



Kelly Brogan – Consultant

Kelly Brogan is a reliable, well-organized consultant/facilitator with more than 25 years experience in the pharmaceutical, natural health, dietary supplement and medical device industries. Her responsibilities have included manufacturing, packaging, QC/QA, materials management, Standard Operating Procedure (SOP) writing and training, and GMP compliance.

Focused and thorough, Kelly advances task completion while ensuring that methodology is sound and results are accurate. Her wide-ranging pharmaceutical experience in auditing, training, technical writing, and quality assurance, as well as her strong coaching skills, her friendly nature, and her scrupulous attention to detail make Kelly a valuable addition to any team.

SKILLS AND HIGHLIGHTS



Quality Assurance/Quality Control Officer (QCO) Services

- Set up and implemented quality assurance systems for importers/distributors and wholesalers
- Initiated, investigated and determined corrective and preventative actions for deviations and non-conformances
- Initiated, determined actions and managed closure of actions for change controls related to all aspects of Quality Assurance
- Developed manufacturing and packaging directions ensuring adherence to GMPs, SOPs, and safety procedures
- Prepared and maintained Site Reference Files
- Coordinated product testing and final releases
- Managed complaint investigations
- Handled correspondence and communication with Health Canada
- Hosted numerous successful HPFBI audits
- Handled drug product recalls
- Reviewed master manufacturing, packaging, labelling, and batch raw materials and finished product data to assess regulatory requirements

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Auditing

- Provided auditing services for numerous pharmaceutical, NHP and dietary supplement companies and API suppliers; performed self-inspections
- Participated in HPFBI and FDA audit of a large Canadian pharmaceutical fabricator
- Performed gap analyses of foreign fabricators /packagers/labellers to Canadian GMP standards
- Hosted Health Canada inspections for numerous clients



Training

- Developed and delivered a GMP training course for a major herbal company to NNFA specified standards
- Developed and delivered the following courses:
 - GMP Fundamentals for Drugs and NHPs
 - Deviations
 - Hygiene and Sanitation: Out of Specification (OOS)
 - SOP Training
 - Good Quality Practices (for a medical device company)



Technical Writing

- Responsible for development and streamlining of over 150 SOPs for an innovative pharmaceutical company, ensuring FDA and Health Canada (HPFBI) regulatory requirements were met, other tasks included ensuring currency of existing SOP manuals
- Responsible for the development of a database for safety, SOP, equipment, and training materials

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- Coordinated development and writing of SOPs for pharmaceutical, NHP and dietary supplement manufacturers, ensuring compliance with GMPs and cGMPs
- Developed associated training
- Produced GMP documentation and SOPs for a medical device importer and distributor, drug fabricator, packager, testing laboratory, importer, distributor, and wholesaler



Consulting

- Experienced in a range of situations, including the following:
 - Importation of pharmaceuticals from international suppliers
 - Coordination and supervision of third-party product suppliers
 - Design of new manufacturing facility
 - Leadership of process re-engineering team



Regulatory

- Compiled and submitted Drug Establishment and NHP site licences
- Compiled Quality Assurance Reports (QARs)

Computer Skills

- Microsoft Office – Microsoft Word, Excel, PowerPoint, Access
- Familiar with SAP and BPCS

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EDUCATION

- Food and Drug Technology (3-year program), Durham College

CONTINUING EDUCATION

- Industrial Drug Legislation, Seneca College
- Fundamentals of Regulatory Affairs, CanReg
- Advanced GMP Auditing
- Audit Skills
- Clinical Trial Overview/Introduction to Quality Assurance
- Drug System Setup (Importer)
- GMP Guidelines 2002 Edition workshop
- HPFBI Audit Management
- ICH Stability Guidelines
- Introduction to Clinical Quality Assurance, PSG
- Introduction to ISO 9001:2000, Q&C
- Langevin Training Generalist Certificate
- Level I Certificate of Achievement, PSG
- Pharmaceutical Label Review, CanReg
- QMI Internal Auditor for Manufacturing
- Review of Changes to Risk Classification for GMP Observations, Q&C
- Technical Writing Course, Q&C
- Total Quality Advantage Facilitator Course, ODI, Boston
- Training Needs Analysis Workshop

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