LISA D. BEILKE, MSPH, PhD, DABT
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SUMMARY OF QUALIFICATIONS

Classically trained toxicologist with over 20 years in the biotechnology industry working on small molecule, polymer, peptide and monoclonal antibody therapeutics. Experience encompasses work at a CRO conducting GLP studies and work in industry (small and large pharma) as a project team toxicologist on early research and late stage development multidisciplinary teams.

- Over 12 years as computational toxicologist, with *in silico* mutagenicity assessment of impurities submitted to various domestic and international regulatory bodies on numerous occasions; author of several *in silico*-related publications
- Performance of risk assessment strategies for large and small molecule impurities, degradants, starting materials, etc, as well as leachable and extractables for device related products
- Conducted various pharmacology/toxicology studies including safety pharmacology (CNS, respiratory, cardiovascular, Langendorff), genotoxicity (Ames, chromosome aberrations, micronucleus), repeat dose chronic toxicity including carcinogenicity and reproductive (Seg I, II) studies
- Experience conducting Occupational toxicology studies, SDS writing, and Occupation Health Categorizations
- Regulatory writing:
    - Primary author of toxicology-related sections (2.4, 2.6.2/2.6.3, 2.6.6/2.6.7, IB) of many INDs across various therapeutic areas including both small and large molecules (mAbs)
    - Prepared toxicology section of annual IND/IB updates, IMPDs and DSURs
    - Primary responsibility for authoring Section 2.6.7 and non-clinical reviewer for two successful drug combination NDA/MAA filings; 4-product (QUAD) and a 2-product combination
- Possess excellent oral and written communication skills and value teamwork in a highly collaborative, creative work environment.

PROFESSIONAL EXPERIENCE

TOXICOLOGY SOLUTIONS, INC. San Diego, CA **12/2012-present**
President/CEO
TSI is an independent consulting company focused on providing nonclinical toxicology services for the development of therapeutics from early discovery through product registration. In additional to general toxicology, specialty services include risk assessment and *in silico* toxicity predictions using 3 major predictive software programs (DEREK Nexus, Leadscope Model Applier, MultiCASE).

TRICIDA, INC. South San Francisco, CA **1/15-3/2015**
Sr. Director, Drug Safety
Responsibilities included overall management of drug safety, including impurity-related CMC and regulatory activities, as well as toxicology and associated activities (management of CROs, protocols, reports, summaries, regulatory submissions, etc.). Involved in strategic decision making, and responsible for authorship of any documentation and conduct of any activities appropriate to support decisions.

ARAGON PHARMACEUTICALS San Diego, CA **7/12-8/2013**
Principal Scientist, Drug Safety and Disposition

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Aragon Pharmaceuticals was a privately held, small-molecule drug discovery company focused on developing breakthrough medicines for the treatment of hormonally-driven cancers. As the sole toxicologist for the company, I was responsible for the design and conduct of all non-clinical toxicology studies in support of breast and prostate cancer projects from discovery through registration. Lead author of toxicology sections for all regulatory filings with input/review of all other sections to ensure proper integration of toxicology conclusions. Collaborated with Regulatory and Clinical on the strategy of filings (e.g., combo INDs, presentation/interpretation of data). Served as Project Leader for SERD program, was responsible for coordination of all project-related activities from Chemistry, Biology and Drug Safety groups, including budget, API needs, timelines, etc. Additional responsibilities included hazard characterization of early research compounds, process chemicals, and impurities; MSDS development and review; lead computational toxicologist. Company was acquired by Johnson & Johnson without acquisition of employees.

GILEAD SCIENCES Foster City, CA **7/08-7/2012**

Research Scientist II, Drug Safety Evaluation

Independent design and conduct of non-clinical toxicology studies in support of anti-viral drug discovery and development projects. Lead protocol review discussions concerning scientific and procedural aspects of toxicology study design. Independently design and conduct various in vitro and in vivo studies to include general, single and repeat dose toxicology, safety pharmacology, genetic and reproductive toxicology, ion channels, receptor binding, and kinase screening. Oversee procedural and scientific aspects of studies throughout duration of study. Data review and interpretation of toxicology study reports. Prepare study protocols, amendments, and other documents as needed. Ensure quality studies are conducted and reported in a timely manner. Preparation and review of regulatory documents, annual reports, INDs, Investigator Brochures and NDAs/MAAs. Represent department on multifunctional project teams. Strategic decision making to anticipate obstacles and difficulties to ensure goals are met. Possess working knowledge of pre-clinical drug discovery and development, along with adherence to appropriate regulatory requirements of study conduct and industry standards of Good Laboratory Practices as well as Gilead SOPs. Additional responsibilities including hazard characterization of early research compounds, process chemicals, and impurities; MSDS development and review; lead computational toxicologist.

UNIVERSITY OF ARIZONA Tucson, AZ **8/03-8/08**

Graduate Research Associate

Completed three years of coursework in pharmacology/toxicology (Advanced Toxicology, Pharmacology, Toxicogenomics/Proteomics, Molecular/Cellular Toxicology, Systems Physiology, Ethics, Drug Disposition/Metabolism, and General Toxicology) and one year for a minor in cancer biology (Molecular Mechanisms of Carcinogenesis, Clinical Cancer Biology, Cancer Biology Seminar Series). The Cherrington Lab focuses on understanding the mechanisms that control drug transporter-mediated excretion of organic anions, specifically in the areas of cholestasis and non-alcoholic fatty liver disease. My project focused on identifying the molecular mechanisms responsible for the hepatoprotection observed following chemical pre-treatment with CAR (constitutive androstane receptor) inducers during bile acid-induced intrahepatic cholestasis. The core work of this project involved the evaluation of protein and mRNA expression and relating changes in expression to functional changes using an *in vivo* mouse model of cholestasis.

PFIZER GLOBAL R&D La Jolla, CA **5/00-8/06**

Sr. Associate Scientist

Formerly Agouron Pharmaceuticals, prior to acquisition by Pfizer. Responsible for managing Chemistry, Manufacturing, and Control (CMC) toxicology functions within Drug Safety Evaluation (DSE) Department. Primary responsibilities included independent design, conduct and interpretation of toxicology and worker safety studies, provided support to Pharmaceutical Sciences Dept. for drug substance and drug product issues (e.g., impurities, degradants, solvents, vehicles/excipients, etc.), liaison to EHS for hazard communication (provided hazard/risk assessments, MSDSs), DSE expert for excipients and vehicle safety. Participated as toxicology representative on project teams to facilitate the development of innovative and highly valued drug candidates. Additionally, acted as the department Safety Officer representing the department on various Safety sub-committees, ensuring departmental compliance with regulations, and evaluating impact of new technologies. Participated as

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toxicologist on global Vehicles Safety Task Force for evaluation of data and maintenance of vehicle/excipient database and evaluation of novel excipients.

TREGA BIOSCIENCES San Diego, CA **10/99-5/00**
Sr. Research Assistant
Conducted *in vivo* pharmacology and pharmacokinetic experiments to support compound screening in drug discovery programs. Responsibilities included development of *in vivo* models for obesity/sexual dysfunction/diabetes, performance of surgical techniques (ICV cannulation), collection and analysis of biological data, presentation of experimental results.

SIERRA BIOMEDICAL San Diego, CA **4/98-10/99**
Intern/Research Associate II
Formerly HTI Bioservices, a small Contract Research Organization. Started as a Toxicology Research Intern, where I learned multiple species animal handling and care, administration (multiple routes) of developmental compounds, data collection (GLP), specimen collection and processing, principles/writing of IACUC documents, SOP's, study protocols, data analysis, and report/abstract writing. Promoted to RA and provided technical support on GLP and non-GLP *in vivo* toxicology and pharmacokinetic studies with concise and accurate documentation. Assisted with protocol development and study data analysis. In a full GLP environment, performed QA data reviews; coordinated the development, organization, and management of projects, and acted as liaison to clients**.**

CALIFORNIA POISON CONTROL SYSTEM San Diego, CA **3/97-4/98**
Poison Information Provider
Provided treatment recommendations to telephone callers in emergent poison situations. Additionally, provided callers with information about general toxicology/pharmacology, including plant-, animal-, and food-related issues.

UCSD MEDICAL CENTER, EMERGENCY DEPT. San Diego, CA **2/91-3/97**
Emergency Trauma Technician
Patient care duties, to include primary and secondary assessment of patients, venipuncture, 12-lead ECG, vital signs, casting/splinting, and assisting physicians with invasive medical procedures.

HARTSON MEDICAL SERVICE San Diego, CA **5/90-6/91**
Emergency Medical Technician
Via ambulance, responded to emergency calls to provide efficient and immediate care to the critically ill and injured, and transports the patient to a medical facility. On scene, determined the nature and extent of illness or injury and established priority for required emergency care. Based on assessment findings, rendered emergency medical care to adult, infant and child, medical and trauma patients. Duties included, but not limited to, opening and maintaining an airway, ventilating patients and cardiopulmonary resuscitation. Provided pre-hospital emergency medical care of simple and multiple system trauma such as controlling hemorrhage, treatment of shock, bandaging wounds, and immobilization of painful, swollen or deformed extremities. Care for medical patients included: assisting in childbirth, management of respiratory, cardiac, diabetic, allergic, behavioral, and environmental emergencies, and suspected poisonings.

EDUCATION & PROFESSIONAL CERTIFICATION

European Registered Toxicologist (ERT) 2014

Diplomat, AMERICAN BOARD OF TOXICOLOGY 2010

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Ph.D	PHARMACOLOGY/TOXICOLOGY Minor: Cancer Biology University of Arizona, Tucson, AZ	2008
M.S.	PUBLIC HEALTH - TOXICOLOGY San Diego State University, San Diego, CA	2000
B.S.	CRIMINAL JUSTICE (and pre-med) San Diego State University, San Diego, CA	1996
A.A.	GENERAL EDUCATION (Emergency Medical Technology) Palomar College, San Marcos, CA	1989

PROFESSIONAL CONTRIBUTIONS

- International Journal of Toxicology
  Editorial Board, Spring 2013-present
- Society of Toxicology, Computational Toxicology Specialty Section (CTSS)
  Co-founded this new specialty section in 2017
  Served as Vice President, President, and Past-President
- American College of Toxicology (ACT)
  Elected to Nomination Committee, 2020-2021
  Elected Councilor, 2016-2019
  Elected Member of Finance Committee, 2012-2015
  Webinar Committee member 2011-2016
  Elected Member of Education Committee, 2009-2011
- Southern California Chapter of the Society of Toxicology (SCC SOT)
  Served as Past President through 2016-2017
  Served as Chapter President through 2015-2016
  Served as Vice President 2013-2014
  Served as Vice President Elect 2012-2013
- Food and Chemical Toxicology Journal
  Editorial Board, Fall 2015-2016
- American Board of Toxicology
  Standard of Knowledge Committee, 2014
- Northern California Chapter of the Society of Toxicology
  Elected Councilor 2012-2013
- County of San Mateo Emergency Medical Care Committee
  Appointed Community Volunteer Member, 2011-2014

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MEMBERSHIPS AND AWARDS

- American College of Toxicology (ACT), 1998-present, Full member
- Society of Toxicology (SOT), 2001-present, Full Member
- Genetic Toxicology Association (GTA), 2013-present
- Round Table of Toxicology Consultants, 2013-present
- Eurotox, 2015-present
- ACT Young Professional Award – 2013
- Northern California Chapter of SOT, 2008-2012
- Southern California Chapter of SOT

RECENT CONTINUING EDUCATION

11/2019	ACT Annual Meeting	Phoenix, AZ
3/2019	SOT Annual Meeting	Baltimore, MD
11/2018	ACT Annual Meeting	West Palm Beach, FL
5/2018	GTA Annual Meeting	Newark, DE
3/2018	SOT Annual Meeting	San Antonio, TX
11/2017	ACT Annual Meeting	Palm Springs, CA
11/2016	ACT Annual Meeting	Baltimore, MD
3/2016	SOT Annual Meeting	New Orleans, LO
11/2015	ACT Annual Meeting	Las Vegas, NV
10/2015	Science of Clinical Trial Design	UCSD Extension
10/2015	SCC SOT Fall Meeting	Carlsbad, CA
3/2015	SOT Annual Meeting	San Diego, CA
10/2014	SCC SOT Annual Meeting	San Diego, CA
9/2014	Eurotox Annual Meeting	Edinburgh, Scotland
4/2014	Lhasa Virtual ICGM: Members of FDA present on ICH M7	
3/2014	SOT Annual meeting	Phoenix, AZ
3/2014	Lhasa 37th IGCM: ICH M7 and Negative Predictions in DEREK	Phoenix, AZ
3/2013	SOT Annual meeting	San Antonio, TX
3/2012	SOT Annual meeting	San Francisco, CA
	CE: Innate Immunity and its Relevance to Toxicology	
11/2012	ACT Annual meeting	Orlando, FL
11/2011	ACT Annual meeting	Phoenix, AZ
	Course Chair: *In Silico* Toxicology	
11/2010	ACT Annual meeting	Baltimore, MD
11/2009	ACT Annual meeting	Palm Springs, CA
	Course Chair: Drug transporters in toxicology	
3/2008	SOT Annual meeting	San Francisco, CA
11/2008	ACT Annual meeting	Tucson, AZ

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PUBLICATIONS

Johnson C, Ahlberg E, Anger L, **Beilke L**, et al. (2020). Skin sensitization in silico protocol. *Regulatory Toxicology and Pharmacol., 116:1-22.*

Hasselgren C, Ahlberg E, Akahori Y, Amberg A, Anger L, Atienzar F, Auerbach S, **Beilke L**, et al. (2019). Genetic toxicology in silico protocol. *Regulatory Toxicology and Pharmacol., 107:1-21.*

Amberg A, Andaya R, Anger L, Barber C, **Beilke L**, et al., (2019). Principles and procedures for handling out-of-domain and indeterminate results as part of ICH M7 recommended (Q)SAR analyses. *Regulatory Toxicology and Pharmacol., 102:53-64.*

Myatt GJ, Ahlberg A, Akahori Y, Allen D, Amberg A, Anger LT, Aptula A, Auerbach S, **Beilke L**, et al. (2018). In silico toxicology protocols. *Regulatory Toxicology and Pharmacol., 96:1-17.*

Myatt GJ **, Beilke LD**, Cross KP (2016). In Silico Tools and their Application. Comprehensive Medicinal Chemistry III: ADME and Toxicology: A Comprehensive Overview of the Current Status and Application of Predictive ADMET (Editor: Alan G.E. Wilson). Elsevier, Inc.

Ahlberg A, Amberg A, **Beilke L**, Bower D, Cross K, Custer L, et al. (2016). Extending (Q)SARs to incorporate proprietary knowledge for regulatory purposes: A case study using aromatic amine mutagenicity. *Reg Tox and Pharmacol.,* 77:1-12.

Amberg, A, **Beilke, L**, Bercu J, Bower D, Brigo A, et al. (2016). Principles and procedures for implementation of ICH M7 recommended (Q)SAR analyses. *Regulatory Toxicology and Pharmacol.,* 77:13-24.

Beilke, LD, 2014. American Academy of Clinical Toxicology. In: Wexler, P. (Ed.), Encyclopedia of Toxicology, 3rd edition vol 1. Elsevier Inc., Academic Press, pp. 170–171.

Beilke, LD, 2014. Thiotepa. In: Wexler, P. (Ed.), Encyclopedia of Toxicology, 3rd edition vol 4. Elsevier Inc., Academic Press, pp. 551–552.

Link J, Bannister R, **Beilke L,** Cheng G, Cornpropst M, Corsa A, Dowdy E, et al. (2010). Nonclinical profile and phase I results in healthy volunteers of the novel and potent HCV inhibitor GS-5885. *AASLD Meeting*. Poster # 1883.

Beilke LD, Aleksunes L, Olson E, Besselsen D, Klaassen C, Dvorak K, Cherrington N. (2009). Decreased apoptosis during CAR-mediated hepatoprotection against lithocholic acid-induced liver injury in mice. *Toxicology Letters.* 188(1):38-44.

Beilke LD, Aleksunes L, Holland R, Besselsen DG, Beger RD, Klaassen CD, Cherrington N. (2009). CAR-Mediated changes in bile acid composition contributes to hepatoprotection from LCA-induced liver injury in mice. *Drug Metabolism and Disposition*. 37(5):1035-45.

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Beilke LD, Besselsen DG, Cheng Q, Kulkarni S, Slitt AL, Cherrington NJ. (2008). Minimal role of hepatic transporters in the hepatoprotection against LCA-induced intrahepatic cholestasis. *Toxicol. Sci.* 102(1):196-204.

Ahern, LD, Holland, RD, Beger, R, Cherrington, NJ. (2005). Induction of multi-drug resistance associated protein 3 (Mrp3) correlates with altered bile acid disposition and hepatoprotection during cholestasis in C57BL/6 mice. *Drug Metabolism Reviews*. 37(2): Abstract #61, p. 45.

Burn-Naas, LA, Lee, C, Evering, W, **Ahern, L**, Webber, S, Zorbas, M. (2005). Lack of respiratory and contact sensitizing potential of the intranasal antiviral drug candidate Ruprintrivir (AG7088): A weight-of-the-evidence evaluation. *Journal of Immunotoxicology*. 2:123-139.

de Peyster A, MacLean KJ, Stephens BA, **Ahern LD**, Westover CM, Rozenshteyn D. (2003). Subchronic studies in Sprague-Dawley rats to investigate mechanisms of MTBE-induced Leydig cell cancer. *Toxicol Sci.* 72(1):31-42.

REFERENCES AVAILABLE UPON REQUEST