Susan Showers

Senior Quality Assurance Consultant

Core Competencies

- Quality Auditor
- Quality Training
- GxP Quality Systems
- GMP Audit Procedures
- Biologics API
- SOP Development
- CMO/CRO Management
- Clinical QA Design
- Vendor Qualifications
- Quality Agreements

Professional Summary

Ms. Showers has 23 years of experience within the Biologics, Pharmaceutical and Parenteral drug industries performing Quality Systems enhancements, remediation, and total overhaul/restructuring. She is an SME in the performance and review of quality documents such as CAPAs, Investigations/Deviations and Customer Complaints with extensive technical writing and data reviews skills for technical and manufacturing records (i.e., Batch Production Record review/generation, and SOPs). Ms. Showers also conducts various types of Quality related training in preparation for a client's FDA and other agencies' audits and helps with the generation, review and approval of standard operating procedures.

Susan has experience with developing new SOPs (from scratch) or remediating Quality Systems for small to medium size companies, in preparation for new product/PAI. She has extensive experience in technical writing and data review for batch records. She also performs quality related training in preparation for audits, such as performing investigations and SOP training.

Education

M.A.	Public Administration	Webster University
B.A.	Criminology	Ohio State University

Professional Experience

Design Space InPharmatics, LLC **2021 - Present**

Senior Quality Assurance Consultant

- Oversees the manufacturing activities and execution of the quality systems in support of the manufacturing, testing, packaging, labeling of clinical products for R & D organization,
- Conducts gap analysis and provide recommendations to QMS for future API manufacturer in order to identify areas for remediation for FDA readiness,
- Performed investigations for outstanding deviations, closed outstanding CAPAs and performed effectiveness checks for CAPAs.

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S3 Management LLC **2012 - Present**

Principal Consultant/Owner

- Performs GMP audits of the manufacturing, filling, packaging processes and functional systems and develops solutions to mitigate identified gaps,
- Provides guidance on cGMPs and the remediation of the quality systems, such as investigations, SOPs, batch records, CAPAs, change controls, complaints, and GDP,
- Performs audits/reviews of manufacturing and packaging batch records ensuring data integrity, processes are in alignment with regulations, client's SOPs and cGMPs,
- Revises and reviews SOPs, approves investigations and CAPAs for various of products, such as OSD, DS, monoclonal antibodies, vaccines, and sterile injectables. Experienced with VeevaVault,
- Performs training for new, revised SOPs and conducts training for "Train-the Trainer" and includes training material,
- Trains and mentors multi-departmental investigators and on performing investigations, utilizing proper DMAIC tools and determining applicable CAPAs,
- Manages and audits external radiopharmaceutical manufacturer for clinical trial manufacturing, ensuring the manufacturing facility is cGMP compliant and ensuring proper corrective actions are implemented for Phase I trial,
- Authored investigations to determine the root causes for aseptic manufacturing, biologics, and environmental monitoring. Recommended CAPAs when appropriate,
- As Workstream Lead, developed and maintained the project plan for remediation of outstanding CAPAs and Deviations in preparation for PAI for first commercial product for clinical biotech CMO. Assessed 322 CAPAs and Deviations for proper criticalities and priority, with a 94% completion rate within the 7 month allotted time frame,
- Assisted and advised clinical CMO with major process improvement initiatives, such as Good Documentation Initiative, Line Clearance, and Labeling,
- Revised deficient SOPs for the quality system in response to medical device's FDA Warning Letter,
- Generated CAPAs for deficiencies for the medical device quality system, such as complaints, non-conformances, investigations, quality review, and quality records,
- Advised and assisted API manufacturer in remediating their Quality System in preparation for Pre-Approval Inspection for new combination device; such as Manufacturing Batch Records and SOPs for recall, investigations, change controls, shipping, warehouse, product review, supplier/internal audits, QA/QC Responsibilities, and Documentation System,
- Revamped deficient SOPs in response to API Manufacturer's FDA 483,
- Authored and investigated internal and external complaints for solid dose, powders, and parenteral drug products,
- Performed product and defect/complaint trending utilizing Trackwise,
- Coordinated with external and international vendors for completion and assistance with complaint investigations,
- Revised Master Batch Records (MBRs) for small molecule manufacturing department.

Padtech AS **2010 - 2012**

Director QA

- Developed a quality system for a startup contract cosmetics/pharmaceutical packaging facility. Included, generating all SOPs, master batch records, training activities and quality metrics,
- Developed supplier management program and performed all quality audits for international raw material suppliers and contracted vendors,
- Managed and oversaw all qualification/validation activities for the new facility's utilities, equipment, cleaning validation, and computer software validation,
- Created and managed the facility start-up, medium and long term budget and strategy for the QA/QC Department,
- Supervised the daily operation of QC personnel during production and incoming QC testing to ensure raw material quality, product quality and release of finished packaged product,
- Reviewed, approved all finished goods batch records and release of finished goods.

Contract Assignments **2007 - 2010**

QA Consultant

- Developed new Standard Operating Procedures (SOPS) and Work Instructions (WI), utilizing Next Docs electronic document system, for a start-up Medical Device Quality System,
- Interfaced with subject matter experts, Hardware/Software Engineers, QA and Operations for documents that technical writing was performed,
- Authored new and revised departmental/global regulated documents (SOPs) and Work Instructions within GxPharma document management system.

Forest Research Institute **2005 - 2007**

Corporate Quality Assurance Specialist

- Developed new and revised Master Batch Records for a new aseptic vaccine manufacturing suite,
- Created and implemented quality agreements with contracted vendors to ensure harmonization of quality standards between Forest and vendors,
- Assessed and approved change controls, performed on-site batch record audits of contractors, investigations for customer complaints, manufacturing incidents and ensuring that proper root causes were identified and CAPAs were implemented,
- Revised and implemented Corporate Procedures for finished drug products.

Sharp Corporation **2003 - 2005**

QA Manager

- Managed 1 QA Supervisor, 22 QA Inspectors, 3 Batch Record Reviewers, and 1 QA Associate and oversaw the daily operation of QA personnel to ensure quality was met during the packaging process and release of oral solid dosage, liquids, and powder product.

Additional Experience

Schering-Plough	**Document Systems Analyst**
United States Marine Corp.	**Captain, Motor Transport Officer**
Union County College	**Certificate Six Sigma Black/Green Belt**