

### Core Competencies

- ASQ Certified Auditor
- Biologics/Sterile Products
- GxP Quality Systems
- GMP Audit Procedures
- Biologics API
- CMO/CRO Management
- Clinical QA Design
- Vendor Qualifications
- Quality Agreements
- Parenteral Fill/Finish
- Deviation Investigation
- Bio Vaccine Purification
- Lyophilization

### **Professional Summary**

Ms. Freisem is an executive level subject matter expert in GXP Quality Assurance. She provides our clients with effective CMC quality system management through the draft of individualized standard operating procedures. Her technical background is in drug substance manufacturing, small molecule and biologic API's, sterile manufacturing, plant design, and technology transfer. She is a proficient negotiator of Quality Agreements and coordinating regulatory interactions with a CMO. Her capabilities include investigation remediation, lot release oversight, inspection preparation assistance, and site inspections using her extensive knowledge of ISO and cGMP requirements.

Ms. Freisem started in industry as a senior biologist before pursuing a Quality Assurance career. She has over 30 years' practical hands-on experience in vaccine development at Wyeth, supplier quality management at Centocor /J&J, and as the Quality department head at Cardiokine.

### **Education**

B.S.            Biology            Grove City College

### **Professional Experience**

**Design Space Inpharmatics, LLC**

**2010 - Present**

**Senior Quality Assurance Consultant**

- GxP Quality Assurance system development for small and large molecules,
- Audits of third-party CRO/CMO manufacturing,
- Develops SOP's and quality agreements,
- Batch review and release,
- Clinical QA system design and management,
- Provide quality systems development and implementation, GXP auditing, and quality assurance services to emerging pharmaceutical and biotechnology companies.



# Robbi Freisem

## Senior Quality Assurance Consultant

### Cardiokine

#### Director, Quality Assurance / Quality Control

- Established quality systems and clinical quality assurance programs for start-up pharmaceutical company,
- Established supplier / vendor qualification program for GMP, GLP, and GCP contractors, CROs and CMOs,
- Performed quality reviews and approved drug API, drug release / disposition, contractor manufacturing labeling and packaging documents, batch records,
- Performed quality reviews of clinical protocols and amendments,
- Managed audit program and performed audits of suppliers, contractors, GMP and GLP study reports, and clinical and regulatory documents.

### Centocor / J&J

#### Manager, Quality Assurance

- Represented QA on cross-functional teams for CMO manufacturing and process transfer of new and existing commercial products,
- Developed primary component specifications, sampling and inspection requirements, and quality agreements for specified suppliers and CMOs,
- Developed systems and reviewed master and production batch records from contract manufacturers/packagegers to recommend final product release to commercial market,
- Performed periodic cGMP and GLP audits of contractors, suppliers, and laboratories; quality lead for inspection of CMOs, coordinated FDA audit of clinical sample test lab,
- Collaborated with a contract organization to establish a product recall system,
- Performed internal oversight GMP and ISO audits of diagnostic testing development, and pharmaceutical manufacturing and testing operations, communicated evaluations to management, monitored follow-up action,

### Wyeth

#### Senior Biologist

- Reviewed and maintained batch records for GMP compliance to assure clinical trial material quality and prepare for product and establishment license application,
- Participated in manufacture of biological vaccines for clinical supply under GMPs, including formulation, filling, lyophilization, tableting, enteric coating, labeling, and packaging including double blind and multi-dose studies; extensive experience with aseptic technique,
- Acted as Biological Development Center coordinator for safety assessment; as a team leader on the waste water reduction team, identified cost-effective solution for specific pollutant problem.