



Allison Westlake

Consultant

Allison is an experienced quality assurance professional with more than 12 years in the pharmaceutical industry. She is a skilled auditor, technical writer, and certified trainer. Her project management skills have generated increased compliance and improved efficiencies in a number of Quality departments. With excellent communication skills, and her education, training, and work experience, Allison is a valued team member who can also work independently as needed to move a project forward. Previous employers include GlaxoSmithKline Canada Inc., Zeneca Bioproducts, Standard Biological Labs (SGS), Whitehall Laboratories, McCain Refrigerated Foods and Ault Foods.

SKILLS AND HIGHLIGHTS



Regulatory

- Completed and submitted Division I Drug Applications and Labelling Standard Drug Applications
 - Completed drug, NHP and cosmetic label reviews
 - Submitted NHP amendments and notifications
- Ensured regulatory compliance of processes with Good Manufacturing Practice and current Canadian, U.S., Rest of World and Global Corporate regulations

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Quality Assurance

- Produced Annual Product Reviews according to schedule for pharmaceutical products by compiling and reviewing data for complaints, deviations, changes, validation, packaging, stability and laboratory tests
 - Performed statistical analysis using Statistica software program
 - Identified trends and made recommendations on course of action
- Maintained databases for completed Product Reviews and outstanding notifications
- Revised Product Quality Review program to incorporate new initiatives and Global Corporate requirements
 - Reviewed Production Batch Records
- Reviewed and approved change controls for logic, accuracy and completeness for the release of drug products
- Initiated, investigated and determined corrective and preventative actions for deviations and non-conformances



Auditing

- Conducted internal compliance audits in Quality Assurance and Manufacturing areas to ensure compliance with corporate quality standards
- Provided support during local and regulatory audits
 - Conducted laboratory audits and prepared reports

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Quality Control Officer (QCO)

- Performed various microbiological tests on finished products, raw materials, media, the environment, water and compressed gases
 - Reviewed tests conducted by analysts and ensured specifications were met
 - Actively participated in investigations
 - Trended data and produced reports
- Worked as part of team to redesign microbiology laboratory
- Dispositioned product



Training

- Performed employee training on standard operating procedures (SOPs)
 - Trained and coached analysts on laboratory procedures



Technical Writing

- Created and revised SOPs, Product Specifications, Training Modules and Performance Assessments



Validation

- Assisted microbiology lab in performing water system validation for new building
- Worked as part of a cross-functional team to bring microbiology autoclave and other laboratory equipment into compliance with 21 CFR Part 11 and internal policies

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- Coordinated and executed autoclave software upgrade and re-qualification

Computer Skills

- Proficient in LIMS, SAP, Statistica.
- Microsoft Office – Microsoft Word, Excel, PowerPoint, Access

EDUCATION

- Bachelor of Science, Honours Applied Microbiology, University of Guelph, Guelph, Ontario

CONTINUING EDUCATION, CAREER DEVELOPMENT

- Technical Writing – Q&C 2009
- Fundamentals of Regulatory Affairs – CanReg 2009
- Conducting Annual Product Reviews – PSG 2007
- Auditing and Regulatory Inspections – GSK 2004
- GMPs for Lab Personnel – GSK 2003
- Computer Validation – PSG 2001
- Microbiological Auditing – PSG 1999
- Internal Computer Training in Statistica, SAP, Word, Excel and PowerPoint

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