

LexaMed

Curriculum Vitae

SENIOR CONSULTANT, QUALITY SYSTEMS/REGULATORY

DONNA M. KOHUT

Phone: 419.693.5307

Summary of Qualifications

Donna has over 27 years of technical experience in quality assurance (QA) / quality control (QC) and regulatory compliance within the device and pharmaceutical industries. She has extensive experience in domestic and international regulatory compliance, customer service with clients as well as suppliers, project management, internal and external compliance auditing, and regulatory response document preparation. Donna is a subject-matter expert in training program development and implementation, not only with designing a program that addresses cGMP training requirements, but also new employee orientation, job and associated task curricula, and employee, trainer and management qualification processes. Furthermore, Donna has a strong manufacturing and business management, including financial, background with robust experience in operations and supply chain management. Her skill-set is further enhanced by her excellent ability to lead diverse teams to meet operational goals within defined cost constraints and timelines.

Professional Experience

SENIOR CONSULTANT, *LexaMed, Ltd.*

Donna provides consulting services for clients primarily from pharmaceutical and medical device companies. Responsibilities to date include technical guidance with respect to the following areas, but not limited to:

- Quality Assurance program development and implementation
- Compliance Auditing
- Supplier corrective action plan deployment
- Regulatory Submissions
- Reporting and tracking of all quality functions

LexaMed Ltd.

705 Front Street, Toledo, Ohio 43605 1.888.232.5227 / 419.693.5307 www.lexamed.net

Donna M. Kohut
Senior Consultant, Quality Systems/Regulatory

- Customer Complaint investigations and Resolution (Corrective Action) plan deployment
- Training program system infrastructure development and deployment focused on employee and/or process enhancements
- Development of Validation / Qualification Protocols for Manufacturing Equipment and Processes
- Supply Chain Management / Inventory Control Program Design and Implementation
- Manufacturing Business Operations

VICE PRESIDENT, GLOBAL SUPPLY CHAIN, *Mayne Pharma Limited*

Primary responsibilities and accomplishments included:

- Establish organizational structure and developed staff in support of global business requirements
- Lead transition of supply chain from regional site alignment to globally based systems
- Identify global priorities for supply chain to ensure corporate goals, operational efficiency objectives and compliance were realized per required timelines
- Direct activities including key projects to improve performance in terms of inventory management, customer service and cost

SITE GENERAL MANAGER, MULGRAVE, AUSTRALIA, *Mayne Pharma Limited*

Responsibilities included, but not limited to:

- Lead parental manufacturing facility with over 600 employees to cause improved operational, quality and personnel performance
- Established key relationships with internal and external customers to ensure understanding of key business requirements, build confidence in site's ability to deliver on commitments and secure future viability
- Developed management controls and reporting systems including staff development, key performance indicators and communications
- Responsible for operation that provided over 70% of sales dollars to company
- Implemented Key Performance Indicators (KPIs) and achieved two-fold increase in manufacturing output and 20% reduction in manufacturing costs while maintaining satisfactory compliance rating with appropriate regulatory agencies (i.e. TGA, US-FDA, etc.)

LexaMed Ltd.

705 Front Street, Toledo, Ohio 43605 1.888.232.5227 / 419.693.5307 www.lexamed.net

Donna M. Kohut
Senior Consultant, Quality Systems/Regulatory

ASSOCIATE, *Lachman Consultant Services, Inc.*

Responsibilities included, but not limited to:

- Provided third-party consultation and oversight for foreign and domestic firms manufacturing aseptically filled and terminally sterilized parenteral solutions in vials, ampoules and syringes, tablets, capsules, ointments, creams, non-sterile liquids, APIs and medical devices
- Operated as third-party compliance specialist for consent decree management and controls management for injunctions and product seizures
- Performed training program assessments and enhancements
- Conducted GMP Audits of solid dose, sterile parenteral and medical device manufacturing operations
- Performed Quality System audits, assessment and establish enhancement plans to ensure sustainable compliance
- Developed of Validation / Qualification Protocols for Manufacturing Equipment and Processes
- Reviewed and recommended enhancements to Standard Operating Procedures related to Production and Control Operations including Packaging and Labeling as well as Materials Controls, Warehousing and Distribution, and Quality Assurance
- Developed, managed and implemented cGMP Compliance Action Plans
- Performed verification activities of Regulatory commitments to determine status and effectiveness of identified actions

DIRECTOR, CORRECTIVE ACTION PLAN AND TRAINING, *Schein Pharmaceuticals, Inc., Quality Unit*

Responsibilities included, but not limited to:

- Established of an acceptable compliance level in response to consent decree
- Primary liaison with independent third party to oversee successful completion of Corrective Action Plan (CAP), facility re-commissioning, product reintroductions and approved product batch release activities
- Conducted full monitoring and trending of progress related to consent decree requirements and individual CAP activities in conjunction with independent third party
- Designed and implemented retrospective and current training system assessments according to the guidelines and requirements outlined in the approved CAP
- Established the training system infrastructure and Training Program Master Validation Plan addressing cGMP training requirements, new employee orientation, job-specific curricula, employee qualification process, and qualified trainer practices

LexaMed Ltd.

705 Front Street, Toledo, Ohio 43605 1.888.232.5227 / 419.693.5307 www.lexamed.net

Donna M. Kohut
Senior Consultant, Quality Systems/Regulatory

EXAMINER, *National Malcolm Baldrige Quality Award*

Responsibilities included, but not limited to:

- Performed Excellence assessments for the healthcare and manufacturing industries including independent applicant reviews and feedback comments for use by judges

DIRECTOR, OPERATIONS AND SUPPLY CHAIN MANAGEMENT, *Schein Pharmaceuticals, Inc.*

Responsibilities included, but not limited to:

- Monitored and reported the progress in response to FDA 483 observations by establishing and facilitating mechanisms for communication and problem solving
- Finalized the optimization of product and documentation release cycles by educating manufacturing and quality personnel regarding the firm's compliance and business objectives, and facilitated process and quality improvements
- Implemented strategic and tactical activities for inspection, packaging, graphics development and label and carton printing operations for aseptically manufactured small volume parenterals
- Responsible for DEA compliance for distribution of controlled substance drug product

MANAGER, OPERATIONS, DISTRIBUTION, RESOURCE PLANNING AND SUPPORT, *Johnson & Johnson / McNeil Consumer Products*

Responsibilities included, but not limited to:

- Instrumental in business planning, personnel development, and operational performance for quality, compliance, safety, workforce and asset management in various functional areas in solid dose and liquid manufacturing, third-party contract operations and supply chain management
- Participated on new product launch teams, contractor and supplier qualifications and facility expansions and upgrades
- Supported cross-functional team selection, installation and implementation of computer based business tools including materials requirements planning, enterprise planning, electronic batch records, paperless distributions and customer service databases
- Completed workplace re-design project to increase competitive advantage within corporate asset base as well as in marketplace
- Directed innovative multi-skilled workforce to meet dynamic business needs to supplement resource base through manufacturing operations

LexaMed Ltd.

705 Front Street, Toledo, Ohio 43605 1.888.232.5227 / 419.693.5307 www.lexamed.net

Donna M. Kohut
Senior Consultant, Quality Systems/Regulatory

- Appointed to facility start-up team as internal expert on material requirements management techniques, bills of material design and resource planning parameter development
- Developed proposal for consolidation of eastern regional distribution operations for consumer division to an existing facility
- Transitioned distribution of specific product base to third party arrangements and subsequently assigned responsibility for on-site management of distribution operations at third-party

Education

- ◆ M.A., Masters in Mathematics, Villanova University, Philadelphia, Pennsylvania
- ◆ B.A., Bachelor in Fine Arts, Temple University, Philadelphia, Pennsylvania