Curriculum Vitae

VICE PRESIDENT, MICROBIOLOGICAL COMPLIANCE
CAROLYN L. KINSLEY

Mobile Phone: 615-423-3152

Summary of Qualifications

Carolyn has been active in the medical products industry since 1976. Her vast experience includes the manufacture, quality control and sterilization of medical devices and pharmaceuticals, biological indicator performance, and monitoring environmental microbial profiles in medical device/pharmaceutical manufacturing facilities, including aseptic filling operations. Moreover, she has extensive experience in ethylene oxide, steam and irradiation sterilization of pharmaceutical and medical device products. She has a great depth of knowledge for FDA / GMP regulations and AAMI / ISO guidelines governing the sterilization and release of medical products to market. She is experienced in management of microbiological and quality control laboratories, validation, retrospective validation, and IQ/OQ/PQ. Certified RAB Lead Auditor for Quality Systems.

Professional Experience

VICE PRESIDENT, MICROBIOLOGICAL COMPLIANCE, *LexaMed, Ltd.*

Provides consulting services in all areas of sterilization and micro-compliance including, but not limited to:

- SOP Content & USP Testing Methods
- Client Audit Preparation
- Training Programs
- Environmental Monitoring
- Product Stability Program
- Sterilization Processes, Development and Protocol Documentation
- Regulatory Submissions

Currently participates on the AAMI and ISO Committee on Industrial Ethylene Oxide. Subject Matter Expert on EO and Radiation sterilization.

SENIOR CONSULTANT, *Pharmaceutical Systems, Inc.*
Participation in client counsel and audit activities for many microbiology and quality functions including:

- SOP Content & USP Testing Methods
- Training Programs
- Environmental Monitoring
- Product Stability Program
- Cleaning/Disinfection Programs
- Development and Validation of Irradiation, EO, and Steam Sterilization Processes
- Aseptic Filling
- Consults on all sterilization issues, including ethylene oxide, steam and radiation
- Laboratory Management
- Regulatory Submissions
- OOS Investigation and Resolution

SENIOR RESEARCH SCIENTIST, *Baxter Healthcare*
Responsible for projects that evaluate "state of the art" sterilization processes, equipment, and laboratory techniques.

- Design and execute experiments to determine the effectiveness of the new sterilization processes or laboratory techniques.
- Responsible for development and delivery of sterilization training programs for Baxter's Quality Organization.
- Participate in standard development for sterilization and laboratory testing.
- Corporate auditor of laboratory and sterilization procedures/techniques, as well as environmental monitoring programs.

DEVICE STERILIZATION MANAGER, *Baxter Healthcare*
Responsible for establishing guidelines for sterilization of medical devices in Baxter Healthcare. Managed a team responsible for:

- Supporting new product development programs.
- Development and maintenance of sterilization processes, including ethylene oxide, steam and radiation.
- Sterility Assurance support in developing regulatory submissions.
- Sterility Assurance support in acquisitions of new companies.
- Routine support for the existing manufacturing facilities concerning environmental and sterilization concerns.
- Assessment microbiological laboratory procedures.

MANAGER OF STERILITY ASSURANCE FOR BDAC AND DIVISION, *Becton Dickinson and Company*

- Responsible for the sterility assurance program to ensure release of "Sterile" product meeting the requirements of our customers.
- Participated on the team to implement ISO in the BD divisions.
- Performed training programs for BD personnel to enable them to implement appropriate programs in their operations
- Performed facility and contract sterilization audits for the division

GROUP QA MANAGER FOR STERILITY ASSURANCE AND LABORATORIES, *Baxter Custom Sterile/W Mueller*

- Designed and developed laboratories necessary to perform biological and chemical studies on new and existing materials as processes and supplies changes in multiple facilities necessary to maintain GMP, GLP'S, and international requirements for sterile medical product.

LABORATORY SERVICES MANAGER, *Baxter Pharmaseal*

- Developed and maintained a quality assurance program for products that included the receipt and release of raw materials and the biological quality of the product through manufacture and sterilization.
- Managed a laboratory staff whose responsibilities included raw material, in process, and final release testing of "Sterile" and Clean medical products.

INSTRUCTOR, *Milligan College and Lycoming College*

- Prepared and instructed microbiology and human anatomy classes for science major and pre-professional students.

MICROBIOLOGIST, *Ohio State Department of Health*

- Served as an Immunologist and Microbiologist conducting laboratory studies to classify and identify Microorganisms for the State of Ohio.

Education

- MS, Microbiology, Ohio State University
- BA, Biology Major/Chemistry Minor, Concordia College

Technical Seminars & Courses

- Continuing education through seminars, business management courses.
- Certified RAB Lead Auditor for Quality Systems

Carolyn L. Kinsley
Vice President, Microbiological Compliance

Professional Associations

To further develop her awareness of technical developments within the pharmaceutical industry, Carolyn Kinsley participates in the following professional associations:

- Member of the AAMI
- Member of the ASQC
- Member of the SIM
- Member of the ASM
- ISO Sterilization Committees