



## *Curriculum Vitae*

### **SENIOR PROJECT MANAGER**

**XIAO-QUN ZENG**

Phone: 419.693.5307

### **Summary of Qualifications**

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Xiao-Qun Zeng is a senior project manager with more than 20 years of technical experience in biotechnology, pharmaceutical and medical device industries. She has extensive experience in development of methods and techniques, management of R&D projects, and assessment of microbiological laboratory procedures. She has successfully generated and executed numerous client-specific protocols in compliance with ISO, USP, AAMI, AOAC, and ASTM standards and guidelines. She is experienced in ethylene oxide and steam sterilization validation of pharmaceutical and medical device products. She has experience in performing OOS investigations/resolution, conducting quality control of Growth-Chek™ products, and providing technical consultation to clients. She has proven skills in a broad range of laboratory testing.

### **Professional Experience**

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#### **SENIOR PROJECT MANAGER, Lexamed, Ltd.**

Responsible for generation of protocols and final reports for in-house and client-specific projects, development and validation of testing methodologies, expansion and quality control of Growth-Chek™ production line, development and implementation of SOPs and procedures, and investigation of OOSs and deviations. Hands-on experience in a broad range of laboratory testing/techniques:

- Disinfectant Efficacy—AOAC Use-Dilution.
- Disinfectant Efficacy—AOAC Tuberculocidal Activity.
- Antimicrobial Effectiveness Testing.
- Antibiotic Assays.
- Endotoxin/LAL Testing.
- Cytotoxicity and Cell Culture Techniques.
- Sterilization Cycle Development and Validation.
- D-value Determination—EO, Steam and Dry Heat.
- Customization of Biological Indicator.
- Spore Crop Production and Population Assays.



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Xiao-Qun Zeng  
Senior Project Manager

- Formulation of Stable Microbial Products.
- Production of Growth-Chek™ Microbial Suspensions.
- Organism Identification.
- Sterility Testing and Method Qualifications.
- Microbial Limits Testing.
- Aseptic Techniques.
- Environmental Monitoring Program.
- Development of new laboratory test offerings.

**MICROBIOLOGY CONSULTANT, *LexaMed, Ltd.***

Provides technical consultation in multiple areas of medical device and pharmaceutical operations, including but not limited to:

- Microbiology laboratory testing including but not limited to Disinfectant Efficacy, Antibiotic Assays, Antimicrobial Effectiveness Testing, Cytotoxicity, sterility Testing, and Endotoxin/LAL Testing.
- Method development and qualification.
- Providing techniques training for laboratory personnel.
- D-value Determination—EO, Steam and Dry Heat.
- Sterilization processes and validations.
- Culture maintenance and preservation.
- Microbial products stability and quality evaluation.
- Investigation and resolution of OOSs and deviations.

Recent examples of consulting activities include:

**Global Manufacturer of Eye Care Products:**

- Authored, reviewed and approved client protocols for Antimicrobial Effectiveness Testing (AET) in compliance with USP method <51>.
- Performed investigation and authored subsequent reports for AET testing failure of pharmaceutical products.
- Conducted on site assessments of laboratory testing procedures and provided techniques training for client personnel.
- Recommended documentation changes and supported the implementation of changes to specifications, tested methods and protocols occur unilaterally.
- Assured all sample testing data was accurate and conducted in strict adherence to the specific method.

**RESEARCH AND TEACHING ASSISTANT, *University of Toledo, Department of Pharmacology***

Studying oxidative stress induced by water disinfection by-products and their mixture with ethanol, monitoring a toxicological lab and cell culture room to meet EPA regulations, and teaching Pharmacology/Toxicology lab course PHCL 3810.

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Xiao-Qun Zeng  
Senior Project Manager

- Monitored a toxicological lab and cell culture room to meet EPA regulations.
- Taught Pharmacology/Toxicology lab course PHCL 3810.
- Extensive mammalian cell culture experience involving CHO, HeLa, and J774A.1 cell lines.
- Protein analysis; Immunoassays.
- Cell based assays for apoptosis, cell proliferation, cell membrane disruption, free radical generation and protein modification.
- Utilized strong computer skills and microplate data analysis.

**LAB TECHNICIAN, *Fred Hutchinson Cancer Research Center, Clinical Research Division***

Identifying potential anti-cancer agents using yeast mutants that are deficient for specific DNA repair and cell cycle checkpoint functions.

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- Performed E.coli and Yeast culture.
- DNA/RNA extraction; plasmid isolation.
- Electrophoresis; Northern blotting.
- PCR; cell transfection; western blotting.
- Microplate cytotoxicity assays; robotic anti-cancer drug screening.
- Establishing sensitivity profile of yeast mutants to X-ray.
- Media and reagents preparation; lab maintenance; ordering of supplies.

**RESEARCH ASSISTANT, *University of Washington, Biology Department***

- Gene cloning; Restriction enzyme analysis.
- Primer design; PCR; RT-PCR.
- RNAi construction.
- Germline transformation.
- ELISA; immunocytochemistry staining.
- Fluorescence microscopy.

**QUALITY CONTROL ANALYST, *Nanchang Feihong Biomedical Company***

- Conducted quality control testing on raw materials, in-process and finished product in accordance with standardized procedures.
- Collected samples from manufacturing area for microbial limits testing to monitor the quality of the production environment.
- Maintained thorough inspection records and files.
- Conducted review for compliance and complete documentation within GMP approved by China SFDA.
- HPLC; plating.

**FOOD QUALITY INSPECTOR, *Nanchang Food & Oil Import and Export Co.***

- Performed visual, dimensional and functional inspections of import and export food product to ensure conformance to established criteria of different countries.



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Xiao-Qun Zeng  
Senior Project Manager

- Coordinated sample collection and shipment for quality testing at designated sites approved by China Customs.
- Maintained all quality assurance inspection records and providing product traceability information for administrative review and customers.

## Education

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- ◆ M.S., Pharmaceutical Science, College of Pharmacy, University of Toledo, Toledo, OH.
- ◆ Post Baccalaureate Studies in Biochemistry, University of Washington, Seattle, WA.
- ◆ B.S., Chemistry, Zhejiang University of Technology, Hangzhou, China.

## Master of Science Thesis

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- ◆ The induction of oxidative stress and cellular death by water disinfection by-products and their mixture with ethanol.

## Abstracts

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1. Zhou, X, Zeng, X and Riddiford, LM. 2006. Transcription factor Broad mediates the hormone regulated morphologic change during *Drosophila* pupariation (poster). The 5<sup>th</sup> International Symposium on Molecular Insect Science, Tucson, Arizona.
2. Zhou, X, Zeng, X and Riddiford, LM. 2006. *Broad*, a bridge between hormones and actin-based morphogenesis? NW regional meeting. Society for Developmental Biology. Friday Harbor Marine Laboratory, Seattle.
3. Won, M, Chung, K, Zeng, X and Simon, JA. 2004. Development of anticancer drugs by chemical genomics using *S. pombe* deletion mutants. The 3<sup>rd</sup> International Fission Yeast Meeting, San Diego.



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