



Alana Reiche

Consultant

Alana is a dedicated and flexible Quality Control professional who leverages strong interpersonal skills and teamwork to achieve business objectives. With over 25 years of experience in quality control for GMP and ISO systems, Alana consistently demonstrates excellent leadership, analytical, and communication skills. Her personal expertise and knowledge make Alana a valuable addition to any team.

SKILLS AND HIGHLIGHTS



Regulatory

- Implemented a risk-based site inspection program that ensured that production and support areas and processes were compliant with good manufacturing practices (GMPs) and maintained focus on the core business objectives
- Developed a process for the implementation and maintenance of a Drug Establishment Licence to ensure compliance with Health Canada requirements
- Participated in detailed investigations of out-of-specification results and production deviations to ensure that products released to the customer met safety and purity requirements
- Ensured compliance regulatory requirements by performing detailed reviews of analytical testing reports for drug products



Auditing

- Prepared responses to Health Canada audit comments
- Acted as a resource and guide to other departments for the implementation of their risk-based departmental/self inspections
- Played an integral role in the support teams of successful Health Authority pre-approval and GMP inspections

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Quality Assurance

- Performed queries on SAP and prepared PowerPoint slides for Quality Metrics purposes
- Created and maintained an Excel spreadsheet for deviation tracking purposes
- Worked with an inter-departmental team to close and improve the quality compliance of deviation reports
- Created an innovative listing of drug products, and the activities associated with those products, as a reference document for compliance purposes
- Improved the format and content of product specifications, which reduced the amount of repeat testing and subsequently improved throughput in the laboratory
- Initiated, determined actions and closed actions for change controls related to all aspects of Quality Assurance
- Initiated, investigated, determined root cause and corrective/preventative actions, and approved deviation and non-conformance reports
- Reviewed Manufacturing and Packaging documentation



GMP Training

- Developed and presented training modules to large numbers of staff on the Canadian, American and European GMPs, and the Canadian Medical Device requirements
- Improved training on standard operating procedures by developing an innovative style of presentation



Technical Writing

- Adapted a periodic product review report for imported and purchased products that not only covered the requirements of the Canadian GMPs but also ensured that performance objectives were met
- Mentored newly-assigned staff on how to effectively summarize information for the periodic product review report
- Participated in the development of an Out-of-Specification standard operating procedure based on the ruling in the Barr Laboratories court case

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Laboratory

- Ensured that raw materials and products were tested, reviewed and released in order to effectively and efficiently meet business needs in a manner consistent with regulatory and GMP standards
- Demonstrated flexibility and adaptability by leading various teams (6 to 8 analysts) throughout the Quality Control department, such as the sampling and packaging component testing area and the raw material and drug product testing laboratory
- Ensured all testing was performed in accordance with the analytical procedures and applicable GMP and regulatory requirements
- Prepared laboratory testing schedules and reviewed Quality Control test reports in a timely and efficient manner to ensure that production schedules would be met and products would be available for the Customer
- Analyzed raw materials and drug products using various wet chemistry and instrumental techniques, such as Gas Chromatography, High Pressure Liquid Chromatography, UV-Visible Spectrophotometry, Infrared Spectrophotometry, etc.

Computer Skills

- Microsoft Office – Microsoft Word, Excel, PowerPoint
- SAP
- TrackWise

EDUCATION

- Chemical Technology Diploma, Honours, Humber College of Applied Arts and Technology, Etobicoke, Ontario

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CONTINUING EDUCATION, CAREER DEVELOPMENT

- Good Manufacturing Practices - Concepts and Implementations (PharmEng Learning Institute)
- Good Manufacturing Practices - Getting More Productivity (PharmEng Learning Institute)
- Level 1 - Liquid Dose Technology (GlaxoSmithKline)
- Level 1 - Basic Solid Dose Technology (GlaxoSmithKline)
- Computer System Inspection Readiness Workshop (GlaxoSmithKline)
- Lean Sigma Advocate (GlaxoSmithKline)
- Update 2009 – Quality Challenges Facing the Pharmaceutical Industry (PSG)
- Medical Devices Regulatory Requirements & the Inspection Program (PSG)
- Regulatory Inspection Programme for Medical Devices (PSG)
- The GMP Guidelines 2002 Edition Seminar (PSG)
- Computer System Validation (PSG)
- Update with TPP Information Exchange (PSG)
- Effective Quality Assurance Auditing for cGMP Compliance (International Pharmaceutical Academy)
- Pre-Approval & GMP Inspections - A Global Perspective (International Pharmaceutical Academy)
- Drug Product Stability & Shelf-Life (The Center for Professional Advancement)
- Good Laboratory Practices (The Center for Professional Advancement)
- ISO 13485:2003 - Essentials Course (Canadian Standards Association)
- Twenty-Sixth International Good Manufacturing Practices Conference (University of Georgia)
- Validation Guidelines for the Pharmaceutical Industry (Non-prescription Drug Manufacturers Association of Canada)

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