

# ***LexaMed***

## ***Curriculum Vitae***

### **TECHNICAL DIRECTOR, TOLEDO OPERATIONS**

#### **JAMES G. WHITCOMB**

Mobile Phone: 815.403.3057

### **Summary of Qualifications**

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James has more than 25 years experience with industrial microbiology and microbiological quality control systems in medical device and pharmaceutical manufacturing facilities, including aseptic filling operations. He has successfully conducted numerous client QS and QC microbiology consulting projects with globally known companies including, but not limited to 3M, B. Braun, Bausch & Lomb, Bioport Corporation, Boston Scientific, Cardinal Health, Teleflex Medical, Tyco Healthcare, Unilever, and US Endoscopy. James has proven leadership and superior written and verbal communication skills facilitating increased productivity through goal-oriented management. He has acquired a thorough knowledge of FDA/GMP/QSR regulations, AAMI/ISO guidelines governing microbiology and the sterilization and release of pharmaceutical and medical products to market as well as USP procedures and guidelines, including <795> and <797> and <1116>.

### **Professional Experience**

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#### **TECHNICAL DIRECTOR, TOLEDO OPERATIONS, *LexaMed, Ltd.***

James provides technical direction and guidance for all aspects of the Toledo operation including providing support for in-house and client development and validation of testing methodologies, facilitating special client-specified projects, establishing personnel training and competency requirements, development of environmental monitoring procedures, protocols and metrics, clean room qualifications. James interfaces with clients and in-house sponsors to author and approve protocols, assists in execution and authors final reports as requires. James also participates as active member of AAMI sterilization committees.

#### **SENIOR CONSULTANT, MICROBIOLOGY/STERILITY ASSURANCE, *LexaMed, Ltd.***

James provides consulting services for various pharmaceutical and medical device companies. Responsibilities included technical guidance with respect to microbiology equipment and methods validation, cGMP compliance of laboratory operations and safety guidelines, FDA regulatory compliance, USP gap analysis of microbiological

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James G. Whitcomb  
Technical Director, Toledo Operations

procedures and <797>, sterility assurance, external auditing and remediation, audit and inspection preparation, SOP development and implementation, QA program development and implementation, environmental monitoring, training, EtO sterilization, and product stability and cleaning/disinfection program development and implementation.

**VICE PRESIDENT QUALITY OPERATIONS, CARE BioPharma, LLC**

- Responsible for establishing the company's quality philosophy, in addition to the policies and procedures for management review, internal audits, corrective and preventive action, out of specification, and deviation.
- Ensured that quality control and assurance procedures, specifications, policies and operating systems were written and implemented to assure all products tested or manufactured were in compliance with SOPs, cGMPs/QSRs and FDA regulations.
- Directed the establishment of all systems, procedures and specifications affecting quality (e.g., Quality Operations specifications, SOPs, validations, protocols and reports) to minimize errors and eliminate non-compliant operations.
- Oversaw all company audits and inspections.
- Forecasted and maintained the Quality Operations budget.

**SENIOR CONSULTANT, Pharmaceutical Systems, Inc.**

- Functioned as counsel and contractor for various clients both on-site and off-site.
- Ensured cGMP compliance of laboratory operations, documentation, and safety guidelines; assured that all data was accurate and testing conducted was in adherence to SOPs, cGMPs/GLPs/QSRs and FDA regulations.
- Authored Master Plans and SOPs on environmental monitoring, sterilization, and microbiology laboratory operations.
- Performed audits and compliance gap analyses against 21 CFR 820, 210/211, ISO 13485 and USP <797>.
- Conducted validation of analytical microbiological equipment and methods including MIDI, Vitek, Omnilog, and Microlog.
- Provided support as interim Manager of Microbiology Quality Control laboratory for medical device and pharmaceutical client's facilities.
- Provided client counsel on audit observations and established remediation plans for microbiology –related functions including:
  - SOP Content & USP/EP Testing Methods
  - Training Programs
  - Environmental Monitoring
  - Product Stability Programs
  - Cleaning/Disinfection Programs
  - Development and Validation of Steam, EtO, and Irradiation Sterilization Processes
  - Aseptic Filling
  - Microbial Identifications
  - Biological Indicator D-value and Z-value Determinations and Applications

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Selective examples of client and related consulting activity include:

**Global Research and Technology Leader in generic pharmaceuticals**

- Conducted steam sterilization process BI D-value and Z-value determinations consistent with ISO 11138-1 for survivor curve and fraction negative methodologies.

**Global Manufacturer of soft contact lenses and lens care products**

- Authored protocols and reports for EtO sterilization process validation including aeration periods meeting ISO 11135, EN 550, FDA, and OSHA requirements of various intraocular lens products.
- Authored protocol and final report for disinfectant efficacy studies pertinent to manufacturing surfaces.

**Global Manufacturer of innovative healthcare products**

- Performed as interim QC laboratory manager
- Responsible for daily operations of department and work schedules for four laboratory personnel. Department's team accomplishments included:
  - Rectified Gentamycin antibiotic assay.
  - Conducted BI D-value assessments.
  - Authored steam sterilization validation protocols and reports consistent with ISO 11134.

**Global Manufacturer of vaccines and plasma derivative products**

- Evaluated compliance to FDA 483 for QC microbiology laboratory.
- Assessed and modified the manufacturing area environmental monitoring program.
- Performed as 'hands-on' classroom training instructor for manufacturing personnel's aseptic technique.

**Global Research and Development Company offering products for minimally invasive surgical procedures**

- Authored disinfectant efficacy protocol and reports for clinical cleaning and reprocessing reusable endoscopic devices.

**Global Medical Device and Pharmaceutical Company offering products and services for the health care industry**

- Participated in FDA inspection readiness of QC microbiology laboratory.
- Authored EM program procedure modifications, data trending, and limit setpoint calculations.
- Conducted out of specification investigations and remediation for EM program.
- Validation of rapid microbial identification systems; Biolog's Microlog and Omnilog.

**Global Manufacturer of medical and surgical products**

- Implemented a device family characterization/segregation program for contract EtO sterilization of 1220+ device configurations.
- Authored protocols for EtO sterilization validation consistent with ISO 11135 and EN 550.

**Medical Device Manufacturer of orthopedic support products**

- Participated in study design for various devices' cleaning and sterilization reprocessing efficacy.
- Provided protocols and reports for devices' gamma sterilization process consistent with ISO 11137 and EN 552.

**Global Researched-based Pharmaceutical Company (under consent decree)**

- Managed 25+ scientists and consultants on-site, team projects included:
- QC microbiology SOP review and modifications for GMP/GLP and USP/EP requirements.
- Protocol and reporting for disinfectant efficacy qualifications.
- VHP process validation for isolator barrier system.
- Department training program content and implementation.
- Equipment qualification protocols and reports for MIDI FAME Rapid ID system, Biolog's Microlog and Omnilog systems, and Omnicon, Inc. Antibiotic Zone Reader.

**International Manufacturer of leading brands in foods, home care and personal care**

- Provided FDA readiness training to management and manufacturing personnel.
- Conducted SOP audit, generation, and training to QA/QC department personnel (good documentation practices, batch record review, document control, change control, out-of-specification, deviation, internal audits, signature registration, line clearance, label issuance, reprocessing control, pest control, etc.).

**MANAGER, MICROBIOLOGY LABORATORY, *Pharmaceutical Systems, Inc.***

- Hands-on experience with direct supervision of microbiology personnel and responsible for coordinating department's work schedule to ensure customer satisfaction for all testing related to:
  - Bioburden Recovery and Method Qualifications
  - Environmental Monitoring Program Development
  - BI Resistance Testing and Performance
  - Sterility Testing and Method Qualifications
  - Antimicrobial Effectiveness Testing

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- Disinfectant Efficacy
  - Microbial Barrier Properties of Packaging
  - Microbial Identifications
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- Accountable for accuracy of all departmental operating and testing SOPs, training program qualifications and implementation, assurance of good documentation practices and complete test record maintenance.
  - Authored clients' specific protocols for custom testing requirements.
  - Procured company license for shipping and handling controlled substances.

**LABORATORY SCIENTIST, *Ethox Corporation***

- Modified and developed SOPs for various testing activities and laboratory functions.
- Participated in testing and authored final reports for EtO sterilization validation.
- Conducted testing, documented results and authored reports for USP sterility testing, biological indicator D-value determinations, and environmental monitoring of production areas.

**Education**

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- ◆ B.S., Molecular Biology, State University of New York at Buffalo