: Development of Vaccine and Vaccine Components in Corn</i>		
M.S. Biochemistry	Middle East Technical University	2000
<i>Thesis: Apoptotic Effects of Retinoic Acid Derivatives on Human Erythrocytes and Lymphocytes</i>		
B.S. Biology	Middle East Technical University	1998

RESEARCH INTERESTS

- Cancer research and medications
- Pharmaceutical and industrial reagent production by use of recombinant DNA technology and their safety assessment
- Drug discovery
- Allergy/autoimmunity/mucosal immunology/immunology
- Protein toxins
- Efficacy and safety studies using standard and transgenic animal models
- Toxicogenomics
- Predictive toxicology
- Use of structural modeling to make inferences about protein function
- Bioinformatics/omics/metagenomics

TEACHING/SUPERVISING EXPERIENCE

Teaching Assistant	Iowa State University	2003
– Assist in class focused on Transformation Techniques		
Supervisor	Iowa State University	2003 – 2006
– Train and supervise undergraduate students on molecular and immunological characterization of recombinant proteins		
– Mentor a high school student during her science project on gene cloning to produce recombinant proteins		

HONORS/AWARDS/SCHOLARSHIPS

Biotech Achievement Award		2010
As a member of Acetylated Amino Acids Toxicology Evaluation Team – DuPont		
NATO-A1		2001 – 2006
Doctorate Support Scholarship – The Scientific and Technological Research Council of Turkey		
Young Scientist Support Program		1995 – 1998
Undergraduate Scholarship – The Scientific and Technological Research Council of Turkey		

PUBLICATIONS

Manuscripts in preparation

1. Author 1, **Karaman S**, Author 3, and Author 4. An X approach to *in silico* allergenicity potential assessment. *Manuscript is in preparation to be submitted to a peer-reviewed journal.*
2. Author 1, **Karaman S**, Author 3, Author 4, Author 5, Author 6, Author 7. Subchronic rodent feeding study with grain from molecular stacked trait *Lepidopteran* and *Coleopteran* resistant (DP-ØØ4114-3) maize. *Manuscript is in preparation to be submitted to a peer-reviewed journal.*

3. **Karaman S**, Author 2. Adaptive responses of salivary glands. *Manuscript is in preparation to be submitted to a peer-reviewed journal.*

Published

1. **Karaman S**, Cunnick J, Wang K. Expression of the cholera toxin B subunit (CT-B) in maize seeds and a combined mucosal treatment against cholera and traveler's diarrhea. *Plant Cell Reports* 2012; 31(3): 527-37.
2. **Karaman S**, Barnett J. Jr., Sykes GP, Hong B, Delaney B. Two-generation reproductive and developmental toxicity study of *N*-acetyl-L-aspartic acid in rats. *Food and Chemical Toxicology* 2011; 49(12): 3192-205.
3. **Karaman S**, Barnett J. Jr., Sykes GP, Delaney B. Subchronic oral toxicity assessment of *N*-acetyl-L-aspartic acid in rats. *Food and Chemical Toxicology* 2011; 49(1): 155-65.
4. **Karaman S**, Myhre A, Donner EM, Munley SM, Carpenter C, Delaney BF. Mutagenicity studies with *N*-Acetyl-L-Aspartic Acid. *Food and Chemical Toxicology* 2009; 47(8): 1936-40.
5. Wolt J, **Karaman S**, Wang K. Risk assessment of plant made pharmaceuticals. *CAB Reviews* 2007; 2(12): 1-9.
6. **Karaman S**, Cunnick J, Wang K. Analysis of immune response in young and aged mice vaccinated with corn-derived antigen against *Escherichia coli* heat-labile enterotoxin. *Molecular Biotechnology* 2006; 32(1): 31-41.
7. Wolt J, **Karaman S**. Estimated environmental loads of alpha-amylase from transgenic high-amylase maize. *Biomass and Bioenergy* 2007; 31(11-12): 831-835.

SELECTED PRESENTATIONS

1. Optimization and evaluation of an *ex vivo* mouse peritoneum mast cell degranulation assay to evaluate potential protein allergenicity. March 14, 2012, Society of Toxicology Annual Meeting. San Francisco, California.
2. Toxic Responses of the Immune System. April 2011, Product Safety Group.
3. Reproductive Toxicity. May 2009, Product Safety Group.
4. Subchronic oral toxicity assessment of *N*-acetyl-L-aspartic acid in rats. March 15-19, 2009, Society of Toxicology Annual Meeting. Baltimore, Maryland.
5. Developmental Toxicity. January 2009, Product Safety Group.
6. Strategies to evaluate safety of genetically modified crops. January 21, 2009, Conference on genetically modified crops: status, issues and awareness. School of Life Sciences, North Maharashtra University, Jalgaon, India.
7. Corn as a production and delivery system for biopharmaceuticals. June 17, 2005, Japanese Expert Delegation, Iowa State University Research Park, Ames, Iowa.
8. Analysis of immune response in young and aged mice vaccinated with corn-derived antigen against *Escherichia coli* heat-labile enterotoxin. March 21-24, 2004, International Symposium on: Plant derived vaccines and antibodies: potential and limitations. Annecy, France.

MEMBERSHIPS TO PROFESSIONAL SOCIETIES

Current

Society of Toxicology

American Association of Pharmaceutical Scientists

Past

Society of Mucosal Immunology

The Protein Society

James Levasseur

998 Lakeview Ave. Lowell, Ma. 01850

(978) 943-2337

JamesLevasseur@outlook.com

Summary

Researcher with 6 years of experience in industry and academia. Special expertise in Animal handling, Histology, Parasitology, and Embryology. Recognized for strong collaboration, communication and problem solving skills.

Key Skills

Research

- Efficient with mammalian ES cell culture used for micro Injections, embryo transfers, and Chimera production.
- Proposed and developed a strategy to overcome an issue with Alzheimer's mouse model that led to continued use of the model and a publication
- Performed survival surgeries, with the use of Isoflurine and other anesthesia's
- Performed Drug studies including tumor cell injection, measurement of tumors, dosing of animals and tumor removal surgeries
- Capable of performing DNA/RNA extraction, Luminescence imaging with IVIS imaging system.
- IATA hazardous material shipping certified 2012

IHC/Histology

- Performed the embedding of samples in paraffin wax, sectioning, and staining of slides, as well as scanning of the samples into Aperio software

Animal Handling skills

- Performed complex husbandry and specialized production duties requiring technical expertise to maintain and monitor the health, production, and physical environment of Charles River animals within isolators and barrier rooms
- Trained ACF staff technical skills which resulted in a reduction of spending on outsourced health monitoring costs.
- Capable of the routine monitoring of laboratory animals, collection of blood, and bacteriological samples as well as Identification of various parasites
- Packing and shipping animals to customers
- Ensuring proper breeding procedures
- Maintaining appropriate levels of assigned specialized rodent breeds including nudes, inbred and SCIDs
- Able to perform gross necropsies, tail, toe, and ear snips, cage wash and prep and health checks.

Previous employers and positions held

Aveo Oncology 2019-2012

Research Associate I

Research Support Technician

Charles River Laboratories 2008- 2009

Technologist, Health Monitoring

Technologist, Embryology

University of Massachusetts Lowell 2006-2008

Research Associate, Biology Department

Animal Care Technician II, office of Research Services

Education

University of Massachusetts Lowell

B.S. 2007 Criminal Justice

Working toward Biology bachelor degree

Harvard Extension, Cambridge, MA

courses include molecular Biology

Publications

S.Perry, J. Levasseur, A. Chan, TB Shea. Dietary Supplementation with S-Adenosyl Methionine was Associated with Protracted Reduction of Seizures in a Line of Transgenic Mice. Comparative Medicine. December 2008. 58:6

Sangmook Lee, Vanessa Doulames, Michelle Donnelly, James Levasseur, Tomas B. Shea. Environmental Enrichment can Prevent Cognitive Decline Induced by Dietary Oxidative Challenge. Journal of Alzheimer's Disease – Volume 28 Number 3 2012

AVEO Pharmaceuticals, Inc
Bioinformatics
75 Sidney St, 4th Fl
Cambridge, MA 02139

15 Lake Shore Ct, Apt 1
Boston, MA 02135
+1 401 484 1155
kh.ericlim@gmail.com

Eric Lim

Research & Professional Experience

COMPUTATIONAL BIOLOGIST

Oct 2011—present

*Bioinformatics, Translational Research
AVEO Pharmaceuticals, Inc, Cambridge, MA*

Leading the computational project in the company's *FGFR* program to discover new biomarkers for breast cancer by integrating various sources of expression data with alternative splicing, genome-wide association studies and copy number data.

Discovering novel molecular pathways in metastatic cancers with machine learning methods such as principal component analysis and unsupervised clustering techniques.

Developing and testing computational pipelines in high performance computing environment to facilitate the analyses of next-generation sequencing.

Ph.D. CANDIDATE

Sept 2007—Sept 2011

*Department of Molecular Biology, Cellular Biology, and Biochemistry
Brown University, Providence, RI*

Proposed and developed a computational method to predict genomic variations that lead to genetic disorders, through integrative statistical analyses of sequence conservations, SNPs, ESTs, and next-generation sequencing data.

Discovered a novel class of nuclear intron that requires a pan-intronic stem loop for correct molecular processing by a large-scale sequence analysis of 23 genomes.

UNDERGRADUATE RESEARCH

Sept 2004—May 2005

*Department of Computer Science
University of North Texas, Denton, TX*

Utilized technologies such as IDS/IPS, firewall, IPsec, and NEMA gateway to propose a global healthcare system that enables proper flow of electronic medical records.

Implemented a geographically distributed test bed with Bayesian and various graph theories to investigate vulnerabilities of the rapidly growing VoIP systems.

SOFTWARE DEVELOPER

Jan 2004—Sept 2004

*GD 2004, an international symposium with participants from 19 countries
New York University, Harlem, NY*

Gathered requirements, designed, and implemented a database-driven software to improve time efficiency of paper submission, committee discussion, and review workflow.

Trained and provided technical assistance during the production deployment of the system.

Eric Lim, Ph.D.

+1 401 484 1155
kh.ericlim@gmail.com

Education	Ph.D. Computational Molecular Biology Department of Molecular Biology, Cellular Biology, and Biochemistry Brown University, Providence, RI	2007—2011
	Sc.M. Computer Science Department of Computer Science Brown University, Providence, RI GPA: 4.000/4.000	2006—2007
	Sc.B. Computer Science College of Engineering University of North Texas, Denton, TX Major GPA: 4.000/4.000	2002—2005

Leadership	PRESIDENT, COACH <i>Men's Club Volleyball</i> <i>Brown University, Providence, RI</i>	Sept 2007—May 2010
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Coached over 60 undergraduates to compete at the nationals level over 3 seasons and trained one novice player into MVP. Finished 1st among Ivy League, 2nd in the broader northeast region, and ranked 12th nationally.

Publications & Manuscripts	KH Lim , L Ferraris, ME Filloux, BJ Raphael, WG Fairbrother (2011) Using positional distribution to identify splicing elements and predict pre-mRNA processing defects in human genes. <i>Proc. Natl. Acad. Sci. USA</i> . 108 :11093-11098
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KH Lim, WG Fairbrother (2012) Spliceman—a computational web server that predicts sequence variations in pre-mRNA splicing. *Bioinformatics*. **28**:1031-1032

KH Lim, L Ferraris, ZF Wang, WG Fairbrother (2012) An ancient class of intron utilizes simple complimentary dinucleotide repeats to enforce accurate splice site pairing. *Being reviewed in PLoS Biology*.

KH Lim, B Feng (2012) Performance assessment of seven batch effects removal methods in expression data collected from three platforms in eight tumors. *Manuscript in preparation*.

R Nicoletti, **KH Lim**, M Robinson, B Feng (2012) Mining RNASeq expression data in multiple tumor types for universal human gene expression modules. *Manuscript in preparation*.

Proficiencies	Fluent in the following programming languages: Perl (bioperl), R, Matlab, PHP Experience with databases and source code management systems Familiar with data repository and annotations, including TCGA Data Portal, UCSC Genome and Table Browser, cBio Cancer Genomics Portal, dbSNP, HGMD, Gene Ontology Strong written and oral presentation skills Creative problem-solving, collaboration and positive team participation In vitro culture systems of mammalian cell lines Techniques of molecular biology, biochemistry, and cell biology
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K R I S T A N A . M E E T Z E , P H . D .

31 FLETCHER AVE #7, LEXINGTON, MASSACHUSETTS 02420
(617) 285-8526 | kristanmeetze@yahoo.com

S U M M A R Y

Scientist/manager with 12 years of experience initiating and leading small molecule and biotherapeutic oncology drug development programs from discovery through IND and early clinical. Pragmatic, delivery-driven approach to solving challenges, driving projects, and managing resources, timelines, and budgets. Proven success in hiring, leading, and developing scientific staff and teams in a matrix environment. Praised at all levels for communication, leadership, strategic, and interpersonal skills.

R E S E A R C H E X P E R I E N C E

AVEO PHARMACEUTICALS, INC., Cambridge, MA

2007- Oct. 2012

Head of Drug Discovery Pharmacology and Preclinical Development

Associate Director (2011-2012)

Principal Scientist (2008-2011)

Senior Scientist (2007-2008)

- Oversaw preclinical pharmacokinetics, pharmacology, and preclinical development studies for all oncology antibody programs.
- Advised all functional scientists regarding the investigation of cellular, molecular and in vivo pharmacology to support and direct clinical trial design, patient selection criteria, and selected Phase II indications.
- Responsible for pharmacology and nonclinical IND filings for ficlatuzumab and AV-203 programs, now in Phase 2 and Phase 1 clinical trials, respectively.
- Identified appropriate combinations for Phase 2 clinical trials for SCCHN indication based on mechanistic approach currently planned as next clinical trial for ficlatuzumab program.
- Identified a biomarker to predict response to AV-203 now being developed as a companion diagnostic, which also aided the design of the Phase 2 clinical trials for that program.
- Served as translational Project Team Leader of ficlatuzumab program leading to the identification of a subset of patients predicted to respond to ficlatuzumab as a single agent currently being evaluated in ISTs.
- Built a tumor bank of over 200 primary human tumor xenografts used to probe the relevance, role, or expression of specific targets, evaluate response across indications, evaluate clinical hypotheses, and to identify biomarkers of response for all antibody programs, which resulted in the validation of a clinical biomarker for the AV-203 program.
- Responsible for the development of preclinical and clinical bioanalytical assays to support Phase I trials, including vendor selection and assay transfer to selected CRO.
- Established and effectively managed timelines and resources for all preclinical development activities and throughout clinical trial stage.
- Created and managed \$6M annual departmental budget.
- Provided leadership, direction and mentoring for eight direct reports in the pharmacology and preclinical development departments.
- Direct report to Chief Scientific Officer.

MILLENNIUM PHARMACEUTICALS, INC., Cambridge, MA

2002-2007

Senior Scientist I, Department of Cancer Pharmacology (2006-2007)

Scientist II, Department of Cancer Pharmacology (2002-2006)

- Managed, developed, and built productive and effective team of scientists and research associates
- Led cell biology and pharmacology efforts for multiple lead optimization projects and several hit-to-lead projects with several successful programs being selected as development programs.
- Developed cell-based mechanism of action assays for high-throughput compound screening in early project stages which led to selection of lead candidate molecules.
- Designed *in vivo* mechanism of action models as well as appropriate tumor models for each project which

resulted in the identification of a pharmacodynamic marker of molecular activity used in clinical trials.

- Contributed as active member on several committees, including cell biology committee, safety committee, and IACUC.
- Initiated development of a computer-based tumor measurement system which streamlined and standardized tumor measurements and data analysis across the company.
- Coordinated activities on numerous projects, including new model development and characterization, target validation, biomarker identification, and integration of PD markers.
- Supported pre-clinical testing of lead project to achieve development stage with reached clinical testing in late 2005.
- Prepared pharmacology section for IND and IB for an Aurora A inhibitor program.
- Served as discovery project team leader for antibody-drug conjugate program in clinical trials, managing all preclinical activities to support clinical trials.

ELI LILLY AND CO., Indianapolis, IN

2000-2002

Post-doctoral Scientist, Cancer Division

- Researched Surrogate Markers as Clinical Endpoints for Antiangiogenesis Agents as Cancer Therapy.
- Focused on novel *in vivo* angiogenesis model development and characterization.
- Developed new technologies for screening multiple cytokines in one assay with outside collaborator.
- Designed studies to explore PK/PD relationships for development candidates.

EDUCATION

Ph.D., Cancer Biology, WAYNE STATE UNIVERSITY SCHOOL OF MEDICINE, Detroit, MI (2000)

B.S., Biochemistry, SUSQUEHANNA UNIVERSITY, Selinsgrove, PA (1996)

HONORS AND AWARDS

- Team Awards, AVEO Pharmaceuticals (2008, 2010, 2011)
- Outstanding Contributor Award, Millennium Pharmaceuticals (2004)
- Dean's Scholarship Training Award (1999-2000)
- National Institute of Health Training Grant (1997-1999)
- Dean's Scholarship Training Award (1996-1997)

AFFILIATIONS

- American Association for Cancer Research (2001-Present)
- Women in Cancer Research (2002-Present)

COMMITTEES

Institutional Animal Care and Use Committee, AVEO Pharmaceuticals, Cambridge, MA

2008-2012

Institutional Animal Care and Use Committee, Millennium Pharmaceuticals, Cambridge, MA

2002-2006

Chair (2005)

Vice-Chair (2004)

ADDENDUM

PUBLISHED MANUSCRIPTS

Note: Maiden name is Keyes

1. Bai A, **Meetze K**, Vo NY, Kollipara S, Mazsa EK, Winston WM, Weiler S, Poling LL, Chen T, Ismail NS, Jiang J, Lerner L, Gyuris J, Weng Z. [GP369, an FGFR2-IIIb-specific antibody, exhibits potent antitumor activity against human cancers driven by activated FGFR2 signaling.](#) Cancer Res. 2010 Oct 1;70(19):7630-9.
2. [Manfredi MG, Ecsedy JA, Meetze KA, Balani SK, Burenkova O, Chen W, Galvin KM, Hoar KM, Huck JJ, LeRoy PJ, Ray ET, Sells TB, Stringer B, Stroud SG, Vos TJ, Weatherhead GS, Wysong DR, Zhang M, Bolen JB, Claiborne CF.](#) Anti-tumor activity of MLN8054, a selective orally active small molecule inhibitor of Aurora A kinase. (2007) PNAS, 104:4106-11.
3. **Keyes, KA**, Mann, L, Sherman, M, Galbreath, E, Schirtzinger, L, Ballard, D, Chen, Y, Iversen, P, Teicher, B. LY317615 decreases plasma VEGF levels in human tumor xenograft-bearing mice. (2004) Cancer Chemotherapy and Pharmacology, 53:133-40.
4. **Keyes KA**, Cox, K, Treadway, P, Mann L, Iversen, P, Chen, Y, Teicher BA. Circulating Angiogenic Growth Factor Levels in Mice Bearing Human Tumors using Luminex Multiplex Technology. (2003) Cancer Chemotherapy and Pharmacology, 51: 321-327.
5. Galbreath, E, Westmore, M, Clapp, C, Considine, E, Smith, S, **Keyes K**, Iversen, P, Sulaimon, S, Zambrano, C, Galvin, R, Ma, L, Sato, M, Martin, T, Alvarez, E. Properties of bisphosphonates in the 13762 rat mammary carcinoma model of tumor induced bone resorption. (2003) Clinical Cancer Research, 9:5705-5713.
6. **Keyes, KA**, Mann, L, Alvarez, E. Site-dependent Angiogenic Cytokine Production in Human Tumor Xenografts. (2003) Cytokine, 21: 98-104.
7. **Keyes KA**, Cox, K, Treadway, P, Mann L, Shih, Chuan, Faul, MM, Teicher BA. An *in vitro* Tumor Model: Analysis of Angiogenic Growth Factor Expression after Chemotherapy. (2002) Cancer Research, 62: 5597-602.
8. **Keyes KA**, Segovia JC, Bueren JA, Parchment RE, Albella B. Latent Hematopoietic Stem Cell Toxicity Associated with Protracted Drug Administration. (2001) Experimental Hematology, 29: 286-294.
9. **Keyes KA**, Albella B, LoRusso PM, Bueren JA, Parchment RE. Cytotoxic Chemotherapy Regimens the Increase Dose per Cycle by Extending Daily Dosing from 5-days to 28-days and Beyond. (2000) Clinical Cancer Research, 6:2474-2481.

ACCEPTED ABSTRACTS

1. **Meetze K**, Connolly K, Feng B, Rideout W, Gyuris J, Han M. Antitumor Activity of Ficlatusumab in Combination with Tivozanib in Primary Human Renal Cell Carcinoma Xenografts. Molecular Targets and Cancer Therapeutics. Proceedings of the International Conference AACR-NCI-EORTC, 2012.
2. **Meetze K**, Connolly K, Zi T, Heyer J, Gyuris J, Han M. Antitumor Activity of Ficlatusumab in Combination with Cetuximab on Squamous Cell Carcinomas of the Head and Neck. Molecular Targets and Cancer Therapeutics. Proceedings of the International Conference AACR-NCI-EORTC, 2012.
3. **Meetze K**, Tyler S, Clark K, Mazsa E, Delpero A, Gyuris J, Vincent S. The anti-tumor Activity of the ERBB3 Inhibitory Antibody AV-203 in Patient Derived Tumor Explant Models. Molecular Targets and Cancer Therapeutics. Proceedings of the International Conference AACR-NCI-EORTC, 2012.

4. Connolly K, **Meetze K**, Boudrow A, Gyuris J, Han M. The effects of combination of ficlatuzumab with anti-VEGF inhibitors in glioblastoma xenografts. Society for Neuro-oncology, 2012.
5. **Meetze K**, Tyler S, Fleet C, Gifford J, Vincent S, Gyuris J. Pharmacokinetics and Pharmacodynamics of AV-203, a Humanized anti-ERBB3 Antibody. American Association for Cancer Research, 2012.
6. Vincent S, Fleet C, Bottega S, McIntosh D, Winston W, Chen T, Tyler S, **Meetze K**, Weiler S, Gyuris. AV-203, a Humanized ERBB3 Inhibitory Antibody Inhibits Ligand-Dependent and Ligand-Independent ERBB3 Signaling *in vitro* and *in vivo*. American Association for Cancer Research, 2012.
7. Bai A, **Meetze K**, Vo NY, Kollipara S, Mazsa EK, Winston WM, Weiler S, Poling LL, Chen T, Ismail NS, Jiang J, Lerner L, Gyuris J, Weng Z. [GP369, an FGFR2-IIIb-specific antibody, exhibits potent antitumor activity against human cancers driven by activated FGFR2 signaling.](#) Essential Role of Fibroblast Growth Factor Receptor 2 (FGFR2) in Tumorigenesis of Human Cancers with Activated FGFR2 Signaling Demonstrated by Functional Blocking Antibodies. American Association for Cancer Research, 2011.
8. Whalen K, Gifford J, Boudrow A, **Meetze K**, Winston W, Liu Q, Lerner L, Feng B, Jiang J, Cook L, DiPrima M, Chen T, Weiler S, Gyuris J, Han H. Anti-tumor activities of antibodies targeting the RON receptor and a biomarker of response. American Association for Cancer Research, 2011.
9. Wang F, McIntosh D, Bottega S, Zhou Y, Fleet C, Tyler S, **Meetze K**, Jiang J, Chen T, Weiler S, Winston W, Heyer J, Clark S, Gyuris J, Vincent S. Novel EGFR Antibodies with Increased Activity Towards Mutant EGFRs and Potentially Reduced Toxicity. American Association for Cancer Research, 2011.
10. O'Hagan R, Okamura H, Kreuter K, Bell A, Perino S, Keane D, Monti A, Rideout W, Winston W, **Meetze K**, Gyuris J. [Monoclonal antibodies to Notch receptors may enable targeting of tumor autonomous and tumor micro-environmental processes.](#) American Association for Cancer Research, 2011.
11. Bai A, **Meetze K**, Vo NY, Kollipara S, Mazsa EK, Winston WM, Weiler S, Poling LL, Chen T, Ismail NS, Jiang J, Lerner L, Gyuris J, Weng Z. [GP369, an FGFR2-IIIb-specific antibody, exhibits potent antitumor activity against human cancers driven by activated FGFR2 signaling.](#) Essential Role of Fibroblast Growth Factor Receptor 2 (FGFR2) in Tumorigenesis of Human Cancers with Activated FGFR2 signaling Demonstrated by Functional Blocking Antibodies. Molecular Targets and Cancer Therapeutics. Proceedings of the International Conference AACR-NCI-EORTC, 2010.
12. H. Okamura, J. LoRusso, A. Bell, S. Perino, D. Keane, J. Brodeur, A. Cooper, W. Rideout, W. Winston, **K. Meetze**, J. Gyuris, R. OHagan. Monoclonal antibodies to Notch receptors inhibit tumor maintenance. American Association for Cancer Research, 2010.
13. **K. Meetze**, K. Connolly, A. Boudrow, S. Venkataraman, S. Medicgerla, J. Gyuris, M. Han. Preclinical efficacy and pharmacodynamics of SCH 900105 (AV-299) an anti-HGF antibody in an intracranial glioblastoma model. Molecular Targets and Cancer Therapeutics. Proceedings of the International Conference AACR-NCI-EORTC, 2009.
14. **K. Meetze**, A. Boudrow, K. Connolly, R. Huang, W. Rideout, J. Gyuris, M. Han. Anti-tumor activity of SCH 900105 (AV299), an anti-HGF antibody, in non-small cell lung cancer models. Molecular Targets and Cancer Therapeutics. Proceedings of the International Conference AACR-NCI-EORTC, 2009.
15. Monti, J. Brodeur, S. Kollipara, K. Connolly, A. Boudrow, H. Tissire, T. Zi, R. Huang, J. Heyer, **K. Meetze**, and W. Rideout. Human HGF knock-in mice support the growth of HGF-dependent human xenografts and improved response to anti-HGF (SCH000105) therapy. Mechanisms and Models of Cancer Meeting, 2009.
16. J. Brodeur, A. Monti, S. Kollipara, K. Connolly, A. Boudrow, H. Tissire, **K. Meetze**, W. Rideout. Knock-in of human HGF into the mouse genome maintains endogenous HGF regulation and supports the growth of HGF-dependent human cancer cell lines. American Association for Cancer Research, 2009.
17. **K. Meetze**, K. Connolly, A. Boudrow, H. Tissire, R. Karp, J. Gyuris, M. Han. Preclinical efficacy and

- pharmacodynamics of SCH 900105 (AV-299), an anti-HGF antibody. American Association for Cancer Research, 2009.
18. Bai, W. Winston, **K. Meetze**, S. Kollipara, J. Woo, N. Vo, M. Kosmatka, L. Breault, S. Weiler, O. Kabbarah, A. Boudrow, K. Connolly, M. DiPrima, H. Tissire, J. Jiang, J. Gyuris, Z. Weng. Mechanistic studies of AV370, a potent FGFR3 antagonistic antibody. American Association for Cancer Research, 2009.
 19. Shi, J, Lasky, K, Zhang, Y, Hsieh, F, Rabino, C, **Meetze, K**, Hibner, B, Veiby, P. Preclinical efficacy of an ADC targeting B7-H4. [Antibodies as Drugs: From Basic Biology to the Clinic, Keystone Symposia, 2007.](#)
 20. K. M. Galvin, J. Huck, O. Burenkova, K. Burke, D. Bowman, V. Shinde, B. Stringer, M. Zhang, M. Manfredi and **K. Meetze**. Preclinical pharmacodynamic studies of Aurora A inhibition by MLN8054, ASCO, 2006
 21. Zhang, M, Silva, M, Claiborne, C, Sells, T, Balani, S, **Meetze, K**, Manfredi, M. MLN8054, an Aurora A Kinase Inhibitor, Demonstrates Potent Anti-tumor Activity in Disseminated Tumor Models. Molecular Targets and Cancer Therapeutics. Proceedings of the International Conference AACR-NCI-EORTC, 2006.
 22. Manfredi, M, Ecsedy, J, **Meetze, K**, Balani, S, Burenkova, O, Chen, W, Hoar, K, Huck, J, LeRoy, P, Sells, T, Stroud, S, Vos, T, Weatherhead, G, Wysong, D, Zhang, M, Claiborne, C. [MLN8054, an orally active Aurora A kinase small molecule inhibitor in phase I clinical trials.](#) American Association for Cancer Research, 2006.
 23. Huck, J, Zhang, M, Burenkova, O, Connolly, K, Manfredi, M, **Meetze, K**. Preclinical Anti-tumor Activity with MLN8054, A Small Molecule Aurora A Kinase Inhibitor. American Association for Cancer Research, 2006.
 24. Zhang, M, Burenkova, O, Chandra, S, Connolly, K, Huck, J, Manfredi, M, Saylor, M, Zhang, Y, **Meetze, K**. Broad-based Anti-Tumor Activity of the Aurora A kinase inhibitor, MLN8054. Molecular Targets and Cancer Therapeutics. Proceedings of the International Conference AACR-NCI-EORTC, 2005.
 25. Burenkova, O, Bond, S, Connolly, K, Galvin, K, Huck, J, Manfredi, M, Stringer, B, Zhang, M, **Meetze, K**. MLN8054, an orally active small molecule inhibitor, mediates tumor growth inhibition *in vivo* through Aurora A kinase. Molecular Targets and Cancer Therapeutics. Proceedings of the International Conference AACR-NCI-EORTC, 2005.
 26. **Keyes, KA**, Mann, L, Marder, P, Cox, K, Treadway, P, Sherman, M, Galbreath, E, Menon, K, Teicher, BA. Determination of Cancer Growth Factor Biomarkers in Plasma from Nude Mice Bearing Subcutaneous Human Tumor Xenografts using Luminex Multiplex Technology. American Association for Cancer Research, 2002.
 27. **Keyes, KA**, Cox, K, Treadway, P, Mann, L, Marder, P, Teicher, BA. Effects of Anticancer Agents on Angiogenic Cytokine Production *in Vitro* in HUVEC, Fibroblasts, Macrophages, SW2 and CaKi1 Tumor Cells. American Association for Cancer Research, 2002.
 28. Jin, S, **Keyes, K**, Lu, K, Menon, K, Cox, K, Treadway, P, Marder, P, Mann, L, Yingling, J, Alvarez, E, Teicher, B. Characterization of Molecular Components of the Transforming Growth Factor-B (TGF-B) in Human Tumor Cell Lines and Xenografts. American Association for Cancer Research, 2002.
 29. Galbreath, E, Westmore, M, Clapp, C, Considine, E, Delafuente, D, Galvin, R, **Keyes, K**, Ma, L, Martin, TJ, Teicher, B, Zambrano, C, Alvarez, E. Properties of bisphosphonates in the 13762 syngeneic rat mammary carcinoma model of tumor induced bone resorption. American Association for Cancer Research, 2002.
 30. Jasti B, Wiegand RA, **Keyes KA**, Grieshaber C, Valeriote F, Parchment R. Technical Feasibility of Placing Biopharmaceuticals Before *In vivo* Evaluation in Drug Discovery Programs. Molecular Targets and Cancer Therapeutics. Proceedings of the International Conference AACR-NCI-EORTC, 2000.

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31. **Keyes KA**, Albella B, LoRusso PM, Bueren JA, Parchment RE. Cytotoxic Chemotherapy Regimens that Increase Dose Intensity by Extending Daily Dosing from 5-days to 28-consecutive days and beyond. American Association for Cancer Research, 2000.
 32. Parchment RE, Jasti B, Kocarek TA, Wiegand RA, Kassab J, Wurster W, **Keyes KA**, Grieshaber C, LoRusso PM. Pharmacologic Issues for Fenretinide Chemotherapy. Molecular Targets and Cancer Therapeutics. Proceedings of the International Conference AACR-NCI-EORTC, 1999.

L A U R A L . P O L I N G

1365 BOYLSTON STREET, # 546, BOSTON, MASSACHUSETTS 02215
(617) 320-5278 | laura.poling@gmail.com

S U M M A R Y

Project-oriented, cancer-focused biochemistry and molecular biology scientist with almost five years experience in the biotechnology/pharmaceutical industry. Effective and motivating team leader efficient at multitasking, workflow prioritization, and organizing/analyzing high volumes of experimental data for several pipeline targets in parallel.

E D U C A T I O N

HARVARD UNIVERSITY - HARVARD MEDICAL SCHOOL, Cambridge/Boston, MA

Ph.D., Biological Chemistry and Molecular Pharmacology (2007)

PENNSYLVANIA STATE UNIVERSITY, University Park, PA

M.S., Genetics (2001)

B.S., Biology, Honors Biology; Minor Microbiology (1998)

P R O F E S S I O N A L E X P E R I E N C E

AVEO PHARMACEUTICALS, INC., Cambridge, MA

2008-2012

Scientist II, Drug Discovery (2010-2012)

- Led a team in all aspects of phage display and collaborated with internal project teams in setting goals and delegating tasks. Individual project components included antibody discovery, validation, *in vitro* biochemical characterization, and protein production.
- Successfully led the discovery of potential therapeutic, reagent, and/or surrogate antibodies for five target programs utilizing phage display libraries.
- Humanized monoclonal antibodies derived from hybridomas using three different methods: traditional CDR grafting with back mutation, human engineering based on site to site mutational risk level, and Superhumanization.
- Established and refined techniques and protocols to engineer antibodies toward therapeutic candidates (such as affinity maturation and sub-library generation).
- Implemented systematic approaches to identify new pipeline targets utilizing AVEO proprietary archives, screens, and databases; and designed key experiments for target validation.
- Drafted sections of a Patent application .
- Managed and mentored a direct report (an M.S. scientist).

Scientist I, Drug Discovery (2008-2010)

- Established phage display initiative as part of in-licensing phage display technology, and led phage display team.
- Served as main scientific liaison to ensure good rapport and working relationship with phage display technology contacts.
- Designed and implemented selection strategies to screen phage display libraries for potential therapeutic, reagent, and surrogate antibodies; and validated positive hits.
- Trained and supervised a direct report (an M.S. scientist).

DANA-FARBER CANCER INSTITUTE/HARVARD MEDICAL SCHOOL, Boston, MA

2002-2008

Postdoctoral Associate, David E. Fisher, current Director Melanoma Program – MGH (2007-2008)

- Integrated bioinformatics with molecular and biochemical approaches to identify new oncogenic mechanisms of the MiT family in melanoma.
- Explored functional role for TFE3 misexpression via oncogenic NFkB in melanoma.

Ph.D. Candidate (2002-2007)

Doctoral Advisor: David E. Fisher, current Director Melanoma Program – MGH

Dissertation: Dysregulation of the MiT family of transcription factors in melanoma

- Integrated bioinformatics with molecular and biochemical approaches to identify new oncogenic mechanisms of the MiT family in melanoma.
- Revealed functional role for TFE3 misexpression via oncogenic NFκB in melanoma.
- Discovered and validated genomic copy gain of TFEB as oncogenic in squamous cell carcinoma.

PENNSYLVANIA STATE UNIVERSITY, University Park, PA

1996-2001

Masters of Science Candidate (1999-2001)

Masters Advisor: S. Blair Hedges

Masters Thesis: Molecular Phylogenetics of Arthropods and Colonization of Land

- Integrated molecular clocks with phylogenetics to estimate the timing of body plan expansion with the changes of the chemical earth.
- Discovered a new sister relationship for myriapods and chelicerates using phylogenetics; metastudy with a combination of new genetic data and published sequences.

Undergraduate Honors Research (1996-1998)

Advisor: S. Blair Hedges

Thesis: Molecular Evolution of Enolase and a Re-examination of Reptile Phylogeny

- Redefined the position of turtles in the reptilian phylogenetic tree using gene sequences.
- Data collection and phylogenetic analyses as a contribution to: Kumar, S. and S.B. Hedges. 1998. A Molecular Timescale for Vertebrate Evolution. *Nature* 392: 917-920.

T E C H N I C A L E X P E R T I S E

Biochemistry: Octet, Biacore, ELISA, MSD, competition ELISA, ligand neutralization, and assay development.

Molecular Biology: Plasmid purification, cloning, PCR, western blot, immunoprecipitation, DNA/RNA isolation from tissue and cell lines, RT-PCR (TaqMan), nuclear run-on, FACS, affymetrix expression array, and SNP array analysis.

Cell Culture: Mammalian expression, transfections, viral infection, luciferase reporter assays, chromatin immunoprecipitation (ChIP), siRNA knockdown, cell proliferation and viability assays, apoptosis, colony forming assay, soft-agar assay, and immunofluorescence.

Antibody Engineering: Traditional humanization with back mutations, human engineering, *Superhumanization*, and affinity maturation (library sub-cloning, hotspot mutagenesis).

Phage Display: Antibody selection from phage libraries, antibody hit screening using ELISA, purification of Fabs using protein A, and conversion to IgG.

Robotics: Evo (Tecan) and EPMotion (Eppendorf)

T E A C H I N G A N D M E N T O R I N G

- **Mentor**, Mentoring in Science Program, Laboratory sessions Grade 8, Medical School (2004)
- **Teaching Assistant**, Biology Lab: Basic Concepts and Biodiversity in Biology, Pennsylvania State University (2000)
- **Teaching Assistant**, Biology Lab: Function and Development of Organisms, Pennsylvania State University(1999-2000)

INVITED LECTURES

- Washington and Jefferson University, Biology Honor Society Induction Ceremony, Washington, PA. (04.1999) **Poling, L.L.** A New Place for Turtles in the Family Tree of Reptiles.
- Pennsylvania State University, Eberly College of Science Alumni Association Meeting, University Park, PA. (04.1999) **Poling, L.L.** A New Place for Turtles in the Family Tree of Reptiles.

PUBLICATIONS

Original Manuscripts

- Bai, A., K. Meetze, N.Y. Vo, S. Kollipara, E.K. Mazsa, W.M. Winston, S. Weiler, **L.L. Poling**, T. Chen, N.S. Ismail, J. Jiang, L. Lerner, J. Gyuris, Z. Weng. 2010. GP369, an FGFR2-IIIb-specific antibody, exhibits potent antitumor activity against human cancers driven by activated FGFR2 signaling. *Cancer Res.* 70(19):7630-9.
- Ozsolak, F., **L.L. Poling**, Z. Wang, H. Liu, X.S. Liu, R.G. Roeder, X. Zhang, J.S. Song, D.E. Fisher. 2008. Chromatin structure analyses identify miRNA promoters. *Genes Dev.* 22(22):3172-83.
- Yokoyama, S., E. Feige, **L.L. Poling**, C. Levy, H.R. Widlund, M. Khaled, A.L. Kung, D.E. Fisher. 2008. Pharmacologic suppression of MITF expression via HDAC inhibitors in the melanocyte lineage. *Pigment Cell Melanoma Res.* 21(4):457-63.
- Pisani, D., **L.L. Poling**, M. Lyons-Weiler, and S.B. Hedges. 2004. The colonization of land by animals: molecular phylogeny and divergence times among arthropods. *BMC Biol.* 2(1):1.
- Hedges, S.B. and **L.L. Poling**. 1999. A Molecular Phylogeny of Reptiles. *Science* 283: 998-1001. (Cover article).

Scientific Review

- Feige, E., **L.L. Poling**, and D.E. Fisher. 2005. "MITF, critical regulator of the melanocyte lineage." Review. *Melanocytes to Melanoma: The Progression to Malignancy*. Hearing, V.J. and S.P.L. Leong, ed. Humana Press.

Abstracts/Posters

- Bai, A., K. Meetze, N.Y. Vo, S. Kollipara, E.K. Mazsa, W.M. Winston, S. Weiler, **L.L. Poling**, T. Chen, S. Haserlat, S. Abbott, H. Tissire, M. DiPrima, N.S. Ismail, J. Jiang, L. Lerner, J. Gyuris, Z. Weng. 04.2011. Essential role of fibroblast growth factor receptor 2 (FGFR2) in tumorigenesis of human cancers with activated FGFR2 signaling demonstrated by functional blocking antibodies. AACR 102nd Annual Meeting. Orlando, FL.
- **Poling, L.L.**, M. Lyons-Weiler, and S.B. Hedges. 04.2001. Independent Land Colonization Events by Myriapods and Hexapods. NASA All-hands Conference. Washington DC.
- **Poling, L.L.**, M. Lyons-Weiler, and S.B. Hedges. 04.2000. Molecular Phylogeny of Arthropods. NASA Astrobiology Conference. NASA AMES, CA.
- **Poling, L.L.** and S.B. Hedges. 07.1998. Molecular Data Support a Turtle-Archosaur Relationship. Howard Hughes Summer Institute. Pennsylvania State University, State College, PA.

D A R R E N R A N D A L L P O T Z

62 FOREST STREET, NEWTON HIGHLANDS, MASSACHUSETTS 02461
(857) 373-9890 | drpotz@hotmail.com

S U M M A R Y

Accomplished and driven researcher with over 15 years of experience in the biotechnology/pharmaceuticals industry. Strong background in *in vivo* pharmacology, protein biochemistry, and cell and molecular biology. Consistently proven ability to exceed goals and effectively multi-task. Recognized as very adaptable and resourceful when faced with new challenges.

E X P E R I E N C E

AVEO ONCOLOGY, Cambridge, MA

2008-2012

Associate Scientist

- Comprehensive set of *in vivo* pharmacology skills applied to a wide variety of projects.
- Designed and executed large, multi-arm drug efficacy and PK/PD studies using various small molecule and antibody-based cancer drug therapies in tumor-bearing mice. Formulated drugs such as tivozanib, sorafenib (Nexavar), crizotinib, ficlatuzumab, and MEK inhibitor compound. Ran related toxicological studies in various models.
- Adept in different modes of drug administration (oral gavage, IP, and IV).
- Carried out *in vivo* bioluminescent imaging and analysis of primary lung and breast tumors in chimeric mice (Caliper Life Science IVIS Spectrum System).
- Performed commonly-used blood and tissue collection techniques in mice.
- Led effort to build and characterize large archive of hepatocellular carcinoma (HCC) tumor lines expressing mutations relevant to patient populations. Completed ahead of schedule, helping to achieve a major milestone with corporate partner, OSI/Astellas. Received award from company.
- Co-led effort to propagate and characterize patient-derived tumor xenografts (PDXs) of different tissue types in mice for generation of an in-house Human Tumor Archive. Employed SQ trocar implantation of tumor pieces and SQ injection of cell suspensions for propagation.
- Familiar with proper handling and administration of anesthetics and analgesics in mice such as isoflurane, buprenorphine, and flunixin.

Ex vivo characterization assays, Cell and Molecular Biology techniques, and related analytical experience.

- Experience in a wide range of tissue culture work including transfections, mouse ES cell cloning, *in vitro* drug compound testing, and reporter assays, such as SEAP Fluorescence Detection System.
- Protein expression analysis of tumor cell lysates on Multi-Spot MSD ELISA and quantitative Western Blot analysis using LI-COR System. Worked independently to develop assays that helped to elucidate mechanisms of action and pathways employed in cancer models.
- Conducted genotyping of tissues: Primer testing, DNA/RNA isolation followed by PCR and RT-PCR analyses.
- Cloning, ligations, gel spot extraction, and purification.
- Carried out IHC assays and histological image analysis on Aperio ScanScope digital slide scanner and Spectrum imaging software.
- Performed tissue embedding, sectioning, and staining (both manual and with Leica Autostainer).

MATRITECH, INC. /INVERNESS MEDICAL INNOVATIONS, Newton, MA

1995-2008

Senior Research Associate

- Co-led creation and use of a breast cancer xenograft model in mice.
- Performed transient and stable transfections in mouse mammary-ca line 4T1.
- Performed injections and tracked levels of GFP-tagged tumor marker in plasma as disease progressed.
- Measured tumor growth and harvested organs for *ex vivo* culture and downstream analysis.
- Played integral role in the discovery and development of the cervical cancer protein marker NMP179 (part of an automated Pap Screen test further developed by Sysmex Corp.)
- Ran and analyzed 2-D gels of extracted nuclear matrix proteins for identification of potential tumor markers.
- Key player in the development of an ICC-based screening assay for NMP179.
- Performed ICC/IHC staining and analysis of specimens in preclinical studies.

- Carried out digital image analysis of ICC-stained specimens (Image Pro software).
- Led tissue culture and hybridoma labs.
- Cultured a variety of mammalian lines for cell fractionation, transfection and cloning, cell synchronization, blast transformation, and IFA/ICC analysis.
- Performed mouse immunizations and fusions, screened and subcloned hybridomas for generation of tumor marker-specific monoclonal antibodies.
- Carried out protein extractions and purifications followed by Western Blot, ELISA, Biacore, 2-D SDS-PAGE, and MS analyses.
- Managed extensive inventories of cell lines, tissue, sera, and mouse ascites.

E D U C A T I O N

Masters ALM, Biology, HARVARD UNIVERSITY EXTENSION SCHOOL, Cambridge, MA

Thesis: Consequences of Cell Cycle-Related Phosphorylation of the Tumor Marker NMP179 on Immunological Detection

Bachelor of Arts, Biology and Psychology, UNIVERSITY OF ROCHESTER, Rochester, NY

P U B L I C A T I O N S

Papers:

- Keese SK, Meyer JL, Hutchinson ML, Cibas ES, Sheets EE, Marchese J, Oreper A, **Potz D**, Wu Y-J. Preclinical feasibility study of NMP179, a nuclear matrix protein marker for cervical dysplasia. *Acta Cytologica*, 1999; 43(6):1015-1022.
- Keese SK, Marchese J, Meneses A, **Potz D**, Garcia-Cuellar C, Szaro R, Solorza G, Osornio-Vargas A, Mohar A, de la Garza JG, Wu Y-J. Human cervical cancer-associated nuclear matrix proteins. *Experimental Cell Research*, 1998; 244:14-25.
- Xu B, Keese SK, Meyer JL, Oreper A, **Potz D**, Schellenberg Y, Quddus MR, Wu Y-J, Hutchinson M. The use of NMP179, a unique nuclear matrix marker, for prediction of behavior of cases designated as ASCUS: a pilot study. *Acta Cytologica*, 1998; 42(5).

Abstracts/Presentations:

- Farlow S, **Potz D**, Zi T, Sun X, Lin J, Chiu MI, Robinson MO, Heyer J, Zhou Y. Variation in response to triple VEGFR inhibitor tivozanib in mouse models of hepatocellular carcinoma. AACR-EORTC-NCI Molecular Targets and Cancer Therapeutics Meeting, Boston, MA, 2009.
- Keese SK, Marchese J, **Potz D**, Obar R, Szaro RP, Wu Y-J. Nuclear matrix proteins in human cervical cancer. International Society for Oncodevelopmental Biology & Medicine Meeting, San Diego, 1996.
- Keese SK, Meyer JL, Marchese J, Oreper A, **Potz D**, Wu Y-J. A unique nuclear matrix protein as a cervical tumor marker. American Association of Cell Biology Meeting, Washington, DC, 1997.
- Keese SK, Meyer JL, Sheets E, Cibas E, Hutchinson M, Marchese J, Oreper A, **Potz D**, St. Clair J, Wu Y-J. A unique nuclear matrix protein marker for cervical dysplasia. AACR, 1998.
- **Potz D**, Rideout WM, Zi T, Bressel A, Monti A, Brodeur J, Chiu MI, Jacks T, DePinho RA, Robinson MO, Zhou Y, Heyer J. Development and use of chimeric lung cancer models in cancer drug discovery. Cold Spring Harbor Labs Mechanisms & Models of Cancer Meeting, Cold Spring Harbor, NY, 2010.
- Stoerker J, Fagan G, Kumar S, **Potz D**, Cooley S, Qiu H, Cheng F, Szaro R, Durda P. Novel biomarker in plasma correlates with disease progression in a mouse model of breast cancer. AACR, Washington, DC, 2006.
- Wu Y-J, Keese SK, Beech S, Oreper A, **Potz D**, Hutchinson M. NMP179 - a nuclear matrix protein marker of occult high grade cervical dysplasia in ASCUS patients. AACR, San Francisco, CA, 2000.
- Zhou Y, Farlow S, Zi T, Jesmer K, Bressel A, **Potz D**, Chiu MI, Robinson MO, Heyer J. Mouse models of hepatocellular carcinoma exhibit features of VEGF-driven angiogenesis. AACR, Denver, CO, 2009.
- Zhou Y, Zi T, Jesmer K, Bressel A, **Potz D**, Monti A, Brodeur J, Rideout WM, Chiu MI, Robinson MO, Heyer J. Preclinical efficacy of the triple VEGFR inhibitor tivozanib (AV-951) in chimeric breast and lung tumor models. AACR, Washington, DC, 2010.

Hamid Tissire

416 Thayer Street, Abington, MA, 02351, (617) 899-2901, tissire@gmail.com

Summary

- Experienced in Protein Biochemistry, Cell and Molecular Biology
- Quick learner, strong attention to details and ability to handle multiple tasks
- Excellent laboratory techniques
- Good data management and record keeping skills
- Expertise with kinetic/interaction analysis platforms
- Experienced with laboratory automation
- Ability to work in a multi-disciplinary team environment

WORK EXPERIENCE

AVEO Oncology, Cambridge, MA, 2007-2012

Senior Research Associate: Antibody Engineering

- Diverse responsibilities focusing on the identification, characterization, and engineering of antibodies
- Protein biochemistry:
 - Kinetic analysis of potential drug candidates using Biacore T100, KinExA and Octet
 - Experimental design and assay development
 - Pharmacokinetic and pharmacodynamic assay development and sample analysis using Meso Scale Discovery instrumentation
 - ELISAs
- Cell culture and molecular biology: routine cloning and expression of antibodies and other soluble proteins by transient transfection of mammalian cells
- Antibody affinity maturation: development of a platform technology using mammalian cells to screen and isolate high-affinity monoclonal antibodies
- Antibody phage display technology: panning, screening, and Fab purification
- Assisted and trained a lab member to use Biacore
- Wrote SOP's for certain lab techniques and assay development

Hynes Lab, Center for Cancer Research, MIT, Cambridge, MA, 2004 – 2007

Studies and Research in The Molecular Basis of Cell Adhesion in Normal and Pathological Situations

Research Assistant

- Assist two post Doc in several research projects
- Perform tissue culture, experience with analytical detection methodologies such as real-time PCR, immunochemical techniques for digoxigenin (DIG) labeling and ELISA, Southern blot, Western blot, PCR, immunoprecipitation, FACS, migration assays, basic bioinformatics analysis, subcloning, cloning of expression constructs, RNAi hairpins viral library construction

Cereon Genomics, Subsidiary of Monsanto, Cambridge, October 2000- June 2002

Research Associate, Monsanto Enterprise Cloning Group

- Cloned 5' ends of plant genes using RACE approach, subcloned PCR fragment
- Assembled full-length open reading frames *in silico*
- Optimized RT-PCR conditions for long RACE
- Designed RACE and nested primers using DNA Start software
- Analyzed DNA sequence results using Sequencher software

Research Technician II, Monsanto Transcription Profile Group

- Operated automation instrument: Tecan Robot/Gemini software, Biomek FX Robot, and Zymark
- Improved PCR fragments production: DNA amplification using different SOP's and MJ thermal cycles, visualizing and sizing of PCR fragments generated using Alpha-ease software
- Tested and implemented multiple software systems into process: Alpha-imager/Alpha-ease, Perl_script, PCR Lims, Agilent software, Spectrometer software and Micro re-array
- Performed large scale RNA purification from different plant tissues
- Trained internal staff to improve their skills
- Participated in hiring and training two new laboratory technician contractors
- Developed and maintained SOP's & database
- Improved existing software resulting in more than 10% reduction in cost of our process

Recruiter Adviser, IFIAG Institute, Rabat, Morocco, January 1998-March 1999

- Established connections between company's managers and their ideal candidates
- Identified candidate's areas of expertise by selecting resumes and interviewing candidates.
- Developed good communication skills.

Laboratory Assistant, Hygiene Institute, Rabat, Morocco, March 1997-January 1998

- Biochemistry Department: prepared samples of imported spring water or tap water for different analysis, determined water physicochemical and mineral characteristics for safety purposes.
- Pathology research Department: used ELISA Analysis to detect infectious diseases as Hepatitis and HIV in blood samples

Publications and training:

- Ulcerative colitis and autoimmunity induced by loss of myeloid v integrins: Adam Lacy-Hulbert*, Aileen M. Smith*, Hamid Tissire, Marc Barry, Denise Crowley, Roderick T. Bronson, Jurgen T. Roes, John S. Savill*, and Richard O. Hynes

- Attended two Biacore training classes: Introduction to Biacore T100 and Advance Kinetic and Affinity Analysis with Biacore
- Phage display training by Dyax

EDUCATION _____

Tufts university, Medford, MA, **December 2005**

Master of Science, Major: Biology, Minor: Biotechnology.

Course Highlights: Molecular Biotechnology, Molecular Biology, Biotechnology Project Laboratory, Biomaterial & Tissue Engineering, Topics in Inflammation, Immunology, Cell Biology, Microbe & Cell cultivation, Topics in Molecular & Cell Biology

Research proposals:

- Monoclonal antibody (IL2) encapsulated alginate beads for the treatment of prostate cancer.
- The Role of alpha v Integrin in Inflammatory Arthritis

Boston University, Boston, MA, **Summer 2000**

Course summary: Principles of Biology II and Biotechnology

Mohamed V University of Science, Rabat, Kingdom of Morocco, **June 1996**

Bachelor's Degree: PLANT BIOLOGY, Minor BIOCHEMISTRY

Other Experience _____

Sebastian's Catering, Boston, **November 2002**

- Worked as a waiter for food service.
- Parties organization and special events

The Atlantis Group, Inc, Newton, **December 2000**

- Boundary Surveys, Environmental surveys, Land surveying rod man

COMPUTER SKILLS _____

MS Word-processing programs, Excel, Powerpoint, Sequencher, DNA Star, DNA strider, Vector NTI, SeqMan, Bioedit, Biacore and Octet software

"Please note that my references contacts are available up on request"

ARNOLD SENGOOBA

92 DEVIR STREET, APARTMENT 408, MALDEN, MASSACHUSETTS 02148
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SUMMARY

Research Scientist passionate about preclinical and biomarker development. Participated in collaborative efforts that resulted in funding for pipeline projects and added overall value to the company. An enthusiastic, hardworking, and sociable individual seeking to join a dynamic workforce.

TECHNICAL EXPERIENCE

- Western blot
- Flow cytometry: cell surface binding of Ron and Met receptors
- Multiplex assays: Multiplex Elisa (MSD)
- Cell culture: isolation and maintenance of primary and tumor-derived cell lines
- Animal work: dosing, fluorescence imaging, tissue isolation, minor surgery, heart bleed, tumor implantation, tumor propagation, bone marrow extraction

RESEARCH EXPERIENCE

AVEO PHARMACEUTICALS

2009-2012

Research Associate II

- *In vivo* testing of various preclinical drug candidates (AV-299 and OSI-027).
- Participated in the development of a metastatic mouse model.
- Investigated biomarkers as potential drug targets.
- Investigated the role of the tumor microenvironment in cancers particularly in the context of macrophages.
- Performed experiments with the focus of developing pipeline components like AV-299 (Met antibody) through *in vivo* pharmacology and *in vitro* assays.

EDUCATION

Master of Science, Biotechnology, NORTHEASTERN UNIVERSITY, Boston, MA (January 2013)
Fields of study: Biotechnology, Pharmaceutical Sciences

Bachelor of Science, Biology, UNIVERSITY OF MASSACHUSETTS AMHERST, Amherst, MA (2007)

ROBERT W. SHINE

14 HAMMOND COURT, QUINCY, MASSACHUSETTS 02169
(508) 558-3390 | rshine@bu.edu | www.linkedin.com/in/rshine1

SUMMARY

Molecular biologist with over four years of academic and industry experience. Special expertise in various tissue culture systems, protein biochemistry, and genetic manipulation/cloning. Recognized as a driven, confident researcher with strong communication and project management skills.

RESEARCH EXPERIENCE

AVEO PHARMACEUTICALS, INC., Cambridge, MA 02/2012-10/2012

Research Associate II, Cancer Biology Model Development Group

- Provided molecular biology support to the model development team.
- Characterized several propagated tumor lines by DNA sequencing.
- Created targeted insertion vector and used it to create three ESC lines.
- Aided group in animal husbandry and began *in vivo* pharmacology study.

NOVARTIS INSTITUTE FOR BIOMEDICAL RESEARCH, Cambridge, MA 01/2012-01/2012

Scientific Associate II (Contract Position)

- Cultured cancer cell lines, extracted protein and RNA, then optimized Western blot antibodies and qPCR primer sets.

BOSTON UNIVERSITY SCHOOL OF MEDICINE, Boston, MA 09/2007-12/2011

Graduate Student, Biochemistry

- Investigated mechanisms of vascular smooth muscle cell proliferation.

UNIVERSITY OF NEW HAMPSHIRE, Durham, NH 09/2003-05/2007

Student Research Assistant, Biochemistry

- Aided in general lab maintenance and basic procedures.

TECHNICAL SKILLS

Cell Culture:

- Primary cell isolation (aortic smooth muscle cells)
- Mammalian cell culture (293, 3T3, 10T1/2)
- Stable cell line generation and characterization
- Lentiviral overexpression of protein
- siRNA knockdown of target gene using electroporation
- Transient transfection
- Proliferation assays: ³H-thymidine, MTT, BrdU
- Murine embryonic stem cell culture
- Electroporation of murine ESC and selection for expressing clones

Molecular Biology:

- gDNA and RNA isolation from cells and tissue
- qRT-PCR
- DNA plasmid cloning and subcloning
- Site-directed mutagenesis
- BAC library creation for partial genome sequencing
- Microarray data analysis
- Southern and Northern blotting

Protein Biochemistry:

- Recombinant protein expression- bacterial and mammalian (293) system
- Recombinant protein purification- BioRad DuoFlow chromatography
- SDS-PAGE, Western blotting
- Immunoprecipitation

Microscopy:

- Immunofluorescence
- Confocal
- Managing Transgenic and Knockout Mouse Colony

***In vivo* pharmacology:**

- Tumor measurement
- Intraperitoneal injection of study drug and control
- Limited experience in sub-cutaneous injection
- IVIS imaging of luciferase *in vivo*

E D U C A T I O N

MA, Biochemistry, BOSTON UNIVERSITY SCHOOL OF MEDICINE, Boston, MA (2012)

BS, Biochemistry, *cum laude*, UNIVERSITY OF NEW HAMPSHIRE, Durham, NH (2007)

R E L E V A N T C O U R S E W O R K

- Cell biology, Molecular biology, Biostatistics, Drug Discovery & Development
- Microbiology, Genetics

A W A R D S A N D S C H O L A R S H I P S

Dean's Scholarship, University of New Hampshire, Durham, NH (2003-2007)

Scholarship, Massachusetts Biotechnology Research Council (2003)

Eagle Scout, Boy Scouts of America, Taunton, MA (2001)

C O M P U T E R S K I L L S

- Experience in both PC and Mac systems
- Highly experienced in Microsoft Word, Excel, PowerPoint, Adobe Illustrator
- Proficient in Microsoft Access, FileMaker Pro, Photoshop, ImageJ, EndNote, KaleidaGraph

P U B L I C A T I O N S

- Schissel SL, Dunsmore SE, Liu X, **Shine RW**, Perrella MA, and Layne MD. Aortic carboxypeptidase-like protein is expressed in fibrotic human lung and its absence protects against bleomycin-induced lung fibrosis. *Am. J. Path.* 174(3):818-28. March 2009.

A B S T R A C T S

- **Shine, RW**, Kandror, EK, and Layne, MD. "The Role of Aortic Carboxypeptidase-Like Protein In Vascular Smooth Muscle Cell Proliferation" (Poster Presentation) Henry I. Russek Student Achievement Day, Boston University School of Medicine, 2011.
- Schissel, SL, **Shine, RW**, Brown, RD, Perrella, MA, and Layne, MD. "Aortic Carboxypeptidase-Like Protein, a Discoidin Domain Protein, Regulates Lung Fibroblast Lamellipodia Formation and Collagen Contraction." [Poster Board #B67]. *Am J Respir Crit Care Med* 79; 2009; A3486.

WEI YIN, P.H.D.

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(617) 484-4166 [H] • (617) 767-6360 [C] • weikyin@hotmail.com

OBJECTIVE

A challenging position where I can contribute to pharmaceutical R&D programs using my extensive experience in clinical pharmacology, population PK/PD modeling and simulation, and DMPK.

SUMMARY

Extensive hands-on and leadership experience in clinical pharmacology, population PK/PD modeling and simulation, and DMPK; supported multiple IND projects for both small and large molecules, and two completed NDA.

EXPERIENCE

Aveo Pharmaceuticals, Inc.

2011-Present

Associate Director, Clinical Pharmacology

Provided leadership in clinical pharmacology for large molecule programs; supported one IND project for a large molecule and one completed NDA; study director of a hepatic impairment study.

- Ficlatusumab, a humanized HGF inhibitory antibody that is being developed to treat solid tumors.
 - Led and developed clinical pharmacology strategies and plans/timelines.
 - As a member of the Global Development Team, contributed to the clinical development plan and overall program development strategy.
 - Provided functional input on the design of clinical studies and resolution of rising issues.
 - Led the design of a clinical comparability study.
- AV-203, a humanized ERBB3 inhibitory antibody that is being developed to treat solid tumors.
 - Led and developed clinical pharmacology strategies and plans/timelines.
 - Provided functional input on the design of FIH study and resolution of rising issues.
- Tivozanib, a VEGF receptor inhibitor that is being developed to treat solid tumors.
 - Completed NDA filing package for Clinical Pharmacology and DMPK sections.
 - Managed population PK and PK/PD analysis using NONMEM.
 - As study director, led the design of a hepatic impairment study, developed the study protocol, and managed the execution of the study.

Antisoma, Inc. (formerly Xanthus Pharmaceuticals)

2007-2011

Director, Clinical Pharmacology (2010-2011)

Associate Director, Clinical Pharmacology (2007-2010)

- Oral fludarabine, a purine analog for the treatment of chronic lymphocytic leukemia.
 - Co-led a successful pre-IND/NDA meeting with FDA for oral fludarabine.
 - Led the design of a clinical PK/ECG study; conducted PK/PD analysis.
 - Completed NDA filing package for Clinical Pharmacology and DMPK sections (NDA approved in December 2008).
- Amonafide, a small molecule DNA intercalator developed to treat acute myeloid leukemia (AML).
 - Led a successful pre-NDA Clinical Pharmacology meeting with FDA; FDA agreed with the Clinical Pharmacology and pre-clinical DMPK studies for NDA filing.

- Conducted population PK analysis for a Phase II study using NONMEM.
- Led the Clinical Pharmacology discussion with EMEA and submission of a Pediatric Investigation Plan.
- For other programs, developed pre-clinical DMPK and clinical pharmacology strategies and specific plans/timelines; conducted/managed pre-clinical DMPK and pharmacology/toxicology studies; conducted population PK and PK/PD analysis (modeling and simulation) using NONMEM and WinNonlin; led dose defining/selection, proof of concept, early clinical trial design, bioanalysis (GLP and non-GLP), and full clinical pharmacology development in multiple pre-clinical and Phase I and II programs.
 - HuHMFG1 (AS1402), a recombinant DNA-derived humanized monoclonal antibody that targets the immunodominant epitope of the MUC1 gene product and has undergone multiple Phase I and II trials in breast cancer.
 - AS1409, a fusion protein comprising a humanized antibody BC1 linked to interleukin-12 (IL-12), designed to deliver IL-12 to tumor-associated vasculature and has undergone a Phase I study in renal cell carcinoma and malignant melanoma.
 - AS1411, an anti-cancer aptamer that targets nucleolin on cancer cells and has undergone multiple Phase II studies to treat AML and renal cell carcinoma.
 - C-1311, a TopoII inhibitor and DNA intercalator and a member of the novel imidazoacridinone family of anticancer agents.
 - Over ten other small molecule clinical and pre-clinical programs in the treatment of cancer and auto-immune diseases.
- Represented Clinical Pharmacology and DMPK, as a core team member in licensing activities.

Millennium Pharmaceuticals

2002-2007

Scientist II, Drug Metabolism and Pharmacokinetics (2005-2007)

Scientist I, Drug Metabolism and Pharmacokinetics (2002-2005)

- PK/PD modeling and simulation.
 - Conducted PK/PD modeling and simulation for Velcade[®], the first oncology drug marketed by Millennium.
 - Investigated interspecies PK differences; conducted allometric scaling and PBPK/mechanistic modeling to predict human PK.
- In the pre-clinical discovery and development setting, represented DMPK as a Primary Investigator and Project Leader.
 - Member of joint development teams with Sanofi-Aventis and Johnson & Johnson.
 - Supported over ten inflammation, oncology and metabolic disease pre-clinical and clinical projects, including Velcade[®].
- As DMPK Primary Investigator, led activities to select potent and selective candidates that had appropriate predicted PK properties in humans, namely good oral bioavailability, suitable effective $t_{1/2}$, clean of potential DDI, PGP, transporter, and reactive metabolite issues. Supported the nomination of Drug Candidates (DC). Prepared technical reports for IND filing.
- Supervised and led a discovery and development DMPK laboratory.
 - Designed and executed *in vivo* drug disposition studies in mouse, rat, dog, and primate (iv, po, and sc; including protocol generation, dose formulation, in-life study conduct, pharmacokinetic data analysis, and data reporting), *in vitro* metabolic stability testing, protein binding, Caco-2 permeability and p-glycoprotein efflux inhibition, plasma stability, metabolite profiling by LC/MS/MS, reactive metabolite screening, CYP450 inhibition, and mechanism-based inhibition studies.

- Designed and executed PK/TK studies, and addressed PK/TK issues. Provided PK/TK support of drug candidates for preclinical studies.
- Developed and validated *in situ* liver perfusion system. Designed and supervised liver perfusion studies to investigate the uptake, metabolism, and excretion of lead compounds in liver.
- Elucidated proof-of-concept in animal models; designed and conducted studies to understand the PK/PD relationship; investigated whether efficacy depends on C_{max} or AUC (or duration of exposure), and how tissue distribution and metabolism affect *in vivo* efficacy.
- Through SAR, addressed such issues as structural metabolic liability, restricted tissue distribution, CYP450 inhibition, and metabolism-mediated *in vitro* genotoxicity (CHO micronucleus).

EDUCATION

Ph.D. in PK and Pharmaceutical Sciences, May 2002, University of Texas at Austin, Austin, TX
Title of thesis: Morphometric Studies of the Microvilli of the Small Intestine of Rats in the Presence of Cyclosporine and Its Formulation Excipients – Pharmacokinetic and Pharmacodynamic Considerations. Advisor: Dr. Salomon Stavchansky

B.S. in Pharmacy, July 1993, Beijing University Medical Center, Beijing, P.R. China

RECENT PUBLICATIONS

- **W. Yin**, E. V. Karyagina, A. S. Lundberg, D. J. Greenblatt and J. Lister-James 2010 Pharmacokinetics, bioavailability and effects on electrocardiographic parameters of oral fludarabine phosphate. *Biopharm Drug Dispos* 31(1), 72-81.
- B. Royer, **W. Yin**, M. Pegram, N. Ibrahim, C. Villanueva, D. Mir, F. Erlandsson and X. Pivot 2010 Population pharmacokinetics of the humanised monoclonal antibody, HuHMFG1 (AS1402), derived from a phase I study on breast cancer. *Br J Cancer* 102(5), 827-832.
- N. Isambert, M. Campone, E. Bourbouloux, M. Drouin, A. Major, **W. Yin**, P. Loadman, R. Capizzi, C. Grieshaber, P. Fumoleau 2010 Evaluation of the safety of C-1311 (SYMADEX) administered in a phase 1 dose escalation trial as a weekly infusion for 3 consecutive weeks in patients with advanced solid tumours. *Eur J Cancer* 46(4), 729-734.
- **W. Yin**, L. S. Gan, J. T. Wu, S. K. Balani, H. Yang, and F. W. Lee 2007. An indirect screen for brain uptake of 1,2-diaryl-ethane melanocortin 4 receptor antagonists in rats. *Drug Met Lett* 1(3), 195-198.
- T. Jenkins, B. Guan, M. Dai, G. Li, T. E. Lightburn, S. Huang, B. S. Freeze, D. F. Burdi, S. Jacutin-Porte, R. Bennett, W. Chen, C. Minor, S. Ghosh, C. Blackburn, K. M. Gigstad, M. Jones, R. Kolbeck, **W. Yin**, S. Smith, D. Cardillo, T. D. Ocain, and G. C. Harriman 2007. Design, synthesis, and evaluation of naphthalene-sulfonamide antagonists of human CCR8. *J Med Chem* 50, 566-584.
- D. F. Burdi, S. Chi, K. Mattia, C. Harrington, Z. Shi, S. Chen, S. Jacutin-Porte, R. Bennett, K. Carson, **W. Yin**, V. Kansra, J.-A. Gonzalo, A. Coyle, B. Jaffee, T. Ocain, M. Hodge, G. LaRosa and G. Harriman 2007. Small molecule antagonists of the CC chemokine receptor 4 (CCR4). *Bioorg Med Chem Lett* 17, 3141-3145.
- L.-S. Gan, F.W. Lee, N. Nagaraja, P. Li, J. Labutti, **W. Yin**, C. Xia, H. Yang, V. Uttamsingh, C. Lu, S. Pusalkar, J.S. Daniels, R. Huang, M. Qian, J.-T. Wu, K. Cardoza, S.K. Balani, and G.T. Miwa 2006. "Case History – Use of ADME Studies for Optimization of Drug Candidates" *Optimization the "Drug-Like" Properties of Leads in Drug Discovery*. Ron Borchardt et al. ed., Springer press. 81-97.

J I A N H U A Z H A O

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S U M M A R Y

Biomedical researcher with ten years of experience in multiple laboratories including six years in the pharmaceutical industry. Proficient in numerous molecular biological techniques and great at both team and independent work. Additionally, three years of administrative experience focusing on research organization and project collaborations between pharmaceutical companies. Recognized for strong communication and interpersonal skills.

E X P E R T I S E

Integrating Research Background into Administrative Support for Research Organization

1. Coordination for project collaborations
2. Due diligence on research literatures and publications
3. Documentation and Records Tracking
4. Meeting and event arrangement

Histology and Immunology

1. Tissue processing, embedding and sectioning
2. Immunohistochemistry, Immunofluorescence, and H&E staining
3. Histological automation operation (Leica APS300, CV5030, ST5020, BOND-MAX, and Aperio ScanScopeXT)
4. Western blotting

Molecular and Cell Biology

1. Nucleic acids and protein extraction from cells and tissues
2. PCR and RT-PCR
3. Cell culture
4. Transfection and infection of cells
5. Plasmid construction, basic cloning, and sub-cloning
6. Northern blotting and Southern blotting

Medical Genetics

1. Chromosome preparation from solid tumor, cell lines, and blood cells
2. G-banding technique and Karyotyping

E X P E R I E N C E

AVEO ONCOLOGY, Cambridge, MA

2006-2012

Senior Research Associate (2006-2012)

1. Conducted histology studies of multiple tumor types in order to screen and validate tumor biomarkers; daily operated tissue processing as part of Histology Core service to support all research groups of the company.
2. Generated, monitored, and propagated numerous Directed Complementary tumor models for internal tumor targets discovery program, as well as collaborations with other pharmaceuticals.
3. Validated tumor models' authenticity by RT-PCR, Western Blotting, IHC, etc. to support translational research and pre-clinical programs.

Administrative Assistant, Research Department (2009-2012)

Additional responsibility to Senior Research Associate

1. Integrated research knowledge into administrative coordination to better support the research department and also saved the company's personnel budget.
2. Coordinated internal and external collaborations, and helped the company to achieve several milestone successes based on collaborations.

BETH ISRAEL DEACONESS MEDICAL CENTER,DIVISION OF ANGIOGENESIS AND CANCER BIOLOGY, Boston, MA

2004-2006

Research Fellow

1. Conducted gene profile analysis in VEGF-induced angiogenesis mouse model.
2. Extracted high-quality RNA from mouse ear and skin tissues and verified gene chip results using real-time PCR, IHC, and Western blot.
3. Constructed wild type and mutant genes into retrovirus vector for functional study.

NEW YORK UNIVERSITY SCHOOL OF MEDICINE,DEPARTMENT OF ENVIRONMENTAL MEDICINE, Tuxedo, NY

2002-2004

Research Associate

1. Confirmed gene chip results using Northern blot to select gene targets related to Ni carcinogenesis.
2. Explored mechanisms of Ni, Co, and hypoxia carcinogenesis.

E D U C A T I O NHARVARD UNIVERSITY EXTENSION SCHOOL, Cambridge, MAGraduate Credit, **Immunology**Undergraduate Credit, **Essentials of Executive Speaking**Undergraduate Credit, **Fundamentals of Academic Writing**PEKING UNION MEDICAL COLLEGE AND CHINESE ACADEMY OF MEDICAL SCIENCES, STATE KEY LABORATORY OF MOLECULAR ONCOLOGY (SKLMO), Beijing, China**Ph.D.**, Cell Biology

Evaluated non-peptidic small-molecule HDM2 inhibitors based on p53-HDM2 complex structure for new cancer drug discovery program.

HARBIN MEDICAL UNIVERSITY, DEPARTMENT OF BIOLOGY AND GENETICS, Harbin, China**MS**, Biology and Genetics

Conducted cytogenetically biomarker study in fresh surgical samples from human ovarian cancer patients.

HARBIN MEDICAL UNIVERSITY, Harbin, China**BS/MD**, Clinical Medicine**L A N G U A G E S**

English and Chinese (Mandarin)

A W A R D S

1. Collaboration Accomplishment Team Award, AVEO Oncology (2011)
2. Collaboration Administrative Support Spot Award, AVEO Oncology (2011)
3. Project Accomplishment Team Award, AVEO Oncology (2007)
4. Metals Specialty Section Award, Society of Toxicology (SOT) meeting (2003)

P U B L I C A T I O N S

1. Zhao J, Chen H, Davidson T, et al. *Toxicol Appl Pharmacol.* 2004 May 1; 196(3): 404-9.
2. Zhao J, Yan Y, Salnikow K, Kluz T, Costa M. *Toxicol Appl Pharmacol.* 2004 Jan 1; 194 (1): 60-68.
3. Zhao J, Wang M, Chen J, Luo A, Wang X, Wu M, Yin D, Liu Z. *Cancer Lett.* 2002 Sep 8; 183(1): 69-77.
4. Zhao Jianhua, Liu Zhihua, Yin Dali, et al. *Chinese Journal of Cancer.* 2001, 20 (4):354-357.
5. Zhao Jianhua, Wang Xiuqin, Liu Zhihua, et al. *Progress in Biochemistry and Biophysics.* 2000, 27(1): 6-8.
6. Liu Guizhong, Zhao Jianhua, Wang Xiuqin. *Progress in Physiology Science,* 2000, 31(4): 337-340.
7. Zhao Jianhua, Song Yan, Xia Jianchuan, et al. *Chinese Journal of Medical Genetics,* 1999, 16(3): 199-200.
8. Zhao Jianhua, Liu Quanzhang. *Foreign Medical Sciences (Genetics),* 1998, 21(4):195-199.

C O N F E R E N C E P R E S E N T A T I O N S

1. Miami Nature Biotechnology Winter Symposium. Feb 4-8, 2006, Miami, FL.
2. BIDMC Vascular Biology Research First Annual Research Retreat. Feb 5, 2005, Boston, MA.
3. SOT annual meeting. Mar 9-13, 2003, Salt Lake City, UT, USA

KELLY A. DONAHUE

130 CLOVER HILL ROAD, WHITINSVILLE, MASSACHUSETTS 01588

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SUMMARY

Versatile Biotech Professional holding roles in Analytical Development, Quality Control, and Quality Assurance with a focus in the method development life cycle from assay development to commercial testing.

- Successful cross functional collaboration for testing support for process validation/comparability and manufacturing investigations. Cross site collaboration for successful method transfer and validation.
- Support writing and reviewing activities for regulatory documents including IND, PIA, PMA, Briefing Document, DSUR updates, and responses to regulatory questions.
- Experience in electronic systems including ELS Smartlab[®], Trackwise[®], Compliance Suite[®], Sample Manager LIMS[®], and Empower[®].
- Effective management of projects of small to moderate scope within the Biotechnology Industry related to high volume testing and startup of a Quality Control Laboratory.
- Subject Matter Expert participation in FDA and Mock PAI Audits.

AREAS OF EXPERTISE

- Methods development, qualification, transfer, and validation per ICH guidelines.
- Technical Writing – technical reports, method validations, regulatory documents, and responses.
- Data trending including use of JMP[®] software for statistical analysis of experimental data and for the application of Statistical Process Control (SPC) principles.

PROFESSIONAL EXPERIENCE

AVEO ONCOLOGY

2012

Manager, GMP Quality

- Managed the Quality review of analytical test data for stability, release, transfer, validations and comparability studies generated at CMOs and ensured compliance to SOPs, specifications, and Quality systems for deviations and OOS or aberrant results.
- Applied a risk based approach to Quality Assurance in line with stage of product development, regulatory expectations, and company policies.
- Proactively evaluated project progress for method validation at CMO to identify risk with methods not being ready in time to perform drug substance release to meet drug product fill date.
 - Solicited feedback and collaborated with CMC team to re-establish achievable drug product fill date with no impact to project drivers.
- Supported Regulatory activities related to biologics programs by performing review of analytical sections of INDs, DSUR annual updates and comparability briefing book.

STRYKER BIOTECH

2011

Manager, Quality Control

- Provided quality oversight of method transfers, release, and stability testing at contract test sites.
- Successfully managed product and placebo stability data backlog to acquire specification documentation, study protocols, data tables, and created stability summaries.

BRISTOL MYERS SQUIBB

2007-2011

Manager, QC, Chemistry

- Drove technical transfer of in process and release test methods for monoclonal antibody analysis including training activities, equipment IQ/OQ, assay set up, and shakedown runs.
- Collaborated with QC managers to successfully establish a QC Laboratory of 32 FTE to support a Large Scale Cell Culture Facility.
- Managed method technical information for lab PAI filing and serve as SME for PAI mock inspection.

- Managed laboratory investigations and supported manufacturing investigations for release assay OOSs and in process critical process parameter failures.
- Managed Quality events and investigations in Trackwise® to ensure timely closure.
- Nominated for and participated in a team to establish a program for employee recognition of exemplary demonstration of company core behaviors as part of establishing company culture during start up activities.

STRYKER BIOTECH(formerly *Creative Biomolecules*)

1996-2007

Supervisor, Analytical Technology (2004-2007)

- Promoted to Supervisor of newly formed group under Quality to lead 4FTE for methods validation and QC assay and critical reagent support.
- Authored company method validation plan to adhere to ICH guidelines and ensured adherence to this document.
- Oversaw method validations and transfers used for product release, manufacturing in process testing and bioanalytical methods used for clinical testing.
- Supported global QC groups (MA, NH and Ireland) as needed for OOS investigations, CAPAs, and deviations.
- Partnered with Regulatory as technical author for method summaries for PMA and draft responses to regulatory questions on analytical methods. Drove various projects within group to support regulatory responses.

Project Co-ordinator (2003-2004)

- Scheduled, tracked, and supervised various projects including assay validations and analytical testing platform for second generation product which included stability indicating, impurity assays, and evaluation of secondary structure changes.
- Instrumental in supporting assay investigations by trending data using JMP® software - control charts, pareto charts, and capability analysis and wrote SOPs to provide instruction to do this.

Senior Research Associate (2001-2003)

- Led a team of analysts to qualify ELISA's in multiple matrices to support process clearance of process residual proteins for process comparability and validation.
- Evaluated process comparability through analysis in residual ELISA, oligosaccharide and sialic acid assays.
- Directed temporary employees to qualify HPLC assay to determine methotrexate concentration and assessment of disulfide integrity.
- Collaborated with scientist to characterize truncated species of OP-1 by Western blot to PVDF and subsequent amino terminal sequencing method.

Research Associate (1996-2001)

- Collaborated with scientist to optimize and qualify panel of HPLC methods for carbohydrate analysis of OP-1 protein including monosaccharide, oligosaccharide by charge and size, and sialic acid analysis.
- Developed and qualified methods (IEF & HPLC for isoaspartate) and demonstrated as stability indicating for OP-1 protein.
- Provided support to a variety of HPLC assays including free amino acid analysis of cell culture media and peptide mapping to support process development and/or test manufacture samples.

BEHRING DIAGNOSTICS

1994-1996

Reagent Support Associate

- Utilized elements of SPC to monitor manufacture of ELISA based reagent kits for clinical laboratory diagnostic purposes and optimized/troubleshoot process based on feedback.

E D U C A T I O N**Bachelor of Science**, Biomedical Science, FRAMINGHAM STATE COLLEGE, Framingham, MA

Cynthia A. McDonough MT(ASCP)

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C: (978)314-8903

SUMMARY

Senior Quality Management professional with extensive experience in Document/ Records Management, Training, Change Control, Investigations, the Software Development Lifecycle and Computer System Validation including Systems Design, Implementation & Migration. Exceptional leader of Operations with strong technical acumen, known for cross functional collaboration in implementation of systems and processes to meet business and regulatory requirements.

Expertise:

- Biotechnology/ Pharmaceutical industry with working knowledge of 21CFRs 210, 211, 11, 600, 610, 820
- Quality Systems Implementation & Compliance oversight
- Lead Business Analyst on several Biopharmaceutical Application Implementations
- Several corporate assignments providing senior leadership and strategic guidance and decision making
- Clinical laboratory/clinical laboratory management

COMPUTER SKILLS

Enterprise Applications:	QUMAS – DocCompliance, ProcessCompliance & MyQumas, Documentum, Webviewer, SAP, Business Intelligence, eRoom, Isotrain, Power2Learn, Plateau, Trackwise, .NET, Groupwise, OmniRIM, Zasio
Microsoft Applications:	Office (Word, Excel, Access, Powerpoint); MS Project, SharePoint, Outlook, OneNote, Visio)
Business Applications:	Kronos, Projeca, Express T&E, SAP
Other:	Adobe Professional/Standard, Photoshop

PROFESSIONAL EXPERIENCE

Aveo Pharmaceuticals **2012 - 2012**

Associate Director, Quality Systems **2012 – 2012**

Provided Senior Leadership and hands on technical expertise to implement AVEO's Quality Management System, QUMAS.

- Direct responsibility for design, configuration, business processes, training and migration of legacy documents & archive for DocCompliance implementation
- Provided project oversight and coordination of ProcessCompliance implementation (CAPA, Deviation, Change Control) & Learning Management System (LMS)
- Worked directly with vendor points of contacts for all aspects of project implementation and project management
- Steering Committee member responsible for project updates and strategic Quality direction

PFIZER, Andover, MA (Formerly Wyeth & Genetics Institute)**2001 – 2011****Client Engagement/Change Management Lead,
Quality Records Management****2010 – 2011**

Provide Senior Project Management for identifying and implementing document and records management enhancements; compliance support of systems and processes; technical support of site Documentum configuration.

- Implemented automated electronic Business Continuity Webviewer which eliminated manual copying of site Controlled Documents and automated redundancy
- Decommissioned legacy site Documentum system
- Oversee migration of Records Management metadata from legacy source to Records Management Tracking (RMT) system
- Consultant to Research & Development VIPER project – migration of legacy Wyeth Documentum systems to Pfizer's enterprise system as the subject matter expert of legacy systems and processes.
- Documentation Leader for Facility Decommissioning of 4 site manufacturing suites

Operations Manager & System Support, Quality Records Management**2010**

Managed high volume GMP documentation and records management group supporting clinical and commercial biotechnology manufacturing, and external supply organizations. Directly supervised 6 employees. Oversaw business processes for document lifecycle management, records management, batch record issuance.

- System Support analyst working in concert with IS supporting validation and operational maintenance of systems
- Sr. Records Manager – liaison to corporate Records Management responsible for site records tracking and archival, policy compliance, Records Tracking System, legal hold compliance, record retrieval

**Global Records Management Liaison & Enterprise System Support,
Quality Records Management****2007 – 2010**

Provided Biotech Network records management program compliance to corporate policy. Lead Business Analyst responsible for design and implementation of enterprise document management solution.

- Lead Business Analyst for Enterprise design and implementation Documentum 5.3 DCM
 - Role encompassed comprehensive global business process development, data cleansing and legacy system migration for clinical and commercial use
- Senior Records Management Professional representing Biotech on Corporate Records Management Governance and Information Architecture council
 - Implemented first Retention Schedule in company with Japanese retention requirements incorporated
- Leader, Global Biotech Documentation and Records Community of Practice (BDRS)

Manager, Training and Documentation Systems**2003 – 2007**

Managed Training and Documentation for the Andover Development organization. Directly supervision of 2 employees and contract resources.

- Developed and implemented Document & Records Management and Training Quality Systems to meet corporate and regulatory requirements
- System Owner of Development's Documentum document management system

Pfizer, cont.

Senior Documentation Specialist

2001 – 2003

Managed startup of QA documentation function to establish system and process for varying documentation needs of the Development organization from early development through clinical manufacturing and Quality Control.

- Wyeth BioPharma and Wyeth-wide initiatives supporting transfer of information and seamless access to information

Mayo Foundation Quality Committee

2000 – 2001

Document Control Manager

1999 – 2001

Quality Assurance Coordinator

1997 – 2001

Assistant Supervisor, Immunochemistry

1995 – 1997

Medical Technologist, Immunochemistry

1988 – 1995

EDUCATION and CERTIFICATION

BS, Medical Technology, University of New Hampshire, Durham, NH
 Mary Hitchcock School of Medical Technology
 American Society of Clinical Pathologists #166321 MT (ASCP)

PROFESSIONAL MEMBERSHIPS/ RECOGNITION

ARMA International

Greater Lawrence Chamber of Commerce –Women in Leadership, 2003
 Successful Sustainable Compliance Initiative Implementation
 SOP Breakthrough Award
 Community of Practice Leadership

Pfizer Biotech Banter, June 2011: *Going Paperless – Completely. Cross-site team helps Andover eliminate paper backup system*; Cynthia McDonough, David Kinnett

AVEO Ten Year Anniversary, Poster Session: *The Implementation of AVEO's Quality Management System, The Next Quality Frontier*

PROFESSIONAL DEVELOPMENT

Wyeth Leadership Priorities
 Women in Leadership – Thomson Course Technology, 2006

THOMAS NICHOLAS MEGLIO

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www.linkedin.com/pub/thomas-meglio

SUMMARY

Cagewash technician with over 11 years of experience working in the Biotech industry and over three years of experience in academic lab research as a graduate student in Biology. Improved efficiency and productivity in the cagewash area as the number of mice in the animal facility doubled over the course of eight years. Strong organizational skills, attention to detail, and the ability to work independently or in a team environment. Eager to take on additional responsibilities, and learn new skills, such as *in vitro* lab research.

PROFESSIONAL EXPERIENCE

AVEO ONCOLOGY, INC., Cambridge, MA 2004-2012

Research Services Specialist III (2011-2012)
Senior Research Support Technician (2007-2010)
Research Support Technician (2006)
Animal Care Technician (2004-2006)

- Performed daily maintenance of rodent cagewash facility as the number of animals doubled over the course of eight years.
- Prioritized and maximized cagewash and autoclave throughput during mechanical breakdowns.
- Maintained accurate record keeping, including Excel spreadsheets.
- Sent MAP samples to Taconic for testing.
- Trained co-workers in all phases of administering the cagewash area and MAP samples.

MILLENNIUM PHARMACEUTICALS, INC., Cambridge, MA 1999-2003

Lab Technician / Technologist II (1999-2003)

- Performed daily maintenance of rodent cagewash facility.

LAB EXPERIENCE

RBI (RESEARCH BIOCHEMICALS INTERNATIONAL), Natick, MA 1999-1999

A division of Sigma Chemical Corporation.

Bottling Technician

- Weighed and bottled various biochemical compounds.

RHODE ISLAND COLLEGE, Providence, RI 1994-1996

Graduate Teaching Assistant, Biology Department

- Prepared laboratory exercises for freshman biology classes, including all chemical solutions; helped to train the students in the proper usage of the laboratory equipment.

RESEARCH EXPERIENCE

RHODE ISLAND COLLEGE, Providence, RI 1993-1997

Graduate Student, Biology Department

Completed a research project involving the characterization of a homeobox-containing gene (isolated from a gastrula-stage cDNA library of the ascidian species *Ciona intestinalis*).

- Conducted experiments designed to determine the temporal and spatial expression patterns of that gene in embryonic development and in various adult tissues.
- Utilized samples of *Ciona* mRNAs (isolated from successive embryonic stages and several adult tissues) in RT-PCR experiments.

- Utilized recombinant viruses, plasmids, and bacterial hosts to isolate and clone fragments of the original cDNA transcript (to serve as templates for the synthesis of sense and antisense RNA probes in whole mount in-situ hybridization experiments).

RESEARCH SKILLS

Agarose gel electrophoresis, RT-PCR, DNA isolation and purification, RNA purification, isolating specific cDNA inserts (using recombinant viruses, plasmids, and transformed bacteria), DNA cloning, whole mount in-situ hybridization (using immunohistochemistry), ability to make buffers and reagents, RNA probe synthesis, and bacterial cell culture.

EDUCATION

Master's Degree in Liberal Arts, History, HARVARD EXTENSION SCHOOL, Cambridge, MA
Dean's List

Master's Degree in Arts, Biology, RHODE ISLAND COLLEGE, Providence, RI
Research Grant and Associate Membership in Sigma Xi, the Scientific Research Society.
Relevant Coursework: Microbiology, Advanced Developmental Biology, Biochemistry I and II, Cell Morphology and Physiology (Molecular/Cell Biology), Endocrinology, and Techniques in Biotechnology.

Bachelor's Degree, General Social Studies, PROVIDENCE COLLEGE, Providence, RI

PROFESSIONAL AFFILIATIONS AND HONORS

- ALAT Certification from AALAS (Sept. 25, 2006)
- Associate Member in Sigma Xi (awarded 1995)
- Research Grant from Sigma Xi (awarded 1994)

LAUREN NICHOLS

596 CAMBRIDGE STREET, BOSTON, MASSACHUSETTS 02134
(207) 838-4826 | laurenwnichols@gmail.com

SUMMARY

Scientist with analytical chemistry background from formulation to drug product. Proven track record of successfully solving challenging technical problems leading to successful regulatory submissions. Unique breadth of skills with excellent analytical, project management, and compliance capabilities.

EXPERIENCE

AVEO PHARMACEUTICALS, Cambridge, MA USA

02/ 2012-10/2012

Senior Technical Services Coordinator

- Key member NDA submission team, responsible for ensuring accuracy of the CMC section, including editing, writing and decision making leading to a timely submission.
- Collaborated with contract organizations in the development, optimization, technical transfer, and validation of analytical methods and tests for small molecule drug substance and drug product.
- Oversaw analytical development, method validation, specification setting, and stability studies, including establishment of specifications and expiration/retest dating. Reviewed and approved protocols and finished reports from contract manufacturers, including stability data.
- Troubleshoot technical issues and improved product quality by providing technical guidance to contract organizations. Initiated and managed technical operation change controls.
- Supported technical audits by providing the documentation required by QA auditors and participating in these audits when needed.

VERTEX PHARMACEUTICALS, INC., Cambridge, MA USA

11/ 2010-09/2011

QA Specialist (Contract)

- Reviewed and edited the CMC section of the NDA and MAA submission, working in a cross-functional team.
- Ensured regulatory reference documentation was in place in support of the successful submission.
- Initiated, updated, and progressed to closure of change controls for the commercial team and compiled for quarterly report.
- Responsible for all activities supporting maintenance, review, transfer, and validation for new analytical test methods for commercial product.

ARGENTA MANUFACTURING LTD, Auckland, New Zealand

04/2007-06/2010

Pharmaceutical Development Chemist

- Independently project managed multiple formulation development projects from concept to commercialization in animal health.
- Developed and performed HPLC analytical and stability methods for detection of active and breakdown products to FDA standards.
- Managed project development and client relations on a critical timeline.
- Wrote, developed, and improved new and existing analytical methods and standard operating procedures.
- Monitored and tested new product developmental stability.
- Provided technical input into the resolution of development, analytical, and quality issues as they arose.
- Performed and provided guidance for validation and transfer of methods.

PACIFIC PHARMACEUTICALS, Auckland, New Zealand

05/2005-03/2007

Validation Analyst (08/2006-03/2007)

- Prepared validation protocols and reports, and performed analytical method and process validation studies to ICH.
- Assisted in method transfer to relevant companies and performed quality control and stability testing of finished drug products.

Products Analyst (05/2005-08/2006)

- Utilized HPLC and other analytical techniques to analyze generic pharmaceutical product, stability, and validation samples to GMP/GLP.
- Responsible for releasing products and checking manufacturing documentation. Involved in the training and staff development.

NUFARM HEALTH AND SCIENCES, Auckland, New Zealand

10/2004-05/2005

Quality Control Analyst

- Applied HPLC, GC, AA, and other analytical techniques to analyze raw materials, packaging components, stability, and finished product samples to GMP/GLP using USP/EP.
- Wrote and updated standard operating procedures and analytical test methods. Exposed to method transfer and validation work.

CADBURY SCHWEPPEES, Auckland, New Zealand

08/2004-11/2004

Food Technologist (Contract)

- Autonomously analyzed products in the food chemistry laboratory performing loss on drying, reducing sugars, water activity, and total soluble solids testing on finished products and raw materials.

E D U C A T I O N

Bachelor of Arts, Biochemistry and Chemistry, SMITH COLLEGE, Northampton, MA, USA (2003)

LEAH PERSICO

<http://www.linkedin.com/pub/leah-persico/2b/723/a71>
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1189 Broadway
 Haverhill, MA
 Email- leahpersico@gmail.com

Highlights of Qualifications:

- Basic Spanish skills.
- Dedicated worker with a positive attitude.
- Extremely reliable with completing hands-on projects.
- Exhibits strong verbal, written, and phone skills.
- High level of adaptability in working environment.
- Proficient in computer platform software including
 - All Microsoft Office applications
 - SharePoint
 - ERP Lite
 - IXRS systems such as INC. Trial Line, and Oracle PhaseForward
 - Ariett Net
 - SAP

Employment History:**Project Coordinator, Investigational Supply Operations****AVEO Oncology**

FEB 2012-OCT 2012 Cambridge, MA

- Provide project direction for Technical Operations and Investigational Supply Operations(ISO)
- Manage all material deliverables related to drug supplies for outpatient use
- Coordinate and track all drug product shipments to and from all clinical sites and orchestrate as needed project planning to ensure timely distribution
- Execute all Change Controls within the department and coordinate related deliverables
- Perform product inventory checks and maintain proper inventory levels of packaged components needed for clinical and investigational trials
- Manage and track all departmental QA documents
- Monitor all packaging and labeling activities as well as ensure proper storage for all investigational product at depots and sites
- Author label text for investigational and commercial drugs used in clinical trials and maintain proper regulatory and quality standards
- Coordinate the approval of label text and label masters with the Clinical, QA, and Regulatory teams
- Arrange domestic and international shipments to and from depots and clinical sites
- Procure concomitant and comparator drugs for clinical trials
- Investigate and document all investigational product temperature excursions
- Oversee ISO contract authorizations and ensure all approvals have been obtained prior to creating an electronic requisition
- Obtain purchase order numbers and reconcile purchase orders with invoices
- Ensure that all packaging exercises occur according to timelines and specifications
- Review and coordinate approval of packaging batch records
- Write and revise Standard Operating Procedures for the Technical Operations department
- Coordinate returns and destruction of investigational product at sites and depots
- Review and approve distribution records, distribution requests, packaging records, and packaging requests
- Author Investigational Supply Operating Plan

Buyer Associate, Inventory Management**AMRI Pharmaceuticals****2010- 2012** Burlington, MA

- Execute all corporate purchases to support all pharmaceutical fill finish operations
- Track all purchase orders to ensure timely delivery and proper inventory
- Own and update GMP material specification library
- Adhere to departmental compliance with cGMP, HAZCOM training
- Handle extensive vendor and customer relations with regards to purchasing and supplying materials
- Cross-trained on various aspects of supply chain to support all departmental needs
- Utilize extensive problem solving skills to facilitate on time delivery of all required materials for production
- Possess the ability to follow up with multiple departments in a team environment to ensure that scheduled tasks occur on time
- Ability to multitask and handle multiple functions with attention to detail in a timely and organized fashion
- Handle all verifications of all approved suppliers and distribution of proper part numbers
- Compliant with all applicable CFR, ISO, and DEA regulations

Event Planner**Planned to Perfection LLC.****2009** Newport, RI

- Utilized management skills to coordinate weddings as well as corporate and charitable events
- Created event timelines, guest lists, and itineraries for all events
- Met with clients in professional settings discussing their wants, needs, and budgets
- Formulated income statements for the company using Microsoft Excel

Event Staff**Johnson & Wales University Athletic Department****2006-2008** Providence, RI

- Ensured each home athletic event was properly prepared for
- Kept logs of equipment and uniform check outs
- Professionally handled cash transactions for game admissions
- Assured that game officials were paid
- Recorded statistics for soccer, hockey, and volleyball

Education:**Johnson & Wales University Class of 2010**

Providence, RI 02903

Bachelor of Science in Management

GPA 3.3

-Emphasis on Sports Entertainment and Event Management

Extra Curricular Activities:**Volunteered for Project S.H.E. / Johnson & Wales University****2009-2010** Providence, RI