MARY E. GERRITSEN, PhD.

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Profile

Highly motivated scientist and leader with over 25 years of experience in the pharmaceutical and biotechnology industry. Broad range of deep expertise in multiple therapeutic areas including oncology, inflammation, autoimmune disease, ophthalmology and cardiovascular disease, and experience in the identification and preclinical development of both small molecule and protein/antibody based therapeutics. Exceptional success record in moving projects from target identification and validation, high throughput screening, lead validation, lead optimization, and early clinical development including the development and implementation of translational biomarker and pharmacodynamic assays for novel targets and novel mechanisms. Strong track record of peer reviewed publications and issued patents. Dynamic individual experienced in high level strategic planning, attention to detail, and solving unique and difficult challenges. Proven leadership, excellence in motivating and empowering direct and indirect reports, and the ability to communicate and present complex data and projects in a clear and comprehensive fashion.

Experience

GERRITSEN CONSULTING. SAN MATEO CALIFORNIA 2010-present
CONSULTING PROFESSOR, DEPARTMENT OF SURGERY, STANFORD UNIVERSITY 2010-present

Independent biotechnology consultant on topics related to biotherapeutics/drug discovery in the therapeutic areas of oncology, immuno-oncology, ophthalmology, autoimmune diseases/ inflammation and angiogenesis related diseases. I have worked on projects requiring expertise in both small molecule and biologic drugs including those targeting protein kinases, matrix metalloproteinases, phosphatase, steroid and other nuclear receptors, CAR-T cell therapy, and novel small molecule approaches such as irreversible and covalent reversible inhibitors, targeted therapies, and bromo-domain targeted therapies. Projects involve assessment of research strategy, target selection and intellectual property positions, compound selection criteria, data quality control and management, selection and development of protocols for cell based assays, pharmacodynamic assays and clinical biomarker studies, translational biology approaches for patient stratification, preclinical assays that can be used to identify potential patient phenotype/genotypes, screening contract research organizations and academic laboratories for contracts and collaborations, establishing collaborations and work orders, preparation and editing of investigator brochures, IND documents, clinical protocols, SOPs for clinical trials, manuscripts, poster and meeting presentations, and evaluation of research and pipeline portfolio strategies for both venture capital firms and companies interested in in-licensing, partnering or acquisition of new compounds/technologies or companies. Consultant on various projects at laboratories in department of vascular surgery at Stanford.

EXELIXIS, SOUTH SAN FRANCISCO, CA 2004-2010
VICE PRESIDENT
MOLECULAR AND CELLULAR PHARMACOLOGY

Biotechnology company focused on the discovery and development of small molecular therapeutics for the treatment of oncology and metabolic disease. Reported to the Executive Vice President of Research and Chief Scientific officer.

- Leader of interdisciplinary teams at all stages of preclinical to early clinical development. Strong track record with increasing responsibility, promoted from Senior Director to Executive Director (2007) and to Vice President (2009). Managed a department of 82 scientists (30 Ph.Ds) with 6 direct reports (Senior Director, 4 Directors, and 1 Administrative Assistant). Prepared and managed multi-million dollar budgets, set priorities and managed costs while remaining extremely productive.

- Led the divisions that were responsible for different roles in drug discovery including target identification and validation, robotic cell culture, cell line acquisition and banking, cell based mechanistic and phenotypic assays and pharmacodynamic studies, and translational medicine.

- Led the biomarker group (~10 PhDs/RAs) responsible for identification, validation and assay of clinical biomarkers to support ongoing clinical trials (Phase I and Phase II). Developed and implemented a number of novel biomarker studies that enabled identification of pharmacodynamics activity for drugs in early clinical development.

- Responsible for the all cell biology and pharmacodynamic sections of multiple INDS: XL228 (IGF1R/Bcr-Abl), XL281 (RAF), XL765 (PI3K/MTOR), XL147 (PI3K), XL888 (HSP90), XL139 (hedgehog), XL019 (JAK2), XL518 (MEK), XL418 (AKT), XL388 (TORC1/TORC2), XL413 (CDC7), XL541(S1P1R), XL499 (PI3Kγ).

- Supervised and led research team leaders in early target validation, lead validation and lead optimization for both oncology and inflammation/autoimmune disease indications around various molecular target classes including protein and lipid kinases, sphingomyelinase, ceramide synthase, methyltransferase, dehydrogenase, ATPase, and GPCRs.

- Member of the Research and Development Management Committee with responsibility for key strategic decisions.

- Provided project updates and strategic evaluations to senior management (CSO, CEO, President) and board of directors.

- Spearheaded the implementation of the "Post-Development Compound" characterization teams that further characterized mechanism of action, combination studies, tumor cell line profiling, and other studies used to assist the clinical project teams in patient stratification strategies for XL compounds. These studies were also instrumental in Exelixis partnering and business development activities.

- Recruited numerous scientists and research associates to build up key areas of expertise in molecular and cellular pharmacology

- Built a world class repository of cancer cell lines integrated with gene expression, protein expression and phosphorylation, and associated sequencing data (mutations, amplifications, translocations). Implemented the utilization of these cell lines and associated data to profile development compounds and identify potential sensitive tumor types.

- Brought in multiple bone marrow and primary cell/tumor specimens to evaluate effects of our DC compounds on stem cell properties. Used these and established cell lines and tissue samples to identify and validate biomarkers for Phase I and II clinical trials.

- Co-authored with colleague David Matthews, "Targeting Protein Kinases for Cancer Therapy" (Wiley Press, 2010), a comprehensive, 700+ page book that featured an overview of protein kinases, their structure and function, and the drugs that inhibit them.

FRAZIER HEALTH CARE VENTURES, PALO ALTO, CA 2003-2004

CONSULTANT

One of the leading providers of venture and growth equity capital to emerging biopharma, medical device and healthcare service companies. As a consultant, involved in the founding of Macusight, an angiogenesis company focused on age-related macular degeneration and diabetic macular edema.

- Established collaborations and agreements with academic and contract labs to move product forward into IND stage.
- Made key scientific presentations to venture firms to enable first round financing.
- Key inventor on IP that enabled the funding and founding of the company.

MILLENNIUM PHARMACEUTICALS, SOUTH SAN FRANCISCO, CA 2002-2003
SENIOR DIRECTOR
VASCULAR BIOLOGY

Formerly COR Therapeutics, Millennium South San Francisco was focused on cardiovascular disease, with two major areas of therapeutic focus: platelet biology and atherosclerosis.

- Developed strategic plan for vascular biology at Millennium.
- Supervised project leaders on three small molecule discovery programs (Targets: GPCR, Growth Factor Receptor, Transcription Factor) at different stages-hit to lead, lead optimization and high throughput screening.
- Supervised multiple functional groups-vascular biology, functional genomics and histology core.
- Initiated collaborations with academic laboratories (to bring in human tissue specimens and timed specimens from animal models of vascular disease) to enable genomic screens in key therapeutic areas.
- Supervised vascular biology target discovery group, responsible for identification of screening targets for Millennium partners (large Pharma companies)
- Presentations to senior management.

GENENTECH SOUTH SAN FRANCISCO, CA 1997-2001
SENIOR SCIENTIST/ASSOCIATE DIRECTOR
DEPARTMENT OF CARDIOVASCULAR RESEARCH

One of the founders of the biotechnology industry, Genentech has been delivering on the promise of biotechnology for more than 30 years. Known throughout the industry as a company using human genetic information to discover, develop, manufacture and commercialize medicines to treat patients with serious or life-threatening medical conditions.

- Coordinated screening efforts of several groups in vascular biology related to endothelial biology for identification of new activities for novel secreted proteins and transmembrane proteins in the areas of angiogenesis and atherosclerosis.
- Senior investigator in angiogenesis research, identifying novel targets for protein based therapeutics.
- Used genomics, protein analysis, tissue microarrays, gene-calling, in situ hybridization and other cutting edge techniques to identify and validate targets.

- Recruited and supervised research associates, post-doctoral fellows, summer interns, visiting scientists and a senior scientist.

- Presentations to senior management and board of directors.

- Filed multiple patent applications (over 1000, with over 40 now issued) and published a number of highly cited articles in the field of angiogenesis.

HARVARD MEDICAL SCHOOL/BRIGHAM AND WOMEN'S HOSPITAL. 1996
VISITING SCIENTIST
DEPARTMENT OF PATHOLOGY, VASCULAR RESEARCH DIVISION

Training in molecular pathology, cloning, expression, and gene promoter analysis. First author or senior author of several highly cited publications arising from the sabbatical. Participated in medical grand rounds, and pathology resident training.

BAYER PHARMACEUTICALS (FORMERLY MILES PHARMACEUTICALS), WEST HAVEN CT 1990-1997
PRINCIPAL STAFF SCIENTIST AND GROUP LEADER
INSTITUTE FOR INFLAMMATION AND AUTOIMMUNITY

North American site for large pharma company specializing in small molecule drug discovery in the areas of oncology, osteoporosis, osteoarthritis, metabolic disease and autoimmunity/inflammation.

- Led screening efforts for small molecule inhibitors of leukocyte adhesion, cyclo-oxygenase, and cytokine release/action.

- Therapeutic thought leader for inflammation/autoimmunity and responsible for development of strategic inflammatory and autoimmune disease research plan and competitive assessment.

- Played a key role in establishing academic and industrial collaborations/contracts for tissue acquisition of synovial fluid, synovial membranes, cartilage and related tissues from RA and OA patients for target discovery and assay development.

- Developed collaborations with leading laboratories in leukocyte adhesion/recruitment

- First to develop methods to isolate and culture human synovial microvessel endothelial cells and use them in drug screens to identify potential compounds for drug development.

- Identified first inhibitor of NF-KB induced gene expression. Drug was later shown to be a specific and irreversible inhibitor of the inflammasome

- Presentations and project updates to senior management in US and Germany.

- Supervised 6 laboratories (6 Ph.D. scientists and 18-25 research associates and post-doctoral fellows).

NEW YORK MEDICAL COLLEGE, VALHALLA NY 1980-1989
ASSOCIATE PROFESSOR OF PHYSIOLOGY

A large private health university with a school of medicine, school of health sciences and a graduate school of basic medical sciences. As a member of the faculty of the department of physiology, responsible for teaching endocrinology and cardiovascular physiology to medical students and graduate students.

- Established research program in endothelial biology, receiving grant support from NIH, AHA and other state and national funding agencies. Research area focus on endothelial biology, eicosanoid biochemistry, and cellular models of endothelial dysfunction with relevance to inflammation, atherosclerosis, hypertension, ophthalmology and diabetes.

- One of the first laboratories to develop methodology to isolate and culture endothelial cells from the microvasculature of animal and human tissues (lung, heart, brain, muscle, retina), and to demonstrate that “all endothelial cells are not created equal”.

- Supervised graduate students, post-doctoral fellows visiting scientists and summer medical student interns.

- Developed methods for the analysis of intraocular fluids and first to demonstrate the presence interleukin 6 and other cytokines in samples from patients with proliferative vitreoretinopathy and diabetic renal disease

- In collaboration with investigators at Boehringer Ingleheim, developed a primate model of asthma, now used by many pharmaceutical companies for screening

Education

Bachelor of Science. Honors major in Zoology, graduating summa cum laude. **University of Calgary** 1975

Ph.D. Endocrinology and Pharmacology **University of Calgary** 1978

Post-doctoral studies in Pharmacology **University of California, San Diego**. 1978-1980

Visiting Scientist, **Harvard Medical School, and Brigham and Women’s Hospital**, Department of Pathology. 1996

Advanced Course in Immunology**, Stanford Medical School and the American Association of Immunology**. 2002

Publications and Patents

Over 100 publications in peer reviewed journals, numerous book chapters and three full length books. Over 1000 patent applications with 49 issued patents.

Awards and Honors

- Province of Alberta Graduate Scholar 1976
- Medical Research Council Studentship 1976-1978
- Isaac Walton Killam Scholar and Merit Award 1977,1978
- Medical Research Council Fellow 1978-1980
- Alexander and Alexandrine Sinsheimer Scholar 1981, 1982
- Pharmacia Young Investigator Award, Microcirculatory Society 1983
- Mary Weideman Award, Microcirculatory Society 1984
- NIH Research Career Development Award 1987-1992
- Miles Science Award 1992
- Kurt Weiderhelm Award, Microcirculatory Society 1998

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