Drug Quality Assurance, LLC.

Quality, Regulatory Compliance.

Database, IT, Software Support, Data Integrity.

Support for manufacturing, testing, clinical development

- **Expert Quality, Regulatory Compliance, CMC Review - all phases of drug, medical device development, commercialization**
- **I help you with manufacturing and test procedures for drugs, clinical trial materials**
- **GMP, GLP, GCP audit, Supplier Qualification, remote/ virtual audits**
- **FDA, European and global requirements**
- **Help work with contract manufacturers, testing laboratories, CROs and suppliers.**
- **Develop practical procedures, quality system, provide training.**
- **Practical approach from years of hands on product and process development, manufacturing, analytical chemistry laboratory and device testing work.**

Regulatory Compliance

- **Wide experience - pharmaceuticals, medical devices, clinical diagnostic reagents, CMO's and suppliers worldwide.**
- **Supported many clinical drug development programs to commercial launch.**

Systems Administration

Ian Champion **BS, Business Administration American University**

- **Network, Database support**
- **Software maintenance, testing, QA, Systems Integration,**
- **Troubleshoot, diagnose and solve issues**
- **FDA 21 CFR Part 11, Electronic Records Data Integrity Compliance for Computerized Systems & Security Expertise**
- **Documentation Systems**

Helena Champion, MS, MBA.

Principal Consultant,

DRUG QUALITY ASSURANCE, LLC.

Over 30 years U.S., global experience in pharmaceutical and biotechnology manufacturing and testing, medical devices and product development.

Wide current experience with drug development companies. Was Quality Assurance Director at Wyeth Biotech /Pfizer, before that held senior positions at Biogen, Genzyme, Millipore, Cambridge Isotope Laboratories/Otsuka.

Education:

Masters in Science, University of Guelph, Ontario, Canada, Thesis: development of HPLC methods for separation of peptides.

MBA, Northeastern University, Boston, MA.

BS Honors, Plant Biochemistry, Rhodes U.

BS, Biological Science & Chemistry, Natal University, Durban, South Africa.

Scientific background in analytical chemistry, organic synthetic chemistry, protein chemistry, biology, microbiology, biochemistry.

Experience in Manufacturing, Quality:

Active pharmaceutical ingredient (API) - small molecule synthesis, cell culture, fermentation, biotech, biologics and vaccines.

Drug product - aseptic processing of biotech drugs, parenterals, oral liquid, tablet, inhaled dosage forms and packaging.

Medical Device, drug device combinations.

Audits - GMP, GLP, GCP, due diligence - manufacturers, laboratories, suppliers, distributors, CRO's, Clinical Trial sites, global.

Prepare for - host FDA, global Inspections, evaluate FDA 483's, Warning Letters, Consent Decrees, write responses, corrective actions.

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www.DrugQualityAssurance.com

Helena Champion, MS, MBA, Drug Quality Assurance, LLC.

Practical, efficient support to fit your needs and budget

Quality Assurance

- Quality Systems and Procedures, Standard Operating Procedures (SOP's), GMP Training
- Audits – GMP, GCP, GLP, GDP Lead Auditor, ISO 9001 Auditor, qualified IPEC Excipient GMP Auditor Supply Chain Management - Contract Manufacturing Organization Selection and Support
- Batch Record Review, Review, Disposition, Batch Release
- Investigations, Corrective Action and Preventive Action
- Review Master Validation Plans, Process Validation Protocols/Reports, Equipment Qualifications
- Quality support of commercial products, provide and review Quality Agreements
- Risk Assessment Programs

Development - Drug Substance and Drug Product

- Chemistry, Manufacturing and Controls Review (CMC)
- Clinical Trial Materials, Technology Transfer
- Master Batch Record development, Phase appropriate GMPs, Device History Records
- Test Method Qualification, Validation, Protocols, Chemistry, Manufacturing and Controls (CMC)
- Process Validation, Preparation for Pre-Approval Inspections, Commercial launch preparations

Supply Chain Management

- Supplier Qualification - set up a robust supplier/vendor/contractor qualification system
- Supplier Risk Assessment - FDA, European, global expectations, Quality Agreements

Regulatory Compliance

- Management responsibility - Meet new FDA and international rules
- Prevent and resolve compliance problems, Consent decree remediation
- Inspection Response and follow up – FDA, European, Global

Industry speaker, publications

- Ensuring Drug Quality in a Global Economy, Contract Pharma May 2014.
- Parenteral Drug Association speaker, New England 2013 "Pharmaceutical Supplier Quality for the 21st Century"
- How to Overcome Industry Challenges Posed by Requirements for More Supplier Audits, IVT 3rd Forum on Supplier Quality, 8 November 2012, Philadelphia, PA.
- Audit-Sharing Can Lead to Fewer Supply Chain Headaches, PDA Letter, October 2012.
- Shared Supplier Audits - A new day for supply chain quality, Contract Pharma, September 2012.
- Keynote speaker at Informa Biopharmaceutical Raw Materials Conference, 2012 Cologne, Germany, topic: Effectively Managing Raw Materials throughout the Product Lifecycle.
- Chairperson at Viral Safety for Biologics Conference (Informa) 2012, Cologne.

Systems Administration, IT, Network, Desktop support as needed for your company by Ian Champion

- Database support
- Data Integrity Compliance for Computerized Systems
- Provide laptop and desktop support for staff, training. Software maintenance, liaison with hardware service support
- Image, setup and deploy Mac/ PC computers to users
- Troubleshoot, diagnose, solve issues, TCP/ IP troubleshooting, Ethernet/ Remote Access
- MS Office, MS Access, Mac OSX, Salesforce, etc., Internet and Web applications
- Software Systems Integration, Quality Assurance/ QA, version control, GIT

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