Vice President, Chief Compliance Officer, Quality Assurance

AREAS OF EXPERTISE

- **API Manufacturing**
- **Audits (GCP, GLP, GMP, and ISO 9000)**
- **Blood Collection and Fractionation**
- **CAPA Management**
- **Clinical Packaging**
- **Computer Validation**
- **Conflict Resolution**
- **DEA/EMA//EPA/FAA/FDA Inspections**
- **Deviation Management**
- **Document Control**
- **GxP Quality System Management Design**
- **IVRS and IxWRS Vendors**
- **Licensing and Permits**
- **Management Reviews**
- **Marketing/R&D Alignment**
- **Pharmacovigilance Quality Systems**
- **Product Implementation**
- **Program Management**
- **Quality Assurance Databases and Metrics**
- **Quality Assurance Systems**
- **Quality Manuals and Standards**
- **R&D Optimization**
- **Regulatory Compliance SME**
- **Regulatory Databases**
- **Regulatory Responses (FDA 483/Warning Letter)**
- **Risk Management**
- **Staff Development**
- **Standard Operating Procedures**
- **Sterile Drug Manufacturing**
- **Strategic Planning**
- **Trackwise and Amgit QAAD**
- **Trial Master Files**
- **Vendor Management and Relationship**

INTRODUCTION

Consultant has over thirty years of experience in the Quality Assurance industry. Directed the Global Quality Assurance Program and Optimal Research SMO to ensure that systems, processes, and procedures were GxP compliant. Served as the principle host during inspections by regulatory authorities and directed the hosting of audits by sponsor auditors. Directed the GxP Compliance and Quality Assurance Program for pharmaceutical drug development. Directed all Quality Team activities for the GMP manufacturing and packaging of GCP clinical investigational pharmaceutical drug products including biosimilars, capsules, medical devices, parenterals, and tablets for shipment to Investigator sites. Provided direction, leadership, support, coaching, and training to QA staff members.

WORK EXPERIENCE

03/2015 – Present
Industry Consultant
Duties:

- Conducts GCP, GLP, GMP, and ISO 9000 audits.
- Conducts high-level quality system reviews, gap analyses, and risk assessments.
- Performs assessments of GMP clinical packaging and clinical supply manufacturing operations.
- Assists clients with remediation efforts prior to regulatory inspections.
- Hosts and/or provides support before, during, and after regulatory inspections.

- Assists clients with implementation and remediation of quality systems in R&D development and manufacturing.
- Designs and implements compliance remediation plans based on compliance reviews.
- Develops, amends, and implements quality system policies and procedures.
- Provides streamlined alternatives to simplify complex systems.
- Conducts remediation of GCP, GLP, and GMP operations for R&D development and manufacturing operations.
- Performs assessments, pre-PAI audits, and mock pre-inspections.
- Responds to FDA 483s, warning letters, and other regulatory notifications.
- Generates procedures, implements GxP systems, and trains personnel.
- Facilitates general problem resolution.

2012 – 2016
Biorasi, Aventura, FL
Vice President, Chief Compliance Officer, Quality Assurance
Duties:

- Provided leadership to the Quality team with a focus on capacity utilization, coaching, development, management, mentoring, performance assessment, recruitment, training, and workload balance.
- Directed the Biorasi GCP, GLP, GMP Quality Assurance audit program focusing on internal audits, investigator audits, and vendor audits.
- Ensured that the Biorasi Compliance and Quality Assurance Program was maintained in a continual state of audit readiness for sponsor client audits, FDA inspections, and other global regulatory inspections.
- Directed pre-inspection preparation activities at Biorasi facilities, investigator sites, and vendor locations to ensure positive outcomes.
- Hosted FDA and other regulatory inspections including the first FDA GCP inspection of a Moscow, Russia investigator site for a major sponsor client biosimilar clinical trial (no FDA 483).
- Hosted sponsor client audits and serves as the single point of contact for scheduling and follow-up.
- Served as internal subject matter expert on regulations, guidelines, and compliance related activities.
- Directed the Biorasi Deviation and CAPA Reporting Programs to ensure reporting and resolution of compliance issues.
- Provided Compliance and Quality Assurance Program Metrics with a focus on audits, deviations, CAPAs, complaints, compliance gaps, and industry trends.
- Served as an advisor for sponsor client program launches with a focus on QA support, supply chain, laboratories, CMOs, packagers, contractors, and vendors.
- Served as liaison to sponsor client teams to facilitate quality and regulatory communication.
- Collaborated with sponsor client teams to support clinical development activities and define compliance strategies for biopharmaceuticals, biosimilars, parenterals, tablets, capsules, liquids, and medical devices.
- Served as project manager for quality system improvements.
- Directed Quality Improvement Meetings to provide leadership, direction, and guidance to other Biorasi departments.
- Approved SOPs, forms, checklists, and templates to ensure regulatory compliance.
- Reviewed GCP, GLP, GMP systems, processes, and procedures before incorporation into the Biorasi Process Infrastructure QMS Integrated System.

2010 – 2012
Fisher Clinical Services, Mount Prospect, IL
Director, Quality Assurance
Duties:

- Provided leadership, GCP/GMP advice, and support to meet clinical manufacturing and packaging needs.
- Directed systematic GCP/GMP quality improvement activities through the PPI Total Quality Management System.
- Directed documentation control activities, batch record review, product distribution, and ensured records archiving.
- Generated Monthly Quality Metrics including internal audits, sponsor audits, CAPAs, complaints, deviations, and trends.
- Held monthly TrackWise deviation reviews to resolve issues, close deviations, and address customer complaints.
- Directed the FCS MP Validation Program including equipment qualification.
- Directed monthly FCS MP QMS Quality Council Meetings and served on the FCS Corporate Quality Council.
- Ensured that the QA team met deadline requirements for goals, policies, and procedures.
- Prepared FCS for sponsor client audits, corporate audits, and regulatory inspections.
- Ensured that CMOs met contract requirements including on-time delivery from global locations.
- Hosted three FDA GCP/ GMP inspections, two US DEA inspections, two Swedish MPA inspections, one US FAA inspection, one State of Illinois inspection, and one TSA inspection at FCS MP.
- Directed the new warehouse transfer of 28 semi-truck loads of GCP documents with 100% accountability.
- Served as member of the FCS MP Senior Leadership Team and FCS Corporate QA Team.
- Directed the GCP/GMP internal audit program and vendor audit program.
- Provided assurance that packaged drugs met required GCP/GMP specifications.
- Directed GCP/GMP training activities and ensured that training was documented in the electronic LMS system.
- Served on the GPM Development Management Team for the introduction of paperless batch records.
- Conducted Annual Management Reviews and ensured that observations were resolved.
- Developed and negotiated Sponsor supply and quality agreements.

2008 – 2010
KV Pharmaceutical, St. Louis, MO
Associate Director, Clinical Quality Assurance
Duties:

- Developed and implemented the first GCP Clinical Quality Assurance Program at KV Pharmaceutical.
- Collaborated with Clinical R&D and Medical Affairs to ensure FDA GCP inspection readiness.
- Hosted the first FDA GCP inspection of a KV clinical trial at four Investigator sites in Saint Petersburg, Russia.
- Served on the KV New Product Development Quality Council for GCP clinical trials of new drug candidates.
- Directed the first KV GCP Internal, investigator, and vendor audit program.
- Established the first KV GCP Deviation Report and CAPA Program for clinical trials.
- Held monthly TrackWise review meetings for GCP related audit tracking, performance metrics, and CAPA closure.
- Directed the first KV GCP Training Program for Clinical and Medical Affairs staff.

2001 - 2007
TAP Pharmaceutical Products, Inc., Lake Forest, IL
Quality Assurance Audit Manager
Duties:

- Managed the TAP QA Audit Group, ensuring that US and International GCP and GLP audits were planned, scheduled, and completed to meet organization goals within the annual budget.
- Conducted GCP and GLP audits throughout North America, South America, Europe, and Africa.
- Provided high level regulatory compliance GCP QA support to Prevacid and Lupron teams including FDA pre-audits.
- Established and modified selected quality initiatives to align with best business GCP practices from industry benchmarks and internal customer feedback.
- Systematically monitored GCP/GLP corrective actions to ensure timely closeout of audit report findings.
- Conducted high level computer systems, IVRS, and medical device audits at Vendor locations.
- Appointed QA Team Leader for the first TAP FDA GCP inspection at Lake Forest, IL.
- Hosted FDA GCP and GMP inspections at the Lake Forest facility, investigator sites, and vendor locations.
- Directly responsible for FDA 483 observation responses and ensured required follow-up action.
- Conducted GCP regulatory compliance training for direct reports, contract auditors, investigators, and vendors.
- Responsible for metrics reporting including GCP audit planning, tracking, gaps, investigator and vendor compliance.
- Implemented the external GCP vendor audit program for Phase 1 Units conducting radiolabeled studies.

1998 – 2001
Searle Pharmacia, Skokie, IL
Corporate Compliance Auditor
Duties:

- Served as lead auditor for GCP audits of clinical research studies at US and international investigator locations.
- Served as lead auditor for GMP audits of commercial pharmaceutical products at US and international locations.
- Conducted due diligence team audits of potential company acquisitions and product licensing.
- Served as team leader for global GCP and GMP regulatory inspections.
- Conducted internal audits at Searle Pharmacia sites in North America, South America, Europe, and Puerto Rico.
- Supported the Celebrex new product development and introduction team.
- Managed cross-functional team audits at international, multi-site locations.
- Conducted 21 CFR Part 11 computer software validation audits at vendors and joint venture partner locations.
- Conducted GCP and GMP training seminars at international joint venture partner locations.
- Reviewed CMC documentation for clinical and commercial manufacturing.

1988 – 1997
Sandoz Agro Inc., Des Plaines, IL
Manager Corporate Quality Assurance (1993 – 1997)
Duties:

- Managed the QA audit team at multiple locations, ensuring that GLP audits were planned, scheduled, and completed to meet organization goals within the annual budget.

- Prepared the R&D ream for EPA GLP inspections at Sandoz Des Plaines and Dallas, TX.
- Hosted the first EPA GLP inspection at Sandoz Des Plaines.
- Effectively implemented and maintained QA training programs to improve regulatory compliance.
- Selected as the Sandoz Agro North America QA representative during US EPA GLP regulatory inspections at the Des Plaines facility and during Swiss IKS GLP inspections at Sandoz, Basel, Switzerland.
- Responsibilities were significantly expanded during the 1993 Sandoz/Zoecon merger.
- Provided Quality Assurance oversight to the Methoprene Development Team in Muttenz, Switzerland.
- Developed the laboratory quality assurance program for radiolabeled non-clinical laboratory studies.

Manager, GLP Quality Assurance / Regulatory Affairs (1988 – 1993)

Duties:

- Introduced and implemented the first Sandoz North American GLP Quality Assurance audit program.
- Expanded GLP operations into the Palo Alto, CA, Wasco, CA, and Greenville, MS facilities.
- Hired and trained auditors to staff the GLP Quality Assurance Unit.
- Worked with European colleagues at European locations to harmonize GLP operations.
- Conducted GLP and GMP European audits at internal sites and vendor locations.
- Represented Sandoz North America during European regulatory inspections.
- Conducted Good Automated Laboratory Practices computer validation audits on LIMS.
- Conducted GLP audits on analytical method protocols and analytical method reports.

1987 - 1988

LyphoMed, Melrose Park, IL

Manager, Paranternal Manufacturing

Duties:

- Responsible for GMP parenteral manufacturing at the Melrose Park and Chicago Grand Avenue plants.
- Directed the activities of 120 persons including 15 supervisors and 105 hourly employees.
- Served on the LyphoMed Business Plan Committee to evaluate new drug production.
- Manufacturing representative for internal team audits at the Melrose Park and Chicago manufacturing plants.
- Responsible to provide weekly, monthly, and quarterly manufacturing yield reports.
- Provided production leadership to the LyphoMed New Product Development Team.
- Served as management team leader during FDA regulatory inspections.
- Conducted GMP regulatory training for the manufacturing, QA, and QC staff.

1982 – 1987

Armour Pharmaceutical, Kankakee, IL

Section Head Tableting & Milling / Process Manager Commercial Packing (1984 – 1987)

Duties:

- Responsible for oral dosage GMP manufacturing of tablets, capsules, powders, creams, and liquids.
- Managed 18 production workers, including one supervisor and 17 hourly employees (ACW Union).
- Served as team leader the process improvement team (Levothroid tablets and Nitrospan capsules).
- Served as a member of the Armour Pharmaceutical Internal Audit Team.
- Provided technical support to the Solid Dose and Parenteral Drug Packaging Development Team.
- Developed the 0.075mg Armour Levothroid (Sodium Levothyroxine) tablet.
- Computer validation team leader for the granulation potency control program.
- Managed the Armour In-Process Oral Dosage Laboratory.
- Served as manufacturing team leader during FDA GMP inspections.

Process Manager Biochemical Bulk Manufacturing (1982 – 1984)

Duties:

- Responsible for process monitoring and yield improvement of Biochemical Manufacturing.
- Worked with R&D to introduce new biochemical products including Armour Thrombinar.
- Served as member of the process development team to improve production yields for Bovine Albumin Powder, Fraction V, Rehavid 30% Solution, and Bovine Fibrinogen Fraction 1.
- Developed SOPs, manufacturing procedures, and product specifications for new products.
- Provided usage report metrics for the Building 5 solvent tank farm.
- Managed the In-Process Bulk Manufacturing Laboratory.
- Validation Team Member for the Modicon GMP Control Process.
- Co-authored the 1983 APC Modicon Computer System Hardware & Software Validation Report.
- Served on the Human Blood Fractionation Committee to improve blood collection, storage, and fractionation.
- Assisted the Plant Manager during FDA GMP inspections.

EDUCATION

University of South Dakota, Vermillion, SD
Master's Degree: Chemistry

University of South Dakota, Vermillion, SD
Bachelor of Science: Chemistry

AREAS OF THERAPEUTIC QA EXPERIENCE

- Anti-infectives
- Asthma/allergy
- Blood products
- Cardiovascular
- Central nervous system
- Critical care
- Dental
- Diabetes
- Dermatology
- Endocrinology
- Endometriosis
- Gastrointestinal
- Genetic testing
- Imaging
- Immunology
- Kidney disease
- Medical devices
- Men's health
- Multiple myeloma
- Multiple sclerosis
- Oncology
- OTC medications
- Pain management
- Parkinson's Disease
- Pulmonary
- Sleep disorders
- Vaccines
- Women's health

PROFESSIONAL ASSOCIATIONS AND CERTIFICATIONS

- Certified ISO 9000 Lead Auditor by the Victoria Group
- Society of Quality Assurance

ELECTRONIC SYSTEMS

- Medidata, Medrio, and OpenClinica Electronic Case Report Forms (eCRFs)
- Veeva Vault
- Modicon GMP Programmable Logic Controller
- Televideo GMP Granulation Potency Calculation System
- 21 CFR Part 11 Systems Validation
- AS 400 Budget System
- Microsoft Office (Excel, Word, Outlook, PowerPoint)

AUDIT EXPERIENCE

- Analytical Laboratories
- API Vendors
- Bioanalytical Laboratories
- Biosimilar Manufacturers
- Biosimilar Vendors
- Biotechnology Vendors
- Clinical Equipment Vendors
- Clinical Investigators
- Clinical GCP Laboratories
- Clinical Manufacturing Vendors
- Clinical Packaging Vendors
- Clinical Supply Vendors
- Chemical Suppliers
- Cytology Laboratory Vendors
- Data Management Vendors
- Drug Storage Vendors
- Non-Clinical Specimen Archives
- Due Diligence
- ECG, ECRF Vendors
- Electronic and Paper Archives
- Ethics Committees
- Expired Drug Destruction Vendors
- Genomic Laboratories
- Medical Device Vendors
- Infusion Pump Vendors
- Institutional Review Boards
- Internal Audits
- IVRS Vendors
- IV Tubing Vendors
- Non- Clinical GLP Laboratories
- LIMS Vendors
- Software Vendors
- Packaging Equipment Vendors
- Pharmaceutical Mfg. Vendors
- Pharmaceutical Packaging Vendors
- Phase 1 Unit Clinical CROs
- Phase 2-4 Clinical CROs
- Radiolabeled Vendors
- Solid Dosage Vendors
- Prescription Drug Waste Vendors
- Specimen Storage Vendors
- Sterile Manufacturing Vendors
- Toxicology Laboratories
- Warehouse Vendors
- Wholly-Owned Joint Ventures