



Jennifer Gyorffy – Consultant

Jennifer is a committed, self-motivated and flexible individual with strong organizational and problem solving skills. With over 20 years of experience in quality assurance and quality control for GMP and ISO systems, she provides valuable depth to the Q&C team. She manages her time effectively, and can work well as a team member or independently. Jennifer is able to establish and meet timelines for activities, managing and executing multiple tasks quickly and efficiently with minimal supervision. Previous employers include Biomira Diagnostics, Brantford Chemicals, McNeil Consumer Healthcare, Roberts Pharmaceuticals and WellSpring Pharmaceutical Canada Corp.

SKILLS AND HIGHLIGHTS



Quality Control Officer (QCO)

- Set up and implemented quality assurance systems for importers and distributors
- Developed QA agreements
- Performed product release and QCO services for GMP-compliant customers
- Assisted in release of finished products, drug products, clinical supplies, raw materials, and packaging materials
- Initiated, investigated and determined corrective and preventative actions for deviations and non-conformances
- Released components and finished products for medical device, pharmaceutical, natural health product and dietary supplement manufacturers
- Reviewed finished product, raw material and stability specifications against compendial monographs
- Reviewed Certificate of manufacture and analysis against Finished Product Specifications
- Initiated, executed, and monitored change controls and deviations
- Reviewed master manufacturing, packaging, labelling, deviations, stability reports and raw material and finished product data to assess whether products met regulatory requirements prior to release in Canada



Quality Assurance

- Developed and maintained specifications (Packaging Materials, Raw Materials, Drug Product, Clinical, Bulk, In-process, Finished Product, Stability) and QA/QC test methods
- Reviewed manufacturing and packaging documentation
- Managed complaint investigation system
- Managed non-conformance and change control programs
- Prepared Annual Product Reviews according to schedule for pharmaceutical products by compiling and reviewing data for complaints deviations, change control, validation, packaging, stability and laboratory tests
- Investigated GMP deviations and implemented corrective and/or preventive actions
- Organized QA department for FDA inspection for Canadian medical device manufacturer
- Performed trend analysis, identified trends and made recommendations for course of action



Regulatory

- Compiled and submitted Drug Establishment Licence Renewals
- Performed impact review of regulatory updates
- Performed label review for regulatory compliance (drug and NHP)
- Compiled and submitted Site Licence Applications, renewals and amendments
- Compiled and submitted Quality Assurance Reports



Auditing

- Performed internal audits to ensure compliance with corporate quality standards
- Hosted Health Canada inspections
- Performed audits to ensure compliance to Health Canada Drug GMP regulations, NHP GMP regulations and FDA cGMP regulations of manufacturers, packagers/labelers, importers and wholesalers
- Coordinated and executed self-inspection program for pharmaceutical and NHP facilities

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GMP Training

- Performed employee training on standard operating procedures (SOPs)
- Developed and delivered GMP training to manufacturers, packagers/labelers, importers and wholesalers for Pharmaceutical and Natural Health Product clients



Technical Writing

- Developed and updated policies, GMP SOPs, Specifications and ISO quality system procedures to meet FDA and HPFBI requirements



Validation

- Reviewed validation documentation
- Supported all aspects of in-house validation activity and at contractor sites for Canadian pharmaceutical manufacturer

Production

- Worked as an animal/research technician and process/product development technician for a Canadian medical device manufacturer

Computer Skills

- Microsoft Office – Microsoft Word, Excel, PowerPoint, Access, Visio
- Adobe Acrobat



EDUCATION

- Bachelor of Science, Honours Biological Science, University of Guelph, Guelph, Ontario

CONTINUING EDUCATION, CAREER DEVELOPMENT

- Annual Product Review, PSG
- Audit Skills
- cGMP Annual Product Reviews
- Change Control Management, IPA
- Conducting GMP & Compliance Quality Audits
- Controlled Drugs and Substances, PSG
- Deviations and Change Control
- Fundamentals of Regulatory Affairs, CanReg
- GMP Fundamentals, PSG
- GMP Training Program, KMI/Parexel Inc.
- GMP Training Update, CanReg
- GMP/GLP Training
- Introduction to Regulatory Affairs, PSG
- Management & Leadership Skills for First-Time Supervisors & Managers
- MS Access® Training
- NHP Regulations, Q&C
- Product Disposition, Q&C
- System Validation and Introduction to 21 CFR Part 11, Invensys
- Technical Writing Course, Q&C
- The Compliance Conference, Insight Compliance Training Group
- WHMIS certification
- Women's Leadership Conference, Rockhurst University CEC, Inc.