



Carmen Fletcher

Consultant

Carmen is a dedicated, flexible professional with excellent organizational and problem-solving skills supported by over 20 years of pharmaceutical experience. She has a strong working knowledge of GMPs, cGMPs, and related regulations. Carmen works successfully in a team-based environment; as well, she demonstrates the ability to work independently on large projects.

SKILLS AND HIGHLIGHTS



Regulatory

- Filed Drug Establishment Licences, DEL amendments, Site Licence applications and category IV DIN submissions
- Filed NHPD product licence application (compendial, non-compendial, traditional)
- Amendments and notification to PLA
- Prepared submissions to Health Canada for drugs, natural health products, medical devices, establishment licenses, and other associated annual correspondence
- Performed product label review for regulatory compliance (drug, cosmetic, NHP)



Quality Control Officer (QCO)

- Set up and implemented quality assurance systems for importers and distributors
- Oversaw all aspects of the Quality Control function for a large Canadian pharmaceutical contract support company
- Reviewed master manufacturing, packaging, labelling, deviations, raw material, and stability reports and finished product data; to assess whether product met regulatory requirements prior to release in Canada
- Worked with clients to revise and complete documentation in order to facilitate speedy release of product

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- Recall: Handled drug, NHP recalls
- Initiated, investigated and determined corrective and preventative actions for deviations and non-conformances



Quality Assurance

- Initiated, determined actions and closed actions for change controls related to all aspects of Quality Assurance.
- Initiated, investigated and determined corrective and preventative actions for deviations and non-conformances
- Developed program to track Laboratory Out of Specification Investigation Reports; used tracked data to prepare monthly trend analysis reports, which were used during Health Canada and FDA inspections
- Prepared QAR reports for NHPD
- Worked with Canadian and U.S. management staff to develop a transition plan for outsourcing Chemistry Lab Analysis to a company's corporate head office
- Coordinated and performed laboratory site certification studies of new products and methods for Canadian pharmaceutical manufacturer
- Performed stability analyses to support ongoing shelf life studies
- Submitted Annual Drug Notification



Auditing

- Hosted Health Canada inspections for numerous clients
- Prepared responses to Health Canada audit comments
- Audited foreign manufacturing, packaging and testing facility against Health Canada Drug GMPs, NHPD GMPs, and FDA cGMPs



GMP Training

- Developed and delivered GMP Fundamentals course for pharmaceutical and NHP clients
- Performed employee training on standard operating procedures (SOPs)

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Technical Writing

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



Validation

- Reviewed new product technical files to determine validation and transfer criteria need to meet current regulatory guidelines
- Performed method validation, process validation, and transfers of new products



ISO Compliance

- Oversaw a self-inspection program to meet ISO 9002 requirements
- Prepared and presented internal self-inspection audits to management staff and tracked closure of action items
- Drafted company quality manual and trained staff in relevant procedures
- Hosted registrar audits



Medical Devices

- Filed medical device licencing for class I and II devices
- Classified medical devices
- Medical Device Establishment Licences and amendments to MDEL
- Hosted Health Canada medical device importer/distributor audit
- Handled medical device customer complaints and adverse events

Computer Skills

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

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EDUCATION

- Bachelor of Science – Applied Chemistry and Biology, Ryerson Polytechnical University, Toronto, Ontario

CONTINUING EDUCATION, CAREER DEVELOPMENT

- Advanced GMP Auditing
- Audit Skills
- Deviations and Change Control
- Fundamentals of Regulatory Affairs, CanReg
- GMP for Wholesalers, Q&C
- GMP Training
- Guidance Workshops for Product Licences and Site Licences (NHPD)
- HPFBI Audit Management
- Industrial Drug Legislation (Seneca College)
- Introduction to NHPD (NHPD)
- ISO 13485 Essentials Course
- ISO 9001:2000 Management Overview (PIC)
- ISO 9002:1994
- OOS/Deviation Reporting (Globepharm)
- Technical Writing Course, Q&C

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