

LexaMed

Curriculum Vitae

SENIOR CONSULTANT, QUALITY SYSTEMS/OPERATIONS

ROBERT M. BROWN

Phone: 419.693.5307

Summary of Qualifications

Robert M. Brown is a Quality and Operations professional with over 20 years of experience in project management, production operations and quality assurance, with a demonstrated record of achievement in the pharmaceutical and medical device industries. He exhibits expertise with aseptic processes and integration of quality roles and responsibilities into company operations. Furthermore, Robert is a results oriented person with experience implementing production strategies and managing projects that contribute to the bottom line. He has experience in the design, implementation and execution of action plans for companies in regulatory distress, including warning letter and consent decree management. He has solid technical knowledge in international regulatory agency cGMP requirements, operational effectiveness, closed loop system and metric development and interpretation.

Professional Experience

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

Robert provides consulting services for pharmaceutical, medical device, biotech and nutritional supplement companies. Responsibilities to date include technical guidance with respect to, but not limited to, the following areas:

- Quality Assurance program development and implementation
- Aseptic Processing
- Controlled documentation and Change Control
- Validation Compliance
- Corrective action plan implementation and revision
- Manufacturing Operations Management
- Environmental Monitoring
- Pre-filled syringe manufacturing

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Recent consulting projects include the following:

- Project Manager at animal health bio-pharmaceutical manufacturers in Spain and Germany. Responsible for leading the projects that consolidate quality, compliance, and product supply initiatives into a single plan designed to focus the site to enhance their operational and quality systems. The plan was designed to remediate issues that were affecting supply of key products to the market and to build a framework for sustainable and continual improvement.
- Lead, Quality Assurance In-Process (QAIP) at an animal health pharmaceutical and biologics manufacturer in The Netherlands. Responsible for establishment of the QAIP function at the site, establishment of focus teams to remediate backlogs in batch release and deviations / CAPAs, and then achievement of sustainable compliance to the goals of the site.
- On-site client Project Manager at a US nutraceutical manufacturer responsible to drive compliance with 21 CFR Part 111. Conducted supplier audits, reviewed and recommended revisions to SOPs to conform with cGMP, delivered training on investigational techniques including RCA & CAPA, remediate backlogs in deviations / CAPAs.

DIRECTOR OF PACKING - MULGRAVE, *Hospira, formerly known as Mayne Pharma Limited, Melbourne, Australia*

- Provided leadership at the department and site level in creating a safety conscious culture. Medical treatment incident rate and lost time incident rate were cut in half in first year.
- Established small run packing line to support many of the European markets and provide flexibility for new product launches.
- Established effective inter- and intra-departmental communications including department-wide meetings and regular reporting of key metrics.
- Implement change management initiatives associated with supervisors and frontline managers.
- Directed management team to meet commitments to maintain department Key Performance Indicators (KPIs).

DIRECTOR, QUALITY ASSURANCE, *Hospira, formerly known as Mayne Pharma Limited, Melbourne, Australia*

- Responsible for compliance with US, Australian and EU regulations relating to the manufacture of sterile injectable pharmaceuticals.
- Directed management team to significant improvement of Quality Management System KPIs related to customer service, safety and regulatory compliance over the financial year. Demonstrated sustained performance of these objectives.

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- Implemented enhancements to Quality Assurance Department management structure to emphasize ownership, accountability and communication for each manager in their area of responsibility.
- Hosted successful regulatory inspections (inspection results necessitate no further regulatory action) including US FDA CBER and TGA.

SENIOR CONSULTANT/SITE MANAGER, *Pharmaceutical Systems, Inc.*

- Director, Quality Assurance at a US biologics manufacturer. Successfully passed a US FDA pre-approval inspection. Responsible for batch release, documentation/change control, deviation management, validation compliance and QA representation in production.
- Director, QA Training at same US biologics manufacturer, as listed above. Directed the establishment of a competency based training program.
- Directed all appropriate training in cGMPs, SOPs, company policies and procedures, and safety in strict adherence to all FDA requirements governing pharmaceutical operations.
- Managed large-scale environmental monitoring projects and conducted environmental monitoring related activities.
- Managed, prepared and delivered training on sub-sections of 21CFR parts 210 and 211, which included but not limited to production and process controls, packaging and labeling controls, laboratory controls, and non-conformance/deviation investigation reports.
- Established requirements and managed the establishment of Master Validation Plans, Design Control Systems, Complaint SOPs and Purchasing Controls.
- Reviewed and approved cGMP documentation and records including deviations, change control documents, validation protocols and reports and process control SOPs.
- Conducted audits and provided guidance to compounding pharmacies organizations against <797> requirements
- Conducted material risk assessments.

PROJECT MANAGER RA/QA, *ROCAP-Division of Sabratek*

- Managed stability program including assignment of lots for stability, review of results and out of specification conditions.
- Established specifications and acceptance criteria for raw materials and finished products.
- Authored and executed protocols and authored final reports of validations pertaining to fill volume, label adhesion and particulate contamination of components.
- Maintained Federal and State registration and licensing.

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SITE QUALITY MANAGER, *ROCAP-Division of Sabratek*

- Managed the development, approval and implementation of quality and production master documentation and procedures for overall plant operations to ensure compliance with FDA regulations, including upgrading staff and training.
- Established finished goods and component specifications and standard operating procedures for FDA application.
- Responsible for managing customer complaint handling, corrective action and final product release.
- Directed the development and validation of equipment, tests, methods and procedures to meet cGMPs.

OPERATIONS MANAGER, *ROCAP-Division of Sabratek*

- Managed manual aseptic fill manufacturing activities with P&L accountability for Operations Department (\$4.2MM budget, 36 employees).
- Continual improvement of direct labor cost per unit and unit volume while meeting all quality objectives.
- Developed performance metrics to ensure compliance with cost and quality objectives.
- Established and managed systems for sample tracking, raw materials, finished goods and label control.

PRODUCTION AND SAFETY MANAGER, *Gambro Healthcare*

- Accountable for two manufacturing departments, kits and dry pack, 3 shifts/day - 7 days/week (80 employees).
- Established company Safety Program, reducing employee injuries by 50% in two years.

QUALITY ASSURANCE MANAGER, *Gambro Healthcare*

- Responsible for the overall QA organization.

PURCHASING MANAGER, *Gambro Healthcare*

- Responsible for the procurement and inventory control of all components used in the company for manufacturing and re-sale.

PRODUCTION SUPERVISOR, *Gambro Healthcare*

- Direct supervision of ten employees on one production shift.
- Responsible for running an efficient production schedule, delegating tasks and adhering to plant procedures.

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Robert M. Brown
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Education

- ◆ B.S., Business Administration, University of Florida

Professional Associations

To further develop his awareness of technical developments within the pharmaceutical industry, Robert M. Brown participates in the Parenteral Drug Association (PDA) professional association and the American Society of Quality (ASQ).