

Robert L. Zeid

PROFESSIONAL WORK HISTORY

7/97 to date

TLI Development, Oak Island, NC

Principal Consultant

International pharmaceutical support service-company that provides medical/ technical writing services for drug and biologics product development programs/ submissions. Other services include assistance with due diligence reviews and product liability support for US and international regulatory filings, such as supervision/ review of client's formulation, analytical, scale-up, and clinical manufacturing activities. Perform GLP, cGMP, and mock PAI inspections. As a certified trainer for controlled substances (CS) compliance, I perform training programs and CS audits. Established and manage a growing international database of contract providers for custom product development and review.

8/94 to 6/97

Applied Analytical Industries, Inc., Wilmington, NC

Manager, Regulatory Affairs

Responsible for regulatory support of client and in-house formulation, analytical, scale-up, and clinical manufacturing activities. Prepared CMC sections for at least five INDs, three NDAs, and five ANDAs for various dosage forms (e.g., solid oral, ophthalmic, injection, and MDIs). Responsible for project management, organization, and submission of CMC data for IND, NDA, ANDA, and PLA documents. Performed GLP and cGMP audits. Key participation on project teams, planning, and budgets. Responsible for DEA/ controlled substances compliance for five registrants; perform in-house and client-based controlled substances training, as well as ARCOS reporting.

10/91 to 7/94

Univax Biologics, Inc., Rockville, MD

Senior Associate, Regulatory Affairs

Managed regulatory development and filing for two vaccine INDs: (1) MEP (mucoid exopolysaccharide) antigen from *Pseudomonas aeruginosa* and (2) *Staphylococcus aureus* Type 5 and 8 Bivalent vaccine for use in renal dialysis patients. Managed the IND filing for a MEP gamma globulin for treating *P. aeruginosa* in cystic fibrosis patients. Managed the review and compilation for WinRho SD (RhO D Gamma Globulin) ELA and CMC portions of the PLA for treatment of ITP (idiopathic thrombocytopenic purpura). Involved with project definition and support for an *E. coli* 12-valent vaccine and sepsis program. Performed FDA interactions and assisted with corporate development/ partnering agreements (e.g., due diligence audits). Assisted with CRA and monitoring compliance issues, clinical site audits. Assisted with setting up clinical documentation systems and RA library.

7/88 to 10/91

Zeid & Co., Philadelphia, PA

Founded a company that provided freelance medical writer/editor services to scientific publishers and local pharmaceutical firms. Worked on numerous clinical reports and publications for peer-reviewed journals. Provided regulatory consulting and submission support for a number of pharmaceutical firms (e.g., compiled an IND for an AIDS drug).

10/82 to 7/88

Smith Kline & French Laboratories, Philadelphia, PA
Regulatory Affairs Associate

Provided regulatory support for both marketed and investigational drug registrations (e.g., INDs, SNDAs, and responses to FDA information requests). Handled investigator documentation for clinical supply shipments. Participated in labelling and promotion review; submitted promotional materials to FDA. Had close interaction with safety reporting group for preparation/ refinement of AE reporting for INDs and NDAs.

Research Associate, Pharmacology & Toxicology

Performed and analyzed *in vitro* drug screening test data for the anti-hypertensive and anti-anginal programs; supervised two technicians; established databases for assessing structure-activity relationships (SAR).

8/80 to 10/82

Wright State University, School of Medicine, Dayton, OH
Research Assistant, Department of Pharmacology

Performed and analyzed *in vitro* and *in vivo* drug screening test data for anti-dopaminergic and cholinergic effects of a long-lasting methadone derivative (LAAM) and behavioral impact of endorphins on reinforcement and learning. Assisted graduate students with doctoral dissertation research in toxicology.

EDUCATIONAL BACKGROUND

BS	Microbiology, Ohio University Athens, OH	1979
Post-baccalaureate courses	Neuroanatomy, pharmacology, and law Wright State University, Dayton, OH	1979 - 1982
Additional Training	Investigating OOS Test Results FDA Team Biologics Field Inspections Biologics 2000 Team Biologics Training, WCBP 2000 Advanced Industrial Bioprocessing, CPC Contemporary Parenteral Drug Technology, CPA DEA Seminar (ARCOS, Quotas, Import-Export) Characterization of Biotechnology Pharmaceutical Products GMP Roundtable Conference Controlled Substances Training Overview of Analytical Methods for Biopharmaceuticals Biotech Regulatory Policy Workshop INTERNET Course Biologics Regulatory Review FDA CMC Reviewer Seminar Advanced GMP Training Controlled Substance Training Potent Compound Training Validation of Biological Manufacturing Processes/Equipment Advanced GMP Workshop GMP Workshop, CPA GLP Workshop, CPA Product Liability Seminar, DIA Validation Workshop, Kaye Instruments	December 2000 December 2000 May 2000 January 2000 August 1998 August 1996 May 1996 December 1995 October 1995 September 1995 July 1995 May 1995 April-June 1995 January 1995 January 1995 August 1994 August 1994 August 1994 May 1994 September 1993 August 1993 May 1993 April 1993 1992

AFFILIATIONS

Regulatory Affairs Professional Society (RAPS) Parenteral Drug Association (PDA)
Drug Information Association (DIA) USP Complex Actives Project Team
Generic Pharmaceutical Association (GPhA): Biotechnology Technical Advisory Committee

PUBLICATIONS

1. Langley AE, Smith SG, Zeid RL: Dopaminergic and Cholinergic Muscarinic Receptor Effects of L-Alpha acetylmethadol (LAAM) and Its Metabolites. *Proceedings of the Society for Experimental Biology and Medicine* 176: 41882, 1984.
2. Ruffulo Jr. RR, Zeid RL: Relationship Between α_2 -Adrenoceptor Occupancy and Response for B-HT 933 in Canine Saphenous Vein. *European Journal of Pharmacology* 111:267-271, 1985.
3. Kaiser C, Dandridge PA, Garvey E, Flaim KE, Zeid RL, Hieble JP: Dopamine Receptor Agonist Activity of Some 5-(2-Aminoethyl)carbostyryl Derivatives. *Journal of Medicinal Chemistry* 28:1803-1810, 1985.
4. Zeid RL, Ruffulo Jr. RR: Role of Prostacyclin, Thromboxane A₂, and Leukotrienes in Cardiovascular Function and Disease in *Oxygen Transport in the Critically Ill*, (JV Snyder, MR Pinsky, ed), Year Book Medical Publishers (Chicago), 1987.
5. Smith III EF, Kinter LB, Jugus M, Zeid RL: Effect of the Thrombolytic Agent, Streptokinase, on the Responses to Endotoxemia in Conscious Rats. *Circulatory Shock* 25:85-94, 1988.
6. Ohlstein EH, Kopia GA, Zeid RL, Valocik RE, Horohonich S, Hieble JP, Wasserman MA: Effects of the Thromboxane Receptor Antagonist SK&F 88046 in the Canine, Monkey, and Human Coronary Vasculature. *Prostaglandins*, 1988.
7. Hieble JP, Sulpizio AC, Sarau HM, Flaim KE, Blumberg AL, McCafferty JP, Zeid RL: SK&F 89124, A Potent and Selective Agonist at Prejunctional Dopamine Receptors. *Fundamentals of Clinical Pharmacology* 3:621-642, 1989.
8. Zeid RL: Generic Biologics: Notes from the Path Less Traveled. *BioPharm* 12(3): 24-32, 1999.
9. Zeid RL: Generic Biologics: Glimpses through the Mist. *Regulatory Affairs Focus*, February 1999.
10. Zeid RL: Generic Biologics: Could the Impossible Become Reality? *Regulatory Affairs Focus*, March 1999.
11. Zeid RL: Regulatory and Development Issues for Demonstrating Therapeutic Equivalence of Multi-source Biotech-derived Products. *Drug Information Journal* 34(3): August 2000 – Special Issue.
12. Zeid RL: Setting the Standards for Biogenerics. *Scrip Magazine* July/August 2000 (Issue 92).
13. Zeid RL: Regulatory and Development Issues for Demonstrating Therapeutic Equivalence of Multi-source Biotech-derived Products. *Drug Discovery Online*: January 2001 – Special Series.
14. Zeid RL: Specifications and Manufacturing Change Control: A Prototypic System for Electronic Document Tracking & Management. *BioPharm* (accepted for publication Feb 2002).

ABSTRACTS/ POSTER PRESENTATIONS

1. Hieble JP, Sulpizio A, Jervay C, Gruber F, Davis D, Zeid RL, Aston D, DeMarinis R: The Discovery of Novel Antihypertensive Drugs Via Pharmacological Differentiation of Alpha-adrenoceptor Subtypes. SmithKline Beckman Poster Meeting, 1983.
2. Zeid RL, Jervay CA, Gruber FH: Blockade of Alpha-adrenoceptor Subtypes by BE2254. SmithKline Beckman Poster Meeting, 1983.
3. Zeid RL, Hieble, JP, DeMarinis RM, Wilson JW: Inhibition of Transmitter Release from Dog Vascular Tissue by a Selective D₂ Agonist. *FASEB*, April 1984.
4. Zeid RL, Langley AE, Smith SG (Hieble JP [Sponsor]): Effects of L-Alpha-acetylmethadol (LAAM) and Its Metabolites on Striatal Dopaminergic (DA) and Muscarinic (M) Receptors. *American Society for Experimental Biology (ASPET)*, Indianapolis, Indiana, 1984.
5. Adejare A, Hamada A, Patil PN, Miller DD, Hieble PJ, Zeid RL, Ruffolo Jr., RR: Synthesis and α -adrenergic Activity of Fluorinated Benzylimidazolines. Medicinal Chemistry and Pharmacognosy, American Chemical Society (ACS) Meeting, 1989.
6. Hieble JP, Boyce AJ, Zeid RL: *In Vitro* Characterization of the Alpha-Adrenoceptors in Canine Prostate.
7. Smith EF, Kinter LB, Jugus M, Zeid RL: Intravenous Administration of the Thrombolytic, Streptokinase, Prolongs Survival in Rats with Endotoxic Shock: A Comparison with Heparin. *FASEB*, 1988.

PRESENTATIONS & PANEL DISCUSSIONS

- **AAI Pharmaceutical Seminars: Controlled Substances – Compliance Issues and Practices for the Pharmaceutical Industry**
- **Generic Pharmaceutical Industry Association (GPIA) 1999 Annual Meeting; March 26-28, 1999 New York City**
 - Generic Biologics: Notes from a Path Less Traveled
- **Drug Information Association (DIA) 1999 Annual Meeting; June 28 – July 1, 1999 Baltimore, Maryland**
 - Success Factors in Generic Registrations (Panel Discussion)
- **IBC 9th Annual International Conference on Rx and Biotech Generics; September 21-23, 1999, Georgetown University Conference Center, Washington, DC**
 - Demonstrating Therapeutic Equivalence for Biotech-derived Products: A Pre-conference Intensive/ Workshop
 - Generic Biologics: Views from a Mist Rising
- **WorldPHARM'99 Show; October 26-28, 1999, Philadelphia, Pennsylvania**
 - Generic Biologics – Part 1: Analytical and Regulatory Evaluation
 - Generic Biologics – Part 2: Legal, Economic, and Political Implications
- **4th Symposium on the Analysis of Well Characterized Biotechnology Pharmaceuticals (WCBP 2000); January 9-12, 2000, San Francisco, California**
 - When Are 'Equivalent' Biotechnology Pharmaceuticals Possible? (Panel Discussion)
- **Management Form/ EGA Conference on Generics: Regulatory Issues for Generics; January 24-25, 2000, London, England**
 - Generic Biologics: Demonstrating Therapeutic Equivalence for Biotech-derived Pharmaceuticals
- **IBC Conference on Team Biologics Field Inspections: December 12-13, 2000, San Diego, California**
 - Specifications & Manufacturing Change Control: Electronic Document Tracking & Management
- **International Generic Pharmaceutical Alliance (IGPA) Annual Conference: June 25-27, Cannes, France**
 - Considerations for the Future of Multi-Source Biotech: Global Policy Update
- **IIR Limited – International Generics Strategy – Comparable Biotech Products: May 22, 2002, Barcelona, Spain**
 - Multisource Biologics – Demonstrating Therapeutic Equivalence for Biotech-derived Products
- **Management Forum – Comparability Issues in the Development of Biotechnology Products ... and a Consideration of Biotech Generics: October 25, 2002, London, UK**
 - Demonstrating Therapeutic Equivalence of Various Biotech Classes: Correlation of Structure-Activity Relationships (SAR) to Clinical Safety and Efficacy
- **Pharmaceutical Training International (PTI) – Regulatory Affairs for Biotech – Critical Steps to Compliance: (Instructor in ongoing course training)**
- **European Generic Association (EGA) – Generic Biotech Conference: May 23, 2003, London, UK**
 - Demonstrating Therapeutic Equivalence of Various Biotech Classes: Correlation of Structure-Activity Relationships (SAR) to Clinical Safety and Efficacy
- **IBC Generic Biopharmaceutical Manufacturing in Asia; March 1-2, 2004, Mumbai, India**
 - Session Chair & presentation: Points to Consider in the Multisource Biotech Initiative: Demonstrating Therapeutic Equivalence vs. Comparability
- **40th Annual DIA Meeting; June 13-18, 2004, Washington, DC**
 - Session Chair: Regulatory & Development Considerations for Multisource Biotech