# Drug Quality Assurance, LLC.

## Quality support for your company

- **Expert on Quality and Regulatory Compliance support and direction for all phases of drug and medical device development and commercialization.**
- **I help you with manufacturing clinical trial materials for drug development.**
- **Expert at audits and supplier qualification, to select the best for your project.**
- **Help you work optimally with contract manufacturers, testing laboratories and suppliers.**
- **Help you meet FDA, European and global requirements.**
- **My scientific background helps me understand your technology and operations.**
- **Develop practical procedures, quality system, provide training.**

## Efficient Regulatory Compliance

- **My expertise is based on wide experience in Regulatory Compliance and Quality Assurance for pharmaceuticals, medical devices and clinical diagnostic reagents, working with CMO's and suppliers worldwide.**
- **I have worked on numerous clinical drug development programs, supported Chemistry, Manufacturing and Controls, commercial launch.**
- **I have a practical approach from years of hands on product and process development, manufacturing, analytical chemistry laboratory and device testing work.**


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### Helena Champion, MS, MBA,

Principal Consultant,
**DRUG QUALITY ASSURANCE, LLC.**


I have over 25 years of U.S. and international experience in pharmaceutical and biotechnology manufacturing and testing, medical devices and product development.

I was Quality Assurance Director at Wyeth Biotech /Pfizer and before that held senior positions at Biogen, Genzyme, Millipore and 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 University.

**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.

Device experience - various devices and drug device combinations, many technologies.

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

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

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

*Practical, efficient support to fit your needs and budget*

## Quality Assurance

- **Audits – GMP, GCP, GLP, GDP. IRCA certified Pharmaceutical Quality Management Systems Lead Auditor /GMP Lead Auditor, ISO 9001 Auditor, qualified IPEA Excipient GMP Auditor**
- **Quality Systems and Procedures, Standard Operating Procedures (SOP's), GMP Training**
- **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**
- **Risk Assessment Programs**

## Development - Drug Substance and Drug Product

- **Clinical Trial Materials, Technology Transfer**
- **Master Batch Record development, Device History Record development**
- **Phase appropriate GMPs, quality systems**
- **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 - comply with 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.**
- **New England Chapter, Parenteral Drug Association speaker. March 13, 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.**
- **Assess the Current GMP Standards for Supplier Quality at Second Annual West Coast Forum on Supplier Audits, San Diego, CA, 2011 (CBI/Institute of Validation Technology).**
- **Workshop - "Establish Risk Assessment Programs for Supplier Quality Management" Supplier Audits Congress, San Diego, CA, 2010 (CBI/IVT).**

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