Susan Fasso

Senior Quality Assurance Consultant

Core Competencies

- Supplier Audits
- QA SOP Development
- Risk Based Approach
- FDA 483 Remediation
- CMO/CRO Selection
- Internal QA Management
- Biologic Experience
- Quality Compliance
- Microbiome
- Global Markets
- ASQ Quality Auditor Certified

Professional Summary

Ms. Fasso has led Global GxP Quality Assurance programs in both the pharmaceutical and biotechnology industries. She has established quality systems from the ground up for several start-up companies.

With more than 26 years of industry experience, Ms. Fasso provides global quality support to external partners/suppliers and holds an ASQ Quality Auditor certification. Ms Fasso is an advocate for client quality oversight of external vendors while building and maintaining relationships with both partners and relevant worldwide health authorities. She supports new drug development efforts with successful clinical trials for several new products.

Education

M.S.	Regulatory Affairs, Quality Assurance	Temple University
B.S.	Chemistry	Drexel University

Professional Experience

Design Space Inpharmatics, LLC **2011 - Present**
Global Pharma GxP Consulting, LLC

Senior Quality Assurance Consultant

- Performs inspection, remediation, and interim controls for a major pharmaceutical company,
- Developed Corrective Action Plans for remediation of FDA 483,
- CMC record reviews as well as GCP and GLP documentation,
- Extensive investigation/CAPA reviews for companies under consent decree,
- Authored Quality SOP's and negotiated quality supplier agreements,
- Audits third-party CMO/CRO manufacturing,
- Audits CROs and CMOs for GLP, GCP, GMP compliance,
- Interacted with Quality Person (QP) and attended several audits with QP,
- PAI and BIMO inspection prepareness.

Iroko Pharmaceuticals **2007 - 2011**

Global Head of Quality Assurance

Head of Global GxP Quality Assurance/Compliance supporting research and development and commercial supply chain.

- Directed quality assurance staff for virtual pharmaceutical company ensuring that quality systems were developed and maintained for clinical and commercial drug product,
- Develop strategic planning, direction and leadership for quality system activities including research, registration, and compliance with governmental regulations,
- Participated in preparation of filings of INDs, IND amendments, CTAs, MAs and other regulatory submissions,
- Identifies regulatory and project development risks and made recommendations to senior management regarding alternatives for risk mitigation,
- Provided strategic and tactical support for complex global external supply chain; successful integration and transition of Merck and Lilly products to Iroko contractors/vendors,
- Supported regulatory CMC activities worldwide for country specific dossiers.

GPC Biotech **2002 - 2007**

Head of Quality GxP Quality Assurance

Head of Global Quality Assurance for a virtual pharmaceutical and biotechnology corporation. Developed and directed QA program for a newly formed company in accordance with GMP/GCP/GLP Regulations and International Quality standards.

- Participated in preparation of filings of INDs, amendments, CTAs, MAAs and other regulatory submissions,
- Directed the effort, implementation and improvement of corporate global GxP Quality Assurance and compliance program for both research and development and commercial activities,
- Developed and maintained quality systems policies and procedures including but not limited to training, document control, vendor qualification, audit program, investigations, complaints, stability, validation, corrective/preventive action and change control systems,
- Project manager for implementation of electronic data management system,
- Primary company contact for all regulated inspections by the Health Authorities worldwide,
- Led all company audits in preparation for pre-approval of New Drug Applications (NDA) and MAA,
- QA/QC review of NDA submission, Clinical. Nonclinical/CMC,
- Hosted successful FDA Bioresearch Monitoring Inspection for NDA with no 483s observations.

G & W Laboratories **2000 - 2002**

Senior Regulatory Affairs/Quality Assurance Manager

Managed quality assurance staff of 27 for a generic manufacturing firm. Responsible for overall implementation, continuous improvement and maintenance of quality systems.

- Performed quality assessment and developed quality systems,
- Managed preparation and content of CMC section for regulatory submissions of developed regulatory strategy for new products,
- Managed staff of inspectors, auditors, QA manager, documentation control, and labeling,
- Conducted customer audits, vendor audits, internal and external audits,
- Hosted FDA inspections, 483's, warning letter response, deficiency letters and PAIs,
- Reported directly to VP to QA/RA jointly developing strategies for new product filings,
- Performed trending of product activities for annual product review.

Wyeth **1994 – 2000**

Senior QA/Compliance Auditor

Senior Quality Assurance professional hired as result of remediation plan under the Application Integrity Policy.

- Managed preparation and content of CMC section for regulatory submissions of NDA/ANDA,
- Performed critical review of regulatory submissions to ensure adequacy, consistency, and conformity to regulatory requirements,
- Developed regulatory strategy for new products,
- Reviewed compliance issues with the scientific groups in the development of veterinary drugs,
- Provided GMP QA review tracking, periodic status and quality trends,
- Coordinated GMP QA support for on-going development projects,
- Performed final review and release of clinical, stability and validation batches,
- Reviewed and approved all relevant GMP documentation, SOPs, validation plans, batch records, methods, method validation plans, audit drug manufacturing facilities and laboratories,
- Participated in pre-approval inspections; successful inspection with no 483s,
- Participated in Inspection with CVM and district FDA; no major observations and FDA lifted the Application Integrity Policy.