Carmen Fletcher

VP, Quality Services

Contact Information

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Carmen Fletcher is a dedicated, flexible professional with excellent organizational and problem-solving skills supported by over 20 years of pharmaceutical experience. She is an effective team leader with expertise in Good Manufacturing Practices (GMPs), Current GMP (cGMPs), and related regulations. She applies a risk-based approach to implementing regulations, providing thoughtful justification for recommendations and/or decisions. Her commitment and dedication to quality makes Carmen a leader in the industry. She has strong people management skills as well as leadership skills.

Skills & Highlights

Project Management

- Manages all aspects of importing regulated products into Canada (Pharmaceuticals, Biologics, Radiopharmaceutical, NHP, and Medical Devices)
- Managed Quality department of various drug importers and reversed NC rating from Health Canada
- Coordinates completion of numerous continuous improvement projects to help organization grow
- Cognizant of maintaining confidentiality
- Provides detailed explanations of processes, regulations, or concepts
- Uses good listening skills to understand another's position and confirm translation
- Set up and implemented quality assurance systems for importers and distributors
- Identified gaps in various quality systems, developed full quality plan for each to implement GMPs; overseeing completion of each plan
- Trained in project management principles

Quality Control Officer (QCO)

- Oversaw all aspects of the Quality Control function for a large Canadian pharmaceutical contract support company
- Responsible for QCO Maintenance and dispositions
- Managed The Rapid Release Team™
- Performed product release and QCO services for GMP-compliant customers
- 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 customers to revise and complete documentation in order to facilitate speedy release of product
- Handled drug and NHP recalls
- Initiated, investigated, and determined corrective and preventative actions for deviations and non-conformances

Quality Assurance

- Providing ongoing QA services and performing GMP compliance activities for a biopharmaceutical company
- Initiated, determined actions and closed actions for change controls related to all aspects of Quality Assurance
- Developed program to track Laboratory Out of Specification (OOS) Investigation Reports; used tracked data to prepare monthly trend analysis reports, which were used during Health Canada and FDA inspections
- Prepared Quality Assurance Report (QAR) 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

Auditing

- Hosted Health Canada inspections for numerous customers (GMP, GVP, and medical devices)
- Prepared responses to Health Canada audit comments
- Audited foreign active pharmaceutical ingredient (API) manufacturing, packaging, and testing facility against Health Canada Drug GMPs, NHPD GMPs, and FDA cGMPs

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Regulatory

- Reviews regulatory pathways to assist companies in importing regulated products to market
- Filed Drug Establishment Licences (DEL), DEL amendments, Site Licence applications and category IV Drug Identification Number (DIN) submissions
- Filed Natural Health Product Directorate (NHPD) product licence application (compendial, non-compendial, traditional) amendments and notification to Product Licence Application (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, Natural Health Product [NHP])
- Submitted Annual Drug Notification

GMP Training

- Developed and delivered GMP Fundamentals course for pharmaceutical and NHP customers
- Performed employee training on Standard Operating Procedures (SOPs)

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 needed 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
- Managed Medical Device Establishment Licences (MDEL) and amendments to MDEL

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- Hosted Health Canada medical device importer/distributor audit
- Handled medical device customer complaints and adverse events

Computer Skills

- Microsoft Access

Education

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

Continuing Education, Career Development

- Advanced GMP Auditing
- Auditing Skills
- Biologics – Health Canada workshop on Lot Release Program
- Deviations and Change Control
- Fundamentals of Regulatory Affairs
- GMP for Wholesalers
- GMP Training
- Guidance Workshops for Product Licences and Site Licences
- GVP Training
- HPFBI Audit Management
- Industrial Drug Legislation
- Introduction to NHPD
- ISO 13485 Essentials Course
- ISO 9001:2000 Management Overview
- ISO 9002:1994
- OOS/Deviation Reporting
- Technical Writing Course
- Workplace Health & Safety
- SOP Writing

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