



Shannon McBrien

Consultant

Shannon is an experienced professional with over 13 years in sterile and non-sterile microbiology laboratories, Quality Assurance, and contract Clinical manufacturing and packaging. Shannon consistently demonstrates excellent leadership and analytical and communication skills. Shannon brings extensive experience in quality assurance and is able to work to tight deadlines without compromising quality.

SKILLS AND HIGHLIGHTS



Large Compliance Project Management

- Managed multiple projects concurrently as Project Manager for a Clinical Services department
- Coordinated the production and shipping of clinical trial materials to clinical sites within the requirements of the clinical trial timeframe
- Managed a Health Canada/FDA compliant Microbiology laboratory



Quality Assurance

- Developed, revised and reviewed specifications, test methods and SOPs in support of WellSpring and client commercial and clinical projects to ensure compliance to regulatory standards
- Managed the Non-Conformance Report (NCR) Corrective Action/Preventive Action (CAPA) and Trending Programs for a large pharmaceutical company, ensuring a timely implementation of corrective actions

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Technical Writing

- Conceptualized, wrote and revised Clinical Services and Quality Assurance Standard Operating Procedures (SOPs) pertaining to manufacturing and packaging clinical trial materials
- Developed, revised and reviewed specifications, test methods, SOPs, and service work instructions to ensure compliance to regulatory standards
- Developed and created SOPs, test methods, and validation protocols according to the United States Pharmacopoeia and industry guidelines for a microbiology laboratory
- Coordinated review & approval process with client



Regulatory

- Evaluated and reported Adverse Drug Reactions to Health Canada
- Provided medical information for drug products to health professionals, patients and caregivers including correct use and administration of drug products, investigating presence of possible allergens and known drug interactions
- Reviewed labels and labeling procedures to ensure they adhere to regulatory requirements of Health Canada, the FDA or EMEA as necessary
- Compiled, prepared and submitted DIN application packages
- Developed procedure for product labeling review
- Addressed client regulatory inquiries



Auditing

- Audited manufacturing facilities of contract manufacturers and component vendors
- Prepared audit reports to document compliance status to regulatory standards

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Validation

- Validated and monitored Purified Water USP systems



Laboratory

- Sampled and tested Water For Injection (WFI), Purified Water USP, and pure steam for microbial bioburden
- Reviewed batch related and non-batch related data
- Identified unknown organisms using the MIS GC method
- Managed the environmental monitoring alert and action report and trending program
- Performed environmental monitoring in all production hygiene classes including sampling in aseptic processing areas



GMP Training

- Assisted in development of custom course, Conducting an Audit

Computer Skills

- Microsoft Office – Microsoft Word, Excel, PowerPoint, Access and Project

EDUCATION

- Bachelor of Science, Honors degree with Microbiology Major and Biotechnology Minor, University of Guelph

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CONTINUING EDUCATION, CAREER DEVELOPMENT

- Complying with GMPs for Clinical Manufacturing, May, 2008
- MS Project, September 2008
- Good Manufacturing Practices: Supplier Qualification Audits, CanReg Inc., April 2005
- Basic Statistics and SPC, Sheridan College Institute of Technology, Winter, 2005
- Effective Investigations & Corrective Actions, International Pharmaceutical Academy, September, 2004
- Quality Concepts, Sheridan College Institute of Technology, Spring, 2004
- Understanding the Qualification of Disinfectants and Cleaning Procedures, September 2003
- Tracking and Trending Environmental Monitoring Results to Compile Meaningful EM Reports, September 2003
- Hazard Identification for the Workplace Inspection, April 2001
- Business and Technical Writing Skills, Pharmaceutical Sciences Group, 2000

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