

LexaMed

Curriculum Vitae

SENIOR CONSULTANT, MICROBIOLOGY/QUALITY SYSTEMS

CHRISTOPHER C. LAU

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Summary of Qualifications

Christopher Lau is a microbiologist who has over 12 years of technical experience in assorted laboratory techniques, including cell culture techniques, nucleic acid amplification and purification, microbial quantitations (bioburden), bacterial identification, D-value determination, USP testing, spore suspension preparation, aseptic techniques, cytotoxicity, LAL and bacterial endotoxin testing, disinfectant efficacy and preservative effectiveness testing. He is experienced in process and cleaning validations and the creation of client specific protocols and procedures for execution. He has experience in direct management and supervision of an ISO 13485-certified microbiology laboratory personnel, equipment and processes, as well as management of a proprietary microbial suspensions product line. Chris is experienced in OOS/OOL and CAPA investigations as well as the development and execution of action plans for their resolution. Chris is also experienced in the development and maintenance of environmental monitoring programs.

Professional Experience

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

- 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 and regulatory compliance.
- Responsible for investigation and resolution of OOSs and deviations including CAPAs.
- Authors, reviews and approves company and client protocols and reports.
- Responsible for all operational aspects of the microbiological laboratory and environmental control.
- Consults on compounding pharmacy operations and procedures, including <797> compliance.
- Performs the testing of products for sterility, bioburden, bacterial endotoxins and environmental monitoring and other test methods as required.
- Ensures cGMP compliance of laboratory and laboratory documentation.

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Christopher C. Lau
Senior Consultant, Microbiology/Quality Systems

- Assures all sample testing data is accurate and conducted in strict adherence to SOPs, cGMPs/QSRs and FDA regulations.
- Authors new and revised department wide SOPs; prepares input for and evaluates new equipment; makes purchasing recommendations; coordinates the generation of Document Change Requests to assure that the implementation of changes to specifications, tested methods and protocols occur unilaterally.

Recent examples of client and related consulting activities include:

Global Manufacturer of Animal Vaccines & Hormones

- Conducted assessments with Site Management to gain a comprehensive and complete understanding of the state of quality and compliance initiatives at the site to allow for development of a GMP Work Plan to be used for continued tracking and reporting on progress to Executive Global Quality management.
- Sponsored and supported implementation of the Quality System enhancements at a site level across the global manufacturing platform for Animal Health, areas included but not limited to:
 - Validation Program Design, Approach and Execution.
 - Warehouse Control Program.
 - Facility Upgrade Program.
 - Environmental Monitoring Program.
 - Quality Control Laboratory Transformation.

Manufacturer of Dietary and Nutritional Supplement

- Provided service to the dietary and nutritional supplement industry for a six month period by supporting on-site remediation efforts to establish compliance with 21 CFR Part 111. Specific areas of involvement included, but not limited to:
 - Quality Systems Implementation.
 - Deviation, OOS and CAPA Program Implementation.
 - Revision of Standard Operating Procedures (SOP) related to laboratory testing and investigation of product complaints.
 - Conducting investigations and generating Quality Investigation Reports for the Closure of Customer Product Complaints.
 - Design and Delivery of Compliance Training for Conducting Investigations into Consumer Product Quality Complaints.

Global Manufacturer of Animal Vaccines & Hormones

- Performed media fill positive result investigation including determining of potential assignable root cause(s) and provided technical review of the media fill report.
- Performed risk assessment and subsequent recommendation of disposition of products bracketed by the bi-annual media fills.
- Established and oversaw the execution of the restart plan for production of vaccines:
 - Assured alignment of all on-site cleaning SOPs.

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- Provided enhanced operator training in aseptic technique and disinfectant use and application.
- Directed a two-fold cleaning process and increased environmental monitoring survey.
- Established an enhanced disinfectant program.
- Increased controls for the movement of materials into the controlled environmental areas.
- Performed investigation and authored subsequent reports, including CAPAs for OOS product in the on-going stability programs.
 - Observed testing and redesigned sample handling and testing process in order to simplify process and reduce potential errors.
 - Recommended manufacturing improvements for material sterilization and equipment performance.
- Performed investigation and subsequent report including CAPA's for product that had received an FDA warning letter.
 - Reviewed APRs and wrote a summary report.
 - Reviewed media fills and wrote a summary report.
 - Wrote a container closure integrity protocol and final report.

PROJECT SECTION LEADER, *LexaMed, Ltd.*

- Hands-on experience and direct supervision of microbiology personnel and responsible for coordinating department's work schedule to assure customer satisfaction for all testing related to:
 - Microbial Limits.
 - Bioburden Recovery and Method Qualifications.
 - Environmental Monitoring Program Development.
 - BI Resistance Testing and Performance.
 - Sterility Testing and Method Qualifications.
 - Antimicrobial Effectiveness Testing.
 - Disinfectant Efficacy.
 - Microbial Identifications.
 - LAL, Bacterial Endotoxin.
 - Cytotoxicity.
 - OOS/OOL and CAPA investigations and their resolution.
 - Clean room design, qualification and maintenance.
- Accountable for accuracy and updating to maintain compliance with FDA and USP requirements of all departmental:
 - Operating and testing SOPs.
 - Training program qualifications and implementation.
 - Assurance of good documentation practices.
 - Complete test record maintenance.
- Author client specific protocols for custom testing requirements.

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GROWTH-CHEK™ MANAGER, B.E.C. Laboratories

- Responsible for production of a proprietary line of microbial suspensions, and the associated research and development and client technical support.
- Responsible for customer complaint resolution.
- Authored and updated all associated standard operating procedures, and corresponding forms.
- Implemented quality based review process for shipping orders.
- Implemented monthly and yearly production summaries with emphasis on trend analysis.
- Successfully completed an internal auditor course and participated in an internal audit.
- Reviewed and edited the company's quality manual.

MICROBIOLOGIST / ENVIRONMENTAL TECHNICIAN, B.E.C. Laboratories

- Performed sterility testing, cytotoxicity, particulate analysis, and water testing.
- Performed bioburden analysis, population verification, and organism identification.
- Conducted environmental monitoring and performed routine cleaning with appropriate disinfectants.
- Revised and updated client specific standard operating procedures.
- Performed calibrations on critical equipment.
- Performed general chemistry tests.
- Received environmental samples and generated laboratory worksheets.

Education

- ◆ Bachelor of Arts in Biology, University of Toledo, Toledo, OH
 - Robert Pocotte Scholar Athlete Scholarship