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PROFESSIONAL WORK HISTORY

7/97 to date **TLI Development (Oak Island, NC)**
Principal Consultant

Founder and principal consultant of TLI Development, we are a pharmaceutical consulting firm that provides cost-effective support in regulatory affairs, medical & technical writing, and quality assurance (QA) areas for a wide range of both drug and biotechnology development programs. We also provide training, standard operating procedures (SOP) writing, project management of technology transfers, comparability protocols, stability reports, development plans, as well as QA audits for current Good Manufacturing Practices (cGMP) and controlled substances.

Special expertise includes (1) writing and reviewing chemistry, manufacturing, and control (CMC) documents for regulatory submissions; (2) preparing documents for meetings with the FDA or other competent authorities or responses to regulatory queries on CMC, non-clinical, and clinical issues; and (3) writing product development plans. Other experience includes regulatory & cGMP training, design, and implementation of environmental monitoring (EM) systems and overall compliance, due business diligence audits for US and international regulatory partnerships.

Specific experience includes:

- **cGMP audits** of API and finished product per US and MHRA criteria
- **Quality Assurance program audits** per ICH Q10 Pharmaceutical Quality System and QSIT
- **Quality systems audits** for manufacturing deviations, OOS, recalls, complaints, and biological product deviation reports
- **PAI preparation**: review of related documents and regulatory filings or information
- **Statistical sampling plans**; justifications for sample size and criteria
- **Batch records**: review and/or development
- **Specifications**: trend analysis and justification
- **Analytical methods & validation reports**: review of validation, transfer reports, & cross-over
- **Controlled substances compliance audits and training**
- **Annual product review (APR)** preparation and review
- **Stability**: protocols and summaries; statistical analysis for regression and pooling
- **Clinical program compliance**: review of investigator and site documentation; informed consents
- **Change control**: audit and review procedures for quality integration with multiple partners
- **Electronic document systems**: review and advise on compliance with 21 CFR Part 11
- **Electronic Submissions Gateway (ESG)**: set up and review of ongoing practices
- **Comparability Protocols**: preparation and/or review
- **Development reports**: review against regulatory filings and manufacturing trended experience
- **Container/closure systems**: qualification of system and compatibility, integrity testing, extractables and leachables protocols
- **Regulatory document preparation**: IND, NDA, BLA, IMPD, ANDA, pre-IND, EOPII, and pre-NDA/BLA submissions

8/94 to 6/97 **Applied Analytical Industries, Inc. (Wilmington, NC)**
Manager, Regulatory Affairs

Provided 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. Responsible for project management, organization, and submission of CMC data for IND, NDA, ANDA, and PLA documents. Performed GLP and cGMP audits and participated 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)**

Provided freelance medical writing and editing services to scientific publishers and local pharmaceutical firms. Authored and co-authored 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 behavorial 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		
	Neuroanatomy, pharmacology, and constitutional law Wright State University, Dayton, OH	1979 - 1982

AFFILIATIONS

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

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 D_2 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.

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)carbostyril Derivatives. *Journal of Medicinal Chemistry* 28:1803-1810, 1985.
4. Zeid RL, Ruffulo Jr. RR: Role of Prostacylin, 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).
15. Zeid RL: Regulatory and Development Considerations of Chiral Compounds in *Chiral Separations of Pharmaceuticals and Biotechnology Products* (in press) (Satinder Ahuha (ed); Wiley Press (publisher)).