



Deirdre Grixti

VP Technical Services

Deirdre Grixti is a congenial team leader with over 20 years QC laboratory and QA experience. A creative problem solver, she is able to conceive, develop, and implement new strategies and processes that improve quality and efficiency. In addition, she is both a dynamic leader and a committed team builder, prioritizing effectively while respecting the priorities of others.

Deirdre communicates easily and openly with people at all levels of the industry. Proficient in GMPs in Canada and the United States, she is also knowledgeable in analytical laboratory procedures involving wet chemistry analysis, and in chemical assays using instruments such as HPLC, GC, IR, UV, and Dissolution. Deirdre's excellent project management skills are complemented by her ability to work with the client in utilizing their systems and their personnel to complete the project.

SKILLS AND HIGHLIGHTS

Large Compliance Project Management

- Developed lot release protocol templates for biological products to support release to various agencies
- Developed approximately 100 specifications for complex pharmaceutical products working with RA, QA and Compliance
- Worked with the operators in manufacturing areas for a large pharmaceutical company to identify action plans to close compliance gaps
- Developed a plan for transitioning a Research & Development drug product development site to a GMP facility; served as Quality Assurance during transition.
- Identified gaps in various quality systems, developed full quality plan for each to implement GMPs; overseeing completion of each plan
- Performing full range of on-site quality control activities and regulatory activities for independently owned Private Label manufacturer of OTC, prescription, narcotics, and herbal products
- Providing ongoing QA services and performing GMP compliance activities for a biopharmaceutical company





- Organized, reviewed and verified stability data for Research & Development department; prepared detailed stability reports
- Evaluated and restructured master document filing systems for a multinational brand-name consumer products manufacturer. Created an index of the documents required for each product and performed a gap analysis
- Performed quality control/assurance gap analysis of process systems and documentation for a pharmaceutical company involved in clinical trials. Worked with client to develop and implement processes and documentation addressing identified gaps
- Established, implemented, and maintained the following systems for a pilot plant: SOPs, Deviations, Change Control, Returns, Recalls, Complaints, Self-Inspection, Preventive Maintenance, Calibration, and Validation
- Implemented protocol for a Historical Data Analysis producing 90 final reports



Quality Assurance/Quality Control (QCO)

- Responsible for QCO Maintenance and dispositions
- Manages The Rapid Release Team™
- Performed product release and QCO services for GMP-compliant customers
- Assisted in release of finished products, drug products, clinical supplies, raw materials, and packaging materials
- Released components and finished products for medical device, pharmaceutical, natural health product and dietary supplement manufacturers
- Reviewed finished product, raw material and stability specifications against compendial monographs
- Reviewed Certificate of manufacture and analysis against Finished Product Specifications
- Initiated, executed, and monitored change controls and deviations



GMP Auditing

- Coordinated 10 Dietary Supplements supplier audits with a time frame of one month
- Coordinated successful completion of a series of eight international supplier audits to a client's corporate standards in a 3-week period
- Coordinated and executed self-inspection program for a major pharmaceutical company

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- Performed GMP audit for an importer
- Provided weekly coaching to plant staff in the implementation of their GMP Quality Systems, achieving an HPFBI compliant rating within 3 months



Regulatory

- Completed and submitted DELs, DINs, and CTDs for phase I clinical trials



GMP Training

- Developed and delivered a course on conducting a cGMP audit
- Delivered a major pharmaceutical company's GMP training course for six months
- Delivered GMP training to various levels for both drug and NHP facilities



Technical Writing

- Coordinated the development, writing, review, and approval of Standard Operating Procedures (SOPs) for a pilot plant (Facilities, Manufacturing, Laboratory, Shipping and Receiving, and Quality Assurance), ensuring that all complied with GMP and cGMP requirements
- Wrote Site Reference Files for a major pharmaceutical manufacturer's main packaging, warehousing, fabrication, and distribution facilities
- Coordinated the drafting and revision of 40 SOPs for a smaller, innovative pharmaceutical manufacturer in a time span of seven weeks. Ensured that these SOPs met end-user needs while complying with GMP and cGMP standards for Canada and the United States



Validation

- Managed a large validation implementation within a tight time frame of three weeks to meet a regulatory deadline
- Designed documents and process for temperature mapping and shipping studies



- Managed computer validation projects for such systems as: customer complaints, adverse events systems, warehouse management systems, various analytical equipment systems (e.g. HPLC) and PLCs for manufacturing equipment

Computer Skills

- Microsoft Office – Microsoft Word, Excel, PowerPoint, Access
- Adobe ISI Toolbox (experienced user)
- Documentum (experienced user)

EDUCATION

- Bachelor of Science, Honours Chemistry, University of Western Ontario, London, Ontario
- Post Graduate Courses: Protein Biosynthesis, Lipids

CONTINUING EDUCATION, CAREER DEVELOPMENT

- Advanced GMP Auditing
- Advanced GMPs and Current Inspection Trends, PSG
- Advanced Instructional Techniques, Langevin
- Auditing Skills
- cGMP Overview, Aventis Pasteur
- Clinical Trial Overview/ Introduction to Clinical Quality Assurance
- Delegation Workshop/Thinc Strategies (Thinc)
- Fundamentals of Regulatory Affairs, CanReg Inc.
- GMP Interpretation and Application, Pharmanet
- GMP Manufacture of Drugs Used in Clinical Trials
- GMP Training, Aventis Pasteur
- HPFBI Audit Management
- Industrial Drug Legislation, Seneca College
- ISO 9001:2000 Overview, Q&C
- Legal Issues in the Pharmaceutical Industry, PSG



- Mechanics of Preparing INDs and NDAs and FDA Regulations, Centre for Professional Advancement
- Pharmaceutical Label Review, CanReg Inc.
- Project Management, Kepner-Tregoe
- SOP Writing
- Technical Writing Course, Q&C

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