



Steven Danglay

Consultant

Steven Danglay is a well-rounded individual with over 10 years experience in Quality Assurance (QA) and Quality Control (QC) in Canadian and U.S. pharmaceutical, Natural Health Product, dietary supplement and biotech companies. His cheerful attitude, expertise, and attention to detail make him a valued project leader and/or team member. His experience, training, and knowledge make him a valuable addition to the Q&C team.

SKILLS AND HIGHLIGHTS



Quality Assurance/Quality Control (QCO)

- Implemented tools to institute metrics and deviations tracking for monitoring laboratory testing performance and promoting cycle-time reductions
- Performed as auditor of QC laboratories and QA systems
- Investigated root causes for cGMP deficiencies and QC testing delays to improve efficiency; created process maps to identify gaps and provide solutions
- Initiated, investigated root causes, analyzed impact, and determined corrective and preventative actions to address deviations and non-conformances
- Initiated, determined actions and closed actions for change controls related to all aspects of Quality Assurance
- Implemented changes and performed follow-up to ensure effectiveness and assess impact of changes
- Implemented CAPAs and monitored their effectiveness
- Monitored manufacturing, validation, and stability testing schedules; developed tools to collect metrics to audit test cycle times, batch release, and assay failures
- Monitored sample distribution and testing by maintaining audit trail systems (e.g., LIMS, tracking calendars)
- Prepared Certificates of Analysis for release of products
- Audited local site practices at biotech company and vaccine manufacturer
- Led a cross-functional task force team which developed an approach for addressing the stability of multi-component vaccine products and substances/intermediates; remedied deficiencies, developed complex stability programs
- Designed and coordinated stability surveillance studies for licensed vaccines with industrial operations (testing laboratories, regulatory affairs, manufacturing)



- Released components and finished products for medical device kitting
- Produced Annual Product Review according to schedule for pharmaceutical products by compiling and reviewing data for complaints, deviations, changes, validation, stability, and laboratory testing



Validation

- Performed Temperature Mapping Validation
- Evaluated computer systems for validation plan requirements
- Developed computer system validation documentation (user requirements specifications and IQ/OQ/PQ scripts)
- Executed computer system validation scripts and audited computer systems against regulatory requirements
- Initiated, determined actions and closed actions for change controls related to Computer Validation
- Initiated, investigated, and determined corrective and preventative actions to address deviations and non-conformances related to computer systems



Large Compliance Project Management

- Planned/monitored release of biotechnology, pharmaceutical and natural health products
- Coordinated stability programs



Regulatory

- Prepared Quality Assurance report and Site Licence Applications for Natural Health Product manufacturer, packager, labeler, distributor, and importer
- Prepared and submitted NHP site licence renewal submissions
- Compiled and submitted NHP product licence applications and DIN submissions
- Evaluated requirements for cosmetic products



Auditing

- Audited QC testing and QA systems



Technical Writing

- Created and revised SOPs
- Authored policies and procedures to implement improvements and harmonization opportunities with global/corporate groups

Computer Skills

- Microsoft Office – Microsoft Word, Excel, PowerPoint, Access, Visio
- SAP
- Labware LIMS
- Sample Manager and Nautilus LIMS
- LIMS Reporter (Infomaker) for Nautilus
- Crystal Reports
- NWA Analyst
- Siebel eDocs
- Radio Beacon, WMS
- Trackwise

EDUCATION

- Bachelor of Science, Honours Life Science (Microbiology, Immunology, Biochemistry, Molecular Biology), Queen's University, Kingston, Ontario

CONTINUING EDUCATION

- Auditing Skills
- Drug Product Stability and Shelf-Life, Center for Professional Advancement
- GMP for Importers/Distributors, Q&C
- GMP Overview
- GMP Training, Biogen Idec



- Graduate Certificate, Administration and Management, Harvard University Extension School, Cambridge, Massachusetts:
 - Communication in Business
 - Information Technology
 - Organizational Behavior
 - Project Management
- Fundamentals of Regulatory Affairs, CanReg
- Industrial Drug Legislation, Seneca College
- Labware LIMS, Biogen Idec & Labware LIMS Solutions, Research Triangle Park, NC
- LIMS Reporter (Infomaker) for Nautilus, Thermo Scientific, MA
- Technical Writing Course, Q&C