



## Janice Fenty – Consultant

Janice is an experienced quality assurance professional with more than 20 years in the pharmaceutical and OTC industries. As a Quality Systems Auditor and QA/QC Technical Specialist, she has developed a strong working knowledge of cGMPs and ISO. Janice is a detail-oriented auditor with a proven track record of implementing and maintaining quality systems in highly regulated environments. She is a customer-focused team player, with a creative and practical approach to problem solving. Previous employers include CIBA Vision and Schering-Plough.

### SKILLS AND HIGHLIGHTS



#### Auditing

- Coordinated a large number of vendor audit teams for a sterile manufacturing company
  - Evaluated conformance and identified opportunities for corrective and preventative action (CAPA)
  - Ensured the preparation of quality audit reports and monitored CAPA effectiveness
- Performed self-inspection audits, monitoring and ensuring site compliance
- Delivered audit training to QA staff
- Experienced with Health Canada /FDA and ISO regulatory audits
  - Handled correspondence and communication with Health Canada
  - Assisted in hosting numerous successful Health Canada audits
  - Wrote audit reports
- Performed self-inspection and third-party audits for suppliers/vendors



## Quality Assurance / Quality Control (QCO)

- 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
- Participated in a project team to consolidate QC and Distribution operations with parent company. (This included the responsibility for review and approval of test method transfer protocols and final reports, documentation and sample transfer, stability program transfer, harmonization of SOPs and disposition of equipment and supplies.)
- Developed and monitored an effective vendor management program
- Negotiated Quality Agreements with third-party service providers and vendors
- Reviewed documentation from internal and contract manufacturers for compliance in the release of finished goods, including Master production documents, batch and packaging records, analytical reports and change controls
- Performed drug and NHP product release activities for various importing clients
- Produced annual product review by compiling and reviewing data from complaints, deviations changes, validations and stability
- Reviewed master manufacturing, packaging, labelling and batch records to access GMP requirements



## Validation

- Compiled and reviewed validation protocols for a major pharmaceutical company
- Monitored production, compiled data and wrote final reports



## Regulatory

- Reviewed product labels and addressed client regulatory inquiries

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### **Technical Writing**

- Prepared and implemented applicable Standard Operating Procedures to ensure compliance to GMPs and corporate guidelines



### **Lab Services**

- Managed calibration of laboratory instruments to meet GMP compliance
- Coordinated and/or performed analytical evaluation of bulks, finished products, stability and complaint samples in accordance with approved methods

### **Computer Skills**

- Microsoft Office – Microsoft Word, Excel, PowerPoint

### **EDUCATION**

- Diploma in Chemical Technology – Industrial, Humber College, Toronto, Ontario
- Diploma in Laboratory Technician, Humber College, Toronto, Ontario

### **CONTINUING EDUCATION, CAREER DEVELOPMENT**

- Novartis Auditor Certification (Aseptic Processing and API) workshop
- ISO 9001:2000 Internal Auditor for Manufacturing - QMI
- Internal Auditor Training for FDA Regulated Industries (ISO 13485:2003)
- GMP Update 2008 - IPA
- Conducting GMP Quality and Compliance Audits - PSG
- CAPA Tracking Software (Trackwise)
- Effective CAPA and Root Cause Analysis
- Current Issues in Medical Device and Pharmaceutical Sterilization - Steris
- Preparing & Hosting FDA Inspections Before, During and After - IPA
- Supervisory Studies, Sheridan College
- Workplace Health & Safety

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