

LexaMed

Curriculum Vitae

Chief Operating Officer MICHAEL A. RUTKOWSKI

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Summary of Qualifications

Michael has near 30 years of experience in true business leadership and technical management in multiple areas of the pharmaceutical and medical device industry, including, but not limited to the areas listed below:

- Validation/qualification protocol guideline creation for computer systems, equipment, and facilities
- Quality assurance/control program development and implementation
- Client GMP certification and Audit regulatory inspection preparation, and corrective action plan implementation and revision
- Supplier management and marketing program development for regulatory compliance
- Cleanroom validation program development, implementation and continuous improvement procedures
- Environmental monitoring program development
- Laboratory management with FDA compliance
- Change control program design and implementation for equipment validations
- Technical writing competence in protocols, reports, specifications, policies and procedures
- Manufacturing operations quality control tracking and implementation
- Capital planning and budgeting
- International cGMP operational compliance

Professional Experience

CHIEF OPERATING OFFICER, *LexaMed, Ltd.*

- Responsible for overseeing domestic and international client base and ensuring that base business fully supports strategic vision of the company.
- Responsible for directing external consulting activities and internal operations (referred to as Toledo Operations for LexaMed) to ensure that client and LexaMed business needs are met and that communications are firmly established to support continued growth of both parties.

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- Key client liaison to assist with operational, quality and compliance initiatives as related to Pharmaceutical, Medical Device, Dietary Supplements and Bio-Technology industries.

VICE PRESIDENT, GLOBAL TECHNICAL OPERATIONS, *LexaMed, Ltd.*

- Provided domestic and international consulting services to pharmaceutical, biotechnology and medical device clients.
- Responsibilities included technical guidance with respect to manufacturing operations, process optimization, critical utilities, regulatory strategy, facility systems validations, quality assurance, regulatory compliance, and client audit preparations with development of GMP/compliance action plans.
- Strong background in sterile pharmaceutical formulations including oncology products, aseptic manufactured products, lyophilized products and terminally sterilized products. Also familiar with production, quality and regulatory aspects of solid dosage formulations.
- Responsible for creation, direction and coordination of multi-functional consulting teams formed to address specific client compliance and/or regulatory deficiencies as well as operational enhancements. Interface with clients to establish scope and responsibilities of consulting projects.

PRESIDENT, GLOBAL MANUFACTURING & SUPPLY, *Mayne Pharma Limited*

- As a member of Mayne Pharma's Executive Committee, set strategic direction for the company and executed due diligence activities related to November 2005 demerger of pharmaceutical division from Mayne Group and November 2006 acquisition of Mayne Pharma by Hospira including finance, operational, quality, business development and compliance reviews
- Based in Melbourne Australia, responsible for 1 API production site and 1 oral/liquids/cream manufacturing site and 3 sterile fill/finish manufacturing sites including one site with cytotoxic capability located across 3 continents as well as global support functions including Operations, Occupational Health & Safety, Technical Services, API Sourcing, and end-to-end Supply Chain comprised of more than 1100 employees and operating expense budgets of AU\$200M and capital budgets of AU\$75M.
- Developed action plan to improve site performance specific to cytotoxic facility in Mulgrave, Australia providing more than 70% of global supply, directed execution activities and provided weekly status reporting to CEO and routine presentation to Board of Directors resulting in improved regulatory compliance and operational

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effectiveness such that capacity increased by the equivalent of one additional sterile fill line.

- Improved customer service performance indicators by over 50% from prior year
 - Established a mechanism for monitoring inventory levels and implemented processes to reduce working capital by greater than 40%
 - Reduced manufacturing standard costs by 7.4% from the prior year
 - Demonstrated improved performance across quality management systems including environmental excursion rate where a greater than 150% improvement was seen from prior years
- Established strategic direction, identified existing manufacturing competencies for each production facility and developed actions plans relating to process technology, quality management systems, OH&S, industrial relationships, capital planning and technical capability
 - Appointed project sponsor by CEO over twenty-five strategic initiatives to contribute annualized net savings of AU\$7M
 - Responsible for developing manufacturing and supply capability in India through strategic partnerships and Joint Venture, ZMOPL, including membership on JV Board and oversight to construction of API and Fill/Finish facilities
 - Improved global operational contribution to total company financials in 2006 by \$18M, 17% through operational effectiveness including optimization of batch size, employee participation in problem solving, resolution of identified and overdue corrective actions, prioritization of activities and resources, clarification of roles, responsibilities and accountabilities and cross-functional teamwork
 - Provided technical oversight during regulatory inspections and interactions with regulatory agencies to ensure acceptable outcomes to meet key business drivers as related to PAI, GMP and new product launch activities

EXECUTIVE COMPLIANCE PROJECT DIRECTOR, *Lachman Consultant Services, Inc.*

- Responsible for establishing and directing compliance project teams comprised of five to twenty consultants/specialists across multiple facilities to address significant regulatory actions and operational deficiencies across multiple firms and client base. Key accomplishments include:
- Directed Consent Decree activities at two clients over multiple sites to achieve GMP certification

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- Developed and implemented a new project management concept for the establishment of “swat teams” to expand on the firm’s penetration at the client and to allow for sustainable remediation efforts through direct on site participation and oversight.
- Established a network and working relationship with multiple consulting firms to ensure required expertise and timely delivery of project objectives
- Provided third-party consultant and oversight for foreign and domestic firms manufacturing aseptically filled and terminally sterilized parenteral solutions in vials, ampoules and syringes, tablets, capsules, ointments, creams and 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 focused on:
 - Process and Product Validation of Sterile and Non-Sterile Products
 - Manufacturing Operations and Quality Control Laboratory Auditing and Upgrading
 - Validation/Qualification Protocols for Equipment, Critical Systems and Facilities
 - Operational Compliance with cGMPs (International exposure)
 - Quality Systems, Procedures and Programs
 - Computerized System Validations
 - Employee Training and Qualification – GMP and Technical
 - Equipment and Critical Utility Qualifications
 - Process Optimization for improved throughput, output and total quality
 - Cleaning Validation Programs (design and practical implementation)
 - GMP Audits and Development/Implementation of Corrective Action Plans
 - Equipment Calibration and Maintenance (Programs, Procedures, Execution)
 - Technical Writing (Protocols, Reports, Specifications, Policies, Procedures)

DIRECTOR OF QUALITY CONTROL, *B Braun Medical, Inc.*

- QA/QC functions associated with the manufacture of large and small volume parenteral solutions and medical devices (total of one-hundred and twenty one reports)
- Reduction of finished product turnaround cycle; service level improvement
- Regulatory compliance and quality management systems oversight
- Validation of critical utility and facility systems

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- Creation and implementation of an active ingredient cleaning validation program
- Facility Qualification Program for a new aseptic manufacturing facility
- Development of a supplier management program for compliance, regulatory and manufacturing devices

MANAGER OF QC LABORATORIES AND SOLUTION COMPOUNDING, *McGaw Laboratories, Inc.*

- QC functions associated with the manufacture of large and small volume parenteral solutions
- Development of GMP Action Plan for compliance deficiencies for cleanrooms
- Compounding parenteral solutions
- Development of validation guidelines and qualification criteria for new manufacturing equipment and production facilities
- Facility compliance and contract manufacturing and laboratory audits

QC SECTION MANAGER, CHEMICAL CONTROL AND MICROBIOLOGICAL ENVIRONMENTAL LABORATORIES, *McGaw Laboratories, Inc.*

- QC functions for manufacture of large and small volume parenteral solutions
- Testing of large and small volume parenteral solutions
- Development of an environmental monitoring program for cleanrooms and controlled spaces
- Establishment of a Chemical Analytical Services Laboratory dedicated to conducting HPLC Amino Acid Analysis (AAA) and FTIR analysis for incoming raw material and finished product solution
- Change Control Program for monitoring of production equipment after modifications and defining the chemical and microbiological requirement for validation

GROUP LEADER OF QC, RAW MATERIAL CHEMIST, *Kendall McGaw Laboratories*

- Implemented, expanded and maintained company quality systems, including failure investigations, CAPA programs, document control, and complaint handling
- Performed QA review and approval of protocols, lab reports, procedures, specifications

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- Responsible for compliance to USP, AAMI, ISO, QSR and GLP guidelines
- Authored company standard operating procedures, and study protocols
- Conducted internal and vendor audits; managed customer and FDA inspections
- Lead multiple projects in Chemistry Laboratories

RESEARCH & DEVELOPMENT TECHNICIAN, *Baxter Travenol Laboratories*

- Lead customized research and development evaluations and protocols
- Experiment approach and design development per project
- Conducted chemistry-based studies, and client proprietary studies

Education

- ◆ B.S., Biology, Loyola University