Michael A. Lutz Ph.D.

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Statement of Intent

As a talented scientist and analytical problem-solver, I desire to utilize my expertise in drug safety, regulatory affairs and pharmacovigilance to advance pharmaceutical/biotechnology products to market and beyond.

Education

Doctor of Philosophy in Pathobiology **1998-2003**
The Pennsylvania State University, University Park, PA

Bachelor of Science in Animal Bioscience **1993-1997**
The Pennsylvania State University, University Park, PA

Professional Experience

Senior Pharmacovigilance / Regulatory Affairs Consultant **2007 - 2009**
Chattem, Inc., Chattanooga, TN
Department of Product Safety & Regulatory Affairs, David Grob, MS, RAC - Director

- Responsible for all pharmacovigilance (PV) activities relating to adverse events (AE), drug safety, and post-marketing surveillance to ensure regulatory compliance. Primary international PV contract liaison (ARISg).
- Chaired the AE Committee Review meetings and prepared Food & Drug Administration (FDA) Medwatch 3500A forms for over-the-counter (OTC) drugs, devices and dietary supplements.
- Conducted InfoMed tracking system database queries, data mining and literature searches to generate trending analyses, establish product histories and detect safety signals.
- Provided technical/scientific support as well as statistical/data analysis for the Department of Product Safety & Regulatory Affairs, Marketing and Product Development to reduce outside consulting costs.
- Wrote and edited standard operating procedures (SOPs), promotional material for health professionals, white papers and technical documents. Primary author and preparer of New Drug Application (NDA) Periodic Safety Update Reports (PSURs). Assembled and maintained safety and efficacy references.
- Reviewed incident data to develop medical terminology, causality and chronologies for AEs to determine if investigations are warranted and initiated in compliance with FDA and Code of Federal Regulations (CFR).
- Implemented the customized versioning and coding of the InfoMed database program to improve efficiency for Consumer Affairs, Quality Control and the Department of Product Safety & Regulatory Affairs.
- Team member for non-clinical/clinical studies including protocol design, monitoring and management.
- Experience in reviewing and preparing 510(K) pre-market notification and NDA submissions. Experience interpreting Pre-Investigational New Drug (IND) processes as well as assessing Chemistry, Manufacturing, and Control (CMC) and current Good Manufacturing Practice (cGMP) requirements.
- Conducted reviews of labeling, artwork and advertising materials for claim support justification, appropriate language and compliance with federal and state regulatory agencies. Reviewed ingredient listings and formulations for safety issues as well as active and inactive ingredient regulatory permissions.
- Drafted responses to Corrective and Preventive Action (CAPA) investigations, FDA 483 Observations/Warning Letters, internal audits and provided product recall support.
- Conducted drug regulation reviews, CFR and OTC drug monograph interpretation and risk analyses. Gave guidance to six consumer affairs representatives on technical inquiries and disposition of complaints. Provided input to Consumer Healthcare Products Association (CHPA) letters addressing industry draft guidances.
- Utilized effective communication and proficient computer skills such as Excel, Word, and PowerPoint daily.
- Member of Drug Information Association (DIA) and attended 2008 Annual DIA Meeting in Boston, MA.

Postdoctoral Fellow **2004 - 2007**

Johns Hopkins University School of Medicine, Baltimore, MD
Department of Oncology - Division of Immunology & Hematopoiesis
Laboratory of T cell Activation and Tolerance, Jonathan Powell M.D., Ph.D.

- Managed multiple independent and collaborative research projects.
- Established *in vivo* models of T cell tolerance/activation and analyzed anergic signaling pathways.
- Characterized transgenic and knockout mouse phenotypes. Performed high-dimensional microarray data analysis studies and mouse colony management.
- Communicated research and ideas through seminars, posters, peer-reviewed journals and continuous appraisal scientific literature. Provided guidance for graduate students and technicians.

Graduate Student / Teaching Assistant **1998 - 2003**

The Pennsylvania State University, University Park, PA
Department of Veterinary & Biomedical Sciences, Pamela (Correll) Hankey Ph.D.

- Analyzed a receptor tyrosine kinase pathway *in vitro* and *in vivo* within models of infection and inflammation.
- Characterized knockout mouse phenotype. Performed equipment repair and trouble shooting.
- Presented independent research through seminars, posters and peer-reviewed journals.
- Designed and taught two semesters of molecular, cellular and developmental biology.

Research Assistant **1997**

Centocor (Johnson & Johnson), Malvern, PA
Immunology and Pharmacology & Toxicology Departments

- Assisted in experiments validating the efficacy of a monoclonal antibody against TNF-α (Infliximab/Remicade) within *in vivo* models of arthritis. Carried out toxicology experiments and ascites production.
- Analyzed clinical chemistries of serum samples. Performed ELISA assays and animal cell culture.
- Dosed laboratory animal and collected samples. Provided animal care and husbandry.
- Conducted information searches and complied with Good Laboratory Practice (GLP) procedures.

Selected Publications (6 of 10)

Huang G.N., Huso D.L., Bouyain S., Tu J., McCorkell K.A., May M.J., Zhu Y., **Lutz M.A.**, Collins S., Dehoff M., Kang S., Whartenby K., Powell J., Leahy D., Worley P.F. NFAT binding and regulation of T cell activation by the cytoplasmic scaffolding Homer proteins. *Science*. 2008 Jan 25; 319(5862): 476-81.

Zheng Y., Collins S., **Lutz M.A.**, Allen A., Kole T., Zarek P., Powell J.D. A role for mammalian target of rapamycin in regulating T cell activation versus anergy. *J Immunol.* 2007 Feb; 178(4): 2163-70.

Scheibner K.A., **Lutz M.A.**, Boodoo S., Fenton J.D. and Horton M.R. Hyaluronan fragments act as an endogenous danger signal by engaging TLR2. *J Immunol*. 2006 Jul; 177(2): 1272-81.

Safford M., Collins S., **Lutz M.A.***, Allen A., Huang C., Kowalski J., Blackford A., Horton M.R., Drake C., Schwartz R.H. and Powell J.D. Egr-2 and Egr-3 are negative regulators of T cell activation. *Nat Immunol*. 2005 May; 6(5): 472-80. (*co-first author)

Lutz M.A., Liu Q-P. and P.H. Correll. Activation of CR3-mediated phagocytosis by MSP requires the RON receptor, tyrosine kinase activity, phosphatidylinositol 3-kinase and protein kinase C ζ. *J Leuko Biol*. 2003 Jun; 73(6): 802-14. (+ cover figure)

Lutz M.A., Gervais F., Berstein A., Hattel A.L. and P.H. Correll. STK receptor tyrosine kinase regulates susceptibility to infection with Listeria monocytogenes. *Infect Immun*. 2002 Jan; 70(1): 416-8.

References

Available upon request.