Curriculum Vitae

SENIOR VICE PRESIDENT

JAMES P. KULLA

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Summary of Qualifications

Jim has been active in the medical products industry since 1967. Jim founded a company in 1980 that offered contract laboratory services and contract sterilization to the medical device and pharmaceutical industries and assembled and packaged custom surgical packs and private label medical devices. In addition, Jim has experience with vendor audits and quality systems. He has developed programs for the chemical analysis of drug substances and the review of new products for EO and gamma sterilization. Moreover, he has managed the corporate sterility testing, environmental microbiology, microbiology manufacturing plant audit and the microbiological product support research programs for a $1 billion+ healthcare firm.

Professional Experience

SENIOR VICE PRESIDENT, *LexaMed, Ltd.*

- Consulting in all areas of medical device, pharmaceutical, and biologics operations including laboratory operations, sterilization, aseptic processing, contamination control, microbiology, environmental monitoring, GMP/QSR compliance, QA/QC, start-up operations and regulatory compliance.

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

  Biotech Manufacturer of Autologous Vaccine
  - Assisted in the design of an Environmental Monitoring Program for a complex aseptic processing facility
  - Provided technical support for the validation of the manufacturing facility
  - Provided on-site technical support during Preapproval Inspections

New Technology Novel-Sterilization Start-Up Company

- Acting Director of Quality Assurance during transition from R&D to a cGMP manufacturing/specification developer mode. Established and proceduralized all Quality Systems
- Provided microbiological guidance and support for the establishment of internal testing capability
- Acted as study coordinator for third-party laboratory studies in support of regulatory filing

Global Pharmaceutical Manufacturer

- Provided guidance on preparation for submission for approval for parametric release of terminally sterilized small volume parenteral drugs
- Performed manufacturing assessment to determine the source of an endotoxin contamination issue

Global Pharmaceutical Manufacturer –Solid Dosage Products

- On-site Project Manager for 6 consultants. Team projects listed below:
- Reviewed and categorized 700+ investigations
- Mentored 8 QA personnel in the performance of deviation/non-conforming product investigations
- Reviewed and critiqued multiple process validation studies
- Performed GMP audits of several manufacturing operations and laboratories in preparation for an FDA Inspection
- Assessed and investigation Water For Injection (WFI) system out of specification events
- Modified the WFI system Preventive Maintenance program and sanitization procedures
- Review and assessed 300+ CAPAs

Dietary Supplement Manufacturer

- On-site Project Manager for 5 consultants. Team projects listed below:
- Investigated and closed 2000+ consumer complaints
- Established a validation program for a large RO water system
- Performed technical review of validation protocols and final reports for several automated filling and packaging lines
- Advised and participated in the revision of all microbiology SOPs
- Developed several new analytical methods for chemical ingredients
- Performed analytical method validations
- Performed multiple supplier audits
- Revised format of all procedures and managed the document control system

VICE PRESIDENT, SUBJECT MATTER EXPERT/MICROBIOLOGY, *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 and regulatory compliance.
- Filled positions of Acting Director of Qualify Control, Microbiology Manager, Chemistry Laboratory Manager for several clients
- Authored, reviewed and approved company and client protocols and reports.

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

Global Manufacturer of innovative healthcare products

- On-site Project Manager for approximately 6 consultants. Team projects listed below:
- Performed gap analysis and assessment regarding biocompatibility of several hundred resins, elastomers, and components in support of 400+ CE Marked devices
- Coordination of relocation and validation of 1500 production molds
- Revision of QC laboratory programs and procedures
- Data collated and wrote validation reports for eight sterilizers, preconditioner, and aerator
- Assist in the closure of OOS investigations
- Assist in QA compliance decisions
- Performed assessments and assisted in the direction of investigations into OOS test results and product deviations

Developer and Manufacturer of liquid and lyophilized sterile products

- Coordination of a project to submit for parametric release of terminally sterilized parenteral solutions
- Audit manufacturing and QC test procedures related to process controls

Biotechnology Company focused on the development and commercialization of novel therapeutics that address the immune system to fight cancer

- Assisted in the resolution of quality problem at contract manufacturing facility
- Performed gap analysis and assessment of validation of two product lines
- Assisted in development of the Environmental Monitoring program for an aseptic processing facility

- Authored, reviewed, and revised numerous standard operating procedures and test method procedures
- Assisted in the closure of investigations and deviation reports

Global Manufacturer of vaccines and plasma derivative products
- Responsible for closure of open deviation investigations and CAPAs
- Assisted in restructure of Validation Compliance function and Change Control procedure
- Assisted VP of Quality Systems and Regulatory Affairs
- Acting Director of Quality Control
- Trained permanent Director of Quality Control and continued on as staff support
- Acting Manager of BioAnalytical (Chemistry) Laboratory
- Established and chaired Raw Material Specifications Committee

Multinational Pharmaceutical Company providing products for humans and animals (Under Consent Decree)
On-site Project Manager for approximately 20 consultants. Team projects:
- Assisted in preparation of 483 response and investigations
- Wrote protocols for 3rd Party Oversight function during Consent Decree
- Assisted in the preparation of the corporation Corrective Action Plan for submission to FDA
- Supervised batch record review and product release
- Assisted in the closure of open deviation investigations and CAPAs
- Responsible for validation of laboratory instruments
- Established a Quality Program and wrote procedures for a new product distribution center
- Assisted in QA product release and responses to Oversight function and in the resolution of a microbial contamination problem
- Responsible for restructuring all Batch Productions Records and environmental monitoring program
- Assisted in the closure of OOS investigations
- Performed retrospective validation of existing product line
- Managed Microbiology Department
- Prepared documentation of critical utilities

Medical Device Manufacturer of Diabetes supporting devices and processes
- Performed audit of contract manufacturing/packaging operations for a new product line

Global Manufacturer of vaccines and plasma derivative products
(Receipt of Notice to Revoke License for Anthrax Vaccine)

- Conduct FDA readiness audit of microbiology and chemistry laboratories
- Participated in PAI Audit and Team Biologics audits (2)
- Acting Director of Quality Control (chemistry, microbiology, environmental monitoring, animal services)
- Trained permanent Director of Quality Control and continued on as staff support
- Assisted in investigations
- Assessed suitability of the Environmental Monitoring program
- Performed audits of Analytical Chemistry and Microbiology Departments in preparation for Team Biologics inspection

Medical Technology Manufacturer of medical supplies, devices, lab equipment and diagnostic products

- Assisted and provided technical support for the validation of a new Aseptic Manufacturing and lyophilization facility
- Trained personnel in Gowning and Gowning Validation
- Trained manufacturing personnel is aseptic procedures for sterile fill operations
- Investigated and determined the root cause for multiple failures during the media fill simulations of a manufacturing process

Global Manufacturer of innovative healthcare products

- Acting Manager of Microbiology Department including QC Microbiology – Sterility testing, Environmental Monitoring, and QA Sterilization batch record review and release
- Performed gap analysis of environmental monitoring program and revised procedures
- Performed audits of various manufacturing processes related to contamination controls
- Closed a major open investigation related to sterilization assurance
- Preparation of protocols for the validation of laboratory controlled temperature equipment and steam sterilizers
- Participated in working committee for Parametric Release
- Audited manufacturing operations that utilized Isolator technology

Developer and Manufacturer of generic as well as a line of specialty branded pharmaceuticals (Under Consent Decree)

- Assisted in the revision of all Microbiology procedures and programs
- Wrote final reports for the validation of Isolators and Vaporized Hydrogen Peroxide generators
- Assisted in the establishment of a new Environmental Monitoring program
- Worked on closure of investigations

PRESIDENT, *BEC Laboratories, Inc.*

- Founder and President of company providing contract testing services to the medical device and pharmaceutical industries and environmental waste and groundwater analysis.
- The company manufactured medical devices on an OEM and proprietary basis including a full line of custom surgical packs.
- The company provided contract sterilization services
- Oversaw all operations of the company including technical, regulatory and quality.
- Total technical staff and production personnel totaled 130 employees at two locations at maximum.

MANAGER MICROBIOLOGY, *NamSA*

Responsibilities included, but not limited to:

- Management of the Microbiology Department operations included testing for bioburden, sterility, program (LAL and rabbit), preservative efficacy, microbial limits, microbial taxonomy, etc.
- Revised sterility test laboratory operations
- Trained sterility test personnel
- Management of Sportrol biological indicator manufacturing department
- Review and approval all client protocols and test reports
- GMP/GLP lab compliance

MANAGER, MICROBIOLOGY STANDARDS, *Baxter Healthcare, Inc.*

Responsibilities included:

- Administration of the Corporate sterility test program
- Managed site sterility test operations
- Trained sterility test personnel
- Design and establishment of the Corporate environmental monitoring program
- Review of all product designs relative to radiation and ETO sterilization and validation
- Audit and approved vendors supplying components of sterile procedural trays
- Performed annual GMP/microbiology audits for all domestic manufacturing facilities
- Established microbiological standards for product packaging for entire sterile disposable product line
- Performance of product functionality testing relative to sterility maintenance

Education

- Bachelor of Science, Biology, Purdue University
- Masters of Science, Microbiology, University of Illinois

Professional Associations

Past and current memberships:

- Health Industry Manufacturer's Association (HIMA)
- Pharmaceutical Manufacturer's Association (PMA)
- Parenteral Drug Association (PDA)
- AAMI Sterilization Committee

Awards

- Toledo Area Small Businessman of the Year
- Entrepreneur of the Year recipient: Technology – Northwest Ohio

Publications

Kulla, J., R.R. Reich, S. Broedel, Jr., 2009. "Sterilizing Combination Products Using Oxides of Nitrogen" Medical Device and Diagnostic Industry, March 2009.