

ERIK FOEHR, PH.D.

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DIRECTOR, BIOANALYTICAL R&D

Bioanalytical expert with over 11 years of research and development experience, resulting in numerous publications, patents, and innovations that propel the advancement of science, medical treatment, and patient care. Strong scientific background, research capabilities, and business acumen that drive effective laboratory operations and project management. Serve as a proactive leader and team collaborator, motivate staff and establish a cohesive environment focused on accountability. Present complex information to diverse audiences as a technical subject matter expert (SME).

Executive Leadership Competencies:

Drug Development & Diagnostics • BioAnalytical Sciences • Team Leadership & Oversight • Good Laboratory Practices (GLP) Staff Training & Development • Budget Management & Expense Control • Project Management • Regulatory Compliance

PROFESSIONAL EXPERIENCE

BIOMARIN PHARMACEUTICALS INC., Novato, CA

2007-2011

Director

Direct bioanalytical laboratory developmental sciences department, including non-clinical and clinical research, regulatory compliance, and operations. Maintain a \$5 million annual operating budget and a 15-person team of scientists, research associates, and lab operations personnel. Implement bioanalysis strategy in alignment with overarching corporate goals. Facilitate clinical and non-clinical studies, enabling the advancement of drug candidates to market. Perform methods selection, assay design, data analysis, and bioanalytical science advisory for 16 drug projects. Produce original peer-reviewed publications. Oversee a dozen active contracts with external organizations.

- **Prepared modules for six drugs to be submitted for FDA and European regulatory agency approval;** conducted bioanalysis for clinical trials investigating bioavailability, bioequivalence, food-effect, and QTC interval studies.
- **Served as pharmacological science SME** as part of the leadership team on four key drug programs. Assessed probability of technical success and identified potential safety and efficacy risks related to immunogenicity.
- **Expanded the scope of bioanalytical research and development** to include a small molecule bioanalysis group with LC-MS/MS and chromatography capabilities, including biomarker identification, implementation, and validation.
- **Reorganized disparate bioanalytical groups** into fully integrated project teams, which produced a more efficient, better integrated department.
- **Recognized as a bioanalysis and immunogenicity expert and thought leader;** invited to speak at industry conferences, and participated in cross-industry organizations and focus groups.

Associate Director

2005-2007

Supervised a team of four scientists that developed and validated methods to measure drug, anti-drug antibodies, and biomarkers in biological matrices. Evaluated and approved validation data, protocols, and reports; presented results to key stakeholders. Partnered with finance and program management to prepare and maintain \$2.5 million annual operating budgets.

- **Established infrastructure, instituted good laboratory practices (GLP),** deployed new technologies, and managed operations of a bioanalytical sciences group. Oversaw the implementation of dozens of new bioanalysis methods.
- **Negotiated with the FDA;** completed post-marketing commitments and negotiated label language for Naglazyme for the treatment of Maroteaux-Lamy Syndrome (MPS).
- **Conducted non-clinical and clinical bioanalytical studies** for FDA approval of Kuvan, a treatment for phenylketonuria (PKU). Involved in Phase 1-3 clinical trials and multiple non-clinical toxicology, pharmacokinetic, and safety pharmacology studies.
- **Supported bioanalytical research for drug projects** that resulted in six published manuscripts and three patents.

DIAMICS, Novato, CA

2004-2005

Senior Scientist / Lab Manager

Contributed to the launch of this entrepreneurial start-up company. Hired, trained, and managed a team of three associates that researched and developed point-of-care cancer diagnostics using molecular and cell biology knowledge and biochemical techniques. Evaluated technical feasibility and intellectual property protection for Pap-Map, an improved diagnostic device for cervical cancer.

- **Directed laboratory construction** and established, instituted, and enforced safety processes and documentation practices; implemented a purchasing system.
- **Designed and conducted experiments** using a variety of technical approaches and cutting-edge technologies; developed a diagnostic cervical cancer device that received FDA approval and European licensing.
- **Identified and secured strategic partnerships** with physicians, experts, and contract research organization as part of a clinical trial of the cervical cancer diagnostic device; interacted with staff to test diagnostic device and collect samples. Enabled 510 (k) diagnostic device application and European CE designation

AGY THERAPEUTICS, South San Francisco, CA

2002-2004

Senior Scientist

Facilitated the design and execution of an independent research program focused on identifying, evaluating, validating, and characterizing target and off-target effects of drugs used to treat central nervous system disorders. Trained and mentored four scientists and research associates. Identified and evaluated four drug candidates through pre-clinical phases of development leveraging nucleic acid analysis, protein biochemistry, cell biology, and analytical methods.

- **Established and characterized animal disease models** for discovery and development. Out-licensed three products; generated intellectual property that generated interest in this start-up company.
- **Discovered and developed therapeutic antibody for glioblastoma cancer indication** that was successfully out-licensed. Named as inventor on two U.S. patents.
- **Authored five peer reviewed manuscripts** supporting pipeline and drug development strategy.
- **Participated in drug program due diligence**; presented project milestones and technical data to stakeholders and biotech companies, including Genentech, Amgen, and Medarex for business development and capital raising.
- **Implemented technologies for cell-based drug screening**, which improved efficiency and quality of work. Evaluated Cellomics High Content Screening platform; leveraged high throughput assays to screen compound libraries.
- **Established strategic partnership with Duke University Cancer Center** that were instrumental in the design and strategy of the therapeutic antibody delivery to treat glioblastoma multiforme.

EDUCATION

Ph.D. in Physiology and Biophysics, UNIVERSITY OF CALIFORNIA, IRVINE, Irvine, CA

Master of Science in Genetics, ARIZONA STATE UNIVERSITY, Tempe, AZ

Bachelor of Science in Molecular Biology, UNIVERSITY OF CALIFORNIA, DAVIS, Davis, CA

PROFESSIONAL CREDENTIALS

Professional Affiliations: American Association of Pharmaceutical Sciences (AAPS), American Society of Human Genetics, Clinical Lab Standards Institute

Inventions & Patents: Assays for detection of phenylalanine ammonia-lyase and antibodies to phenylalanine ammonia-lyase • Assays for detection of antibodies to lysosomal enzymes • Prodrugs of tetrahydrobiopterin • Methods of administering tetrahydrobiopterin, associated compositions, and methods of measuring • Use of biomolecular targets in the treatment and visualization of tumors • Monoclonal antibodies directed to receptor protein tyrosine phosphatase zeta.

Computer Skills: Watson Lab Information Management System (LIMS), SoftmaxPro, JMP statistical software, MS Office Suite, MS Project, Citrix, LiveLink

INVITED ORAL PRESENTATIONS

Development and implementation of a comprehensive immunogenicity assessment plan for an enzyme therapeutic and the impact of antibodies on PK and biochemical markers. Immunogenicity and PK/PD, Informa Life Sciences, 2011

Risk assessment and monitoring of antibody responses to biopharmaceuticals, Immunogenicity Summit, Cambridge Healthtech Institute, 2010

Building the three pillars of clinical bioanalysis: immunogenicity, pharmacodynamics, and pharmacokinetics, Biopharmaceuticals: Exploring synergies across drug formats, Society for Biomolecular Sciences, 2010

Bioanalytical challenges of enzyme therapeutics: from assay development to clinical correlations, Bioanalytical method development, IIR, 2010

Development and validation of drug specific IgE antibody assays for use in clinical trials, Immunogenicity Summit, Cambridge Healthtech Institute, 2009

PUBLICATIONS

Martell LA, Cunico RL, Jayoung O, Fulkerson W, Furneaux RH, **Foehr ED** (2011). Validation of an LC/MS/MS assay for detecting relevant disaccharides from keratan sulfate as a biomarker for Morquio A syndrome. *Bioanalysis*, 3 (16): 1855-1866.

Koren E, **Foehr E**, and O'Neill C (2011). Principles of risk assessment and monitoring of antibody responses to biopharmaceuticals, Michael G. Tovey, Editor. Detection and quantification of antibodies to biopharmaceuticals. Practical and applied considerations. John Wiley and Sons, Inc.

Musson DG, Kramer WG, **Foehr ED**, Bieberdorf FA, Hornfeldt CS, Kim SS, Dorenbaum A (2010). Relative bioavailability of sapropterin from intact and dissolved sapropterin dihydrochloride tablets and the effects of food: a randomized, open-label, crossover study in healthy adults. *Clin Ther.* 32(2):338-46.

Zhao Y, Cao J, Chen YS, Zhu Y, Patrick C, Chien B, Cheng A, **Foehr E** (2009). Detection of tetrahydrobiopterin by LC MS/MS in plasma from multiple species. *Bioanalysis*, 1(5): 895-903.

Feillet F, Clarke L, Meli C, Lipson M, Morris AA, Harmatz P, Mould DR, Green B, Dorenbaum A, Giovannini M, **Foehr E**; Sapropterin Research Group (2008). Pharmacokinetics of sapropterin in patients with phenylketonuria. *Clin Pharmacokinet.* 47(12):817-25.

White JT, and **Foehr ED** (2008). Impact of immunogenicity screening assay format on the overall clinical immunogenicity testing program. *American Pharmaceutical Research.*

White JT, Martell LA, Van Tuyl A, Boyer R, Warness L, Taniguchi G. and **Foehr ED** (2008) Development, validation, and clinical implementation of an assay to measure total antibody response to Naglazyme (galsulfase). *AAPS J.* June 10(2): 363-372.

White, JT, Martell LA, Prince W, Boyer R, Crockett L, Cox C, Van Tuyl A, Aguilera A, and **Foehr ED** (2008). Comparison of neutralizing antibody assays for receptor binding and enzyme activity of the enzyme replacement therapeutic Naglazyme (galsulfase). *AAPS J.* Sep;10(3):439-49.

Foehr ED, Lorente G, Kuo J, Ram R, Nikolich K, Urfer R (2006). Targeting of the receptor tyrosine phosphatase beta (RPTPb) with a monoclonal antibody delays tumor growth in a glioblastoma model. *Cancer Research* 66:2271-8.

Foehr ED, O Mahoney A, Raber J, Montano M, Han V, Lu SM, Kwon H, LeFevour A, Chakraborty-Sett S, and Greene WC. (2006). NFkappaB/Rel regulates inhibitory and excitatory neuronal function and synaptic plasticity. *Mol Cell Biol.* 26: 7283-98.

Ram R, Lorente G, Nikolich K, Urfer R, **Foehr ED**, and Nagavarapu U (2006). Discoidin domain receptor 1 promotes invasion and adhesion in association with matrix metalloproteinase-2. *J. Neuro-Oncology.* 76:239-48.

Lorente G, Nelson A, Mueller S, Kuo J, Urfer R, Nikolich K, and **Foehr ED** (2005). Functional comparison of RPTPbeta

long and short receptor splice forms: Implications for glioblastoma treatment. *Neuro-Oncology*. 7:154-63.

Shashidhar S, Lorente G, Nagavarapu U, Kuo J, Nikolich K, Urfer R, and **Foehr ED** (2005). GPR56 is a GPCR that is over expressed in gliomas and functions in tumor cell adhesion. *Oncogene* 24:1673-82.

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PUBLICATIONS - CONTINUED

Foehr ED, Lorente G, Vincent V, Nikolich K, and Urfer R (2005). FAS associated phosphatase (FAP-1) blocks apoptosis of astrocytomas through dephosphorylation of FAS. *J. Neuro-Oncology*. 74:241-8.

Foehr ED, Raffioni S, Murray-Rust J, and Bradshaw RA (2001). The role of tyrosine residues in FGF Receptor 1 signaling in PC12 cells: Systematic site-directed mutagenesis in the endodomain. *Journal of Biological Chemistry*. 276:37529-33.

Foehr ED, Bohuslav L, Chen LF, DeNoronha C, Geleziunas R, Lin X, O'Mahoney A, and Greene WC (2000). The NF-kB inducing kinase NIK induces PC12 cell differentiation and prevents apoptosis. *Journal of Biological Chemistry*. 275: 34021-24.

Foehr ED, Tatavos A, Tanabe E, Raffioni S, Goetz S, Dimarco E, DeLuca M, and Bradshaw RA (2000). Discoidin domain receptor 1(DDR1) signaling in PC12 cells: Activation of juxtamembrane domains in PDGFR/DDR/TrkA chimeric receptors. *FASEB J.*, 14: 973-81.

Foehr ED, Lin X, O'Mahoney A, Geleziunas R, Bradshaw RA, and Greene WC (2000). NF-kappaB signaling promotes both cell survival and neuritogenesis in nerve growth factor stimulated PC12 cells. *Journal of Neuroscience*, 20:7556-63.

Raffioni S, Thomas D, **Foehr ED**, Thompson LM, and Bradshaw RA (1999). Comparison of the intracellular signaling responses by three chimeric fibroblast growth factor receptors in PC12 cells. *Proceedings of the National Academy of Sciences*. 96:7178-83.

Foehr ED, Raffioni S, Fujii R, and Bradshaw RA (1998). FGF Signal Transduction in PC12 Cells: Comparison of the responses induced by endogenous and chimeric receptors. *Immunology and Cell Biology*. 76:406-13.