

# ***LexaMed***

## ***Curriculum Vitae***

### **SENIOR CONSULTANT, MICROBIOLOGY/QUALITY SYSTEMS**

#### **JAMES D. LATHAM**

Mobile Phone: 847.370.1069

### **Summary of Qualifications**

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James Latham is a microbiologist who has over 15 years of technical experience in the medical device, pharmaceutical and biotechnology industries. He has extensive laboratory skills, including DNA isolation, purification, sequencing, cell culture techniques, nucleic acid amplification, RNA isolation, purification, electrophoresis, southern blot, bacterial and mould identification, D-value determination, USP testing, package integrity testing and evaluation, spore suspension preparation and aseptic techniques. He is experienced in process and cleaning validations, the calibration of spectrophotometric, clean room qualifications, electrochemical and thermal sensors/systems. He also has expertise in IQ, OQ and PQ for sterilization equipment which includes barrier technology and SIP systems. Evaluation of suitability of client quality systems, equipment and procedures against FDA, ISO and USP standards and guidelines, including 21 CFR 820 and 210/211, ISO 13485 and USP <795> and <797>. He has experience in creation of client specific protocols and procedures for execution in house and at client sites. Moreover, he has experience in direct management and supervision of microbiology laboratory and validation services.

### **Professional Experience**

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#### **SENIOR CONSULTANT, MICROBIOLOGY / QUALITY SYSTEMS, *LexaMed, Ltd.***

- Responsible for consulting in all areas of
  - medical device and pharmaceutical operations including but not limited to:
    - Sterilization
    - Equipment and Process Validation
    - Aseptic Manufacturing
    - Microbiology
    - Environmental Monitoring
    - GMP/QSR Compliance

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- Compounding pharmacies
- Quality Assurance / Quality Control / Sterility Assurance
- Start-up Operations and Regulatory Compliance
- 21 CFR Part 111 Auditing and Compliance
- Novel Medical device evaluation, qualification and generation of data for regulatory submissions
- Establishment of Action Plans to address regulatory compliance issues
- Client recalled product investigation and remediation
- Client product packaging integrity testing and evaluation

Numerous projects with major pharmaceutical and medical device companies while employed with LexaMed, Ltd. include the following selected consulting examples:

#### **Major U.S. Based Dietary and Nutritional Supplement Manufacturer**

Jim has provided service to the dietary and nutritional supplement industry for a two-year period. During that time he was involved with supporting on-site remediation efforts to establish compliance with 21 CFR Part 111. Specific areas of involvement include, but not limited to:

- Auditing and compliance surveillance activities
- Practice versus Procedure Gap Analyses
- Compliance Plan Development and Execution
- Quality Systems Design and Implementation
- Compliance Training inclusive of GMP, Conducting Investigations, Good Documentation Practices and Responsibilities in a GMP Environment
- CAPA Program Implementation and Effectiveness Evaluation
- Product Non-Conformance investigation and resolution
- Standard Operating Procedure (SOP) generation and amendment for production and laboratory practices

#### **Multi-National Terminally Sterilized Parenterals Manufacture**

- Acting Manager of Microbiology/Sterilization Assurance with direct oversight of five Supervisors and one Section Manager comprising the following areas of responsibilities with approximately 60+ employees and temporary technicians:
  - Environmental Monitoring Group
    - Facility monitoring of critical utilities and environmental conditions within filling suites
    - Pre-sterilization monitoring of product bioburden to support parametric release criteria
    - Bacterial Endotoxin Testing of raw material and product
  - Sterilization Assurance Group (Saturated Steam)

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- Review sterilization batch records to ensure conformance to acceptance specifications
- Review sterilization related deviations, initiate failure investigations, and recommend disposition of implicated materials
- Review sterilization qualification/requalification packages
- Evaluate sterilization data trends to ensure that the sterilization process is operating normally and that appropriate corrective actions are taken to correct deviations
- Technical Services Group
  - Onsite laboratory support service for main plant (terminally sterilized product) operations and validation support
  - Container Closure Integrity (CCI) Testing
  - D-value determination, biological indicator resistance testing
  - Bacterial identification
  - Antibiotic assay
  - Bioburden testing
  - Indicator organism recovery from test articles in support of sterilization qualification/re-qualification activities
- Media-Sterility and Particulate Matter Group
  - Preparation and sterilization of growth media and laboratory equipment for use in all QC Microbiology laboratories
  - USP Sterility testing of terminally sterilized product
  - Equipment qualification and annual re-validation of QC Microbiology Department assets
  - USP Particulate matter testing of terminally sterilized product
- Compounding Pharmacy QC Laboratory Support and Testing Group
  - QC support for 23 CAPS pharmacies within the U.S.
  - USP Sterility testing of compounded drug products
  - Dose audit testing for irradiated compounded products
  - Bacterial Endotoxin Testing (Gel Clot LAL and Kinetic Turbidimetric methods)
  - Bacterial identification
  - Environmental monitoring trending of all CAPS facilities
  - Bioburden testing
- QC Laboratory for Cephalosporin Drug Delivery System Manufacturing
  - Support aseptic fill operation within isolator/barrier systems
  - QC release testing for finished product
    - USP Sterility Test, Bacterial Endotoxin Test, Particulate Matter
  - Environmental monitoring of aseptic operations within manufacturing isolators

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- QC support for cephalosporin facility critical utilities and equipment validation activities
- Container closure integrity testing of cephalosporin drug delivery devices
- QC support for bi-annual media fill process validation

#### **U.S. Based Generic Non-sterile Oral Solid Dose Manufacturer**

- Conducted USP Purified Water investigation in support of Total Bacterial Plate Count and Total Coliform Count excursions
- Performed USP Purified Water system walk through / critical utility inspection
- Performed Municipal and USP Purified Water sampling / testing observations
- Addressed previous Microbiology internal investigation observations and audit issues
- Performed water sampling and water testing training for Microbiology department
- Performed assessment for the implementation of an environmental monitoring program for the Florida facility

#### **Fortune 500 Multi-national Drug Delivery Systems Manufacturer**

- Authored performance qualification (PQ) protocols for the steam sterilization of vaccine tools and components within a Rapid Transfer Port (RTP) for Phase I clinical production trials
- Executed PQ protocols
- Performed validation oversight and training for client personnel
- Performed data compilation and analysis
- Authored final report for validation package

#### **Terminally Sterilized Orthopedic Implant Manufacturer**

- Performed critical utilities/facility inspection and USP Purified Water excursion investigation
- Assisted in the design and implementation of new Purified Water system to replace inadequate previous system
- Performed water sampling, testing and training for client personnel

#### **Ethylene Oxide Terminally Sterilized Medical Device Manufacturer**

- Performed facility inspection and bioburden excursion investigation for the UltraCLIP family of tissue markers
- Performed environmental monitoring, product component bioburden testing
- Performed mould taxonomy to identify source contaminant organism
- Implemented appropriate corrective action and disinfections/decontamination procedures to eliminate contamination source
- Authored facility inspection and investigative final report and product impact assessment

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

- Responsible for consulting in all areas of medical device and pharmaceutical operations including sterilization, aseptic manufacturing, microbiology, environmental monitoring, GMP/QSR compliance, QA/QC, start-up operations, compounding pharmacies and regulatory compliance
- Authored, reviewed and approved company and client protocols and reports
- Supervised microbiological laboratory, specifically in the ID preparation area
- Responsible for all operational aspects of the microbiological laboratory, environmental control and sterilization
- Performed the testing of products for sterility, bioburden, bacterial endotoxins and environmental monitoring and other test methods required
- Ensured cGMP compliance of laboratory and laboratory documentation
- Assured all sample testing data is accurate and conducted in strict adherence to SOP's, cGMP's/QSR's and FDA regulations
- Created new and revised department wide SOP's; prepared input for and evaluated new equipment; made purchasing recommendations; coordinated the generations of Document Change Requests to assure that the implementation of changes to specifications, tested methods and protocols occurred unilaterally
- Numerous projects with major pharmaceutical and medical device companies. including the following selected consulting examples:

**Multi-national Medical Device Manufacturer**

- Performed gap analysis and assessment regarding ISO 10993 biocompatibility of several hundred resins, elastomers, and components in support of 400+ CE Marked devices
- Revised QC laboratory programs and procedures
- Generation of IQ, OQ, PQ protocols for the validation of laboratory sterilizer
- Trained of laboratory personnel in aseptic technique and microbiological procedures
- Assisted in the closure of OOS investigations
- Assisted in QA compliance decisions

**U.S. Based Non-Sterile Generic Pharmaceutical Liquid Dosage Form Manufacturer (Under Consent Decree)**

- Assisted in the resolution of quality/compliance issues at generic pharmaceutical manufacturing facility
- Authored position papers relating to operation and procedures within the Microbiology Department
- Implemented a new media growth promotion program and trained laboratory personnel on the new procedures
- Assisted in the closure of open deviation investigations and CAPAs
- Authored and revised Microbiology Department SOPs and Test Methods
- Assisted in the closure of OOS investigations

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- Assisted in the implementation of a LIMS system

#### **Midwest Regional Trauma and Medical Center**

- Creation and execution of protocols for evaluation of the disinfection of semi-critical medical devices
- Evaluation of the deviation of standard procedure and relative health risks to hospital patients
- Advisor to hospital administration regarding disinfection procedures for medical instruments
- Authored final reports for investigative protocol studies

#### **Fortune 500 Multi-National Aseptically Processed Parenteral Manufacturer**

- Supervised 2<sup>nd</sup> shift contracted employees in the QC Microbiology Department
- Responsible for execution of protocols for critical utilities (WFI, compressed gasses, HVAC), environmental monitoring, bioburden, LAL and microbial identification for validation of new, state of the art, manufacturing facility

#### **Fortune 500 Pharmaceutical Manufacturer (Aseptic Filling Facility and Laboratory)**

(Site Manager responsible for 10 consultants)

- Acting QC Microbiology Supervisor
- Direct supervision of all employees and operations within the Microbiology department supporting a 24/7 aseptic filling/packaging facility
- Responsible for 40+ employees consisting of microbiologists, environmental monitoring technicians, subject matter specialists and group leaders
- Supervised and facilitated all aspects of finished product release testing
  - Sterility testing
  - Intermediate and finished product bioburden
  - Bacterial Endotoxin testing (BET) for product and Water for Injection
  - Raw material testing
- Supervised daily, weekly, monthly monitoring of facility and utilities
  - Environmental monitoring of aseptic operations, ancillary and support areas
  - Monitoring of Water for Injection
  - Support for all validation exercises (equipment, process, media fill)
  - Bacterial and mould taxonomy
  - D-value determination
- Responsible for all department investigations and deviation/non-conformance resolution
- Signature authority for final release disposition of finished product
- Department spokesman for all client customer audits and observations of operation

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### **Fortune 500 Multi-National Off-Shore Pharmaceutical Manufacturer**

(Operating under Consent Decree)

- Assisted in the creation of protocols for the validation of isolator trains in the Microbiology Department
- Authored and executed PQ protocols for the sterilization of laboratory supplies and sterility testing equipment

### **Government Funded Vaccine Manufacturer**

(Receipt of Notice to Revoke License for Critically Important Vaccine)

- Acting Senior Validation Engineer / Quality Assurance Specialist
- Conduct FDA readiness audit of Validation Department
- Participated in PAI and Team Biologics audits
- Trained permanent validation engineers and technicians
- Responsible for validation department change control assessments
- Authored and executed process and equipment validation protocols in response to Regulatory Agency commitments and observations
- Quality Assurance department support for product and equipment deviation/non-conformance investigations
- Authored standard procedures for facility wide implementation

### **Multi-National Biological Indicator and Sterilization Products Manufacturer**

- Authored and executed IQ, OQ, PQ protocols for sterilizers in the biological indicator manufacturing facility
- Performed calibrations on manufacturing equipment

### **Multi-National Terminally Sterilized Parenterals Manufacture**

- Executed IQ, OQ, PQ protocols for Microbiology Department laboratory equipment (incubators, refrigerators, freezers, sterilizers, heat blocks and water baths)

## **Education**

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- ◆ Bachelor of Arts and Sciences, Biology, University of Louisville
- ◆ Molecular Biology Graduate Program, East Carolina University

## **Scholastic Awards**

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- ◆ Golden Key National Honor Society
- ◆ Alpha Epsilon Delta – Premedical Honor Society
- ◆ Phi Eta Sigma – Freshman Honor Society

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