Former Consumer Safety Officer

AREAS OF EXPERTISE

- **Medical device QS regulation and related regulation (e.g., Part 803, Part 806, Part 821) audits**
- **Remediation of regulatory deficiencies and assisting in responses to FDA**
- **Pharmaceutical cGMP training in specific dosage forms and APIs**
- **Medical device QS regulation training**
- **Pharmaceutical cGMP audits, including pre-approval inspection preparation**
- **Technical writing help with procedures, policies and reports**
- **Gap analysis for medical device, pharmaceutical, and combination product procedures**
- **ISO 13485**

INTRODUCTION

Consultant has more than 38 years of experience in the pharmaceutical, biological, and medical device industries. Conducted cGMP and QS regulation inspections and audits as an FDA Investigator, pharmaceutical company employee, and consultant domestically and internationally. Served as FDA district medical device specialist and third-party performance auditor. Performed pharmaceutical cGMP training for government and academic groups. Knowledge and experience with a variety of pharmaceutical, biological, medical device, and combination product technologies, and has strong organizational, teamwork, and technical writing skills.

WORK EXPERIENCE

01/2009 – Present
Industry Consultant
Duties:

- Conducted pharmaceutical/biologic cGMP audits of two sterile vaccine manufacturers.
- Conducted mock pre-approval inspections for medical device QS regulation and pharmaceutical camps for a combination product manufacturer. Conducted follow-up remediation for deficiencies.
- Conducted a QS regulation audit at a contract ethylene oxide sterilizer.
- Performed pharmaceutical cGMP training for engineering students at the University of Kentucky, and for Turkish government personnel.
- Assisted two medical device firms with FDA inspections.
- Conducted mock pre-approval inspections and follow-up remediation for three pharmaceutical companies.
- Conducted mock QSIT inspections of four medical device manufacturers and one device sponsor.
- Conducted full quality system audits of 10 medical device manufacturers, to include QS regulation and ISO 13485 requirements.
- Conducted a cGMP audit and follow-up gap analysis, and assisted in writing standard operating procedures for a sterile compounding pharmacy.
- Assisted a start-up medical device company in understanding QS regulation and ISO 13485 requirements, and with writing standard operating procedures.

- Assisted combination product companies with procedural gap analysis, writing corporate quality policies, and writing quality manuals.
- Conducted internal monthly quality system audits for a medical device manufacturer over a one-year period.
- Conducted cGMP and USP <797> audits for Phase 2 sterile clinical supplies at four compounding pharmacy manufacturers on behalf of a pharmaceutical sponsor.
- Conducted cGMP audits at two API manufacturers and two film coated tablet drug product manufacturers on behalf of a pharmaceutical sponsor.
- Served as quality assurance/cGMP representative for a pharmaceutical sponsor conducting Phase 2 clinical trials. Duties included revision of SOPs, review/approval of contractor quality agreements, review/approval of master and batch production and control records, and cGMP auditing.

05/1994 – 01/2009
09/1976 – 01/1988
U.S. Food and Drug Administration, Detroit, MI, Grand Rapids, MI, & Kalamazoo, MI
Customer Safety Officer
Duties:
- Conducted inspections and investigations of medical device, pharmaceutical, bioresearch, biologics, and food facilities in Michigan and Indiana to enforce the FD&C Act. Included were inspections of all main types of technologies and products.
- Conducted international medical device and pharmaceutical inspections in 18 countries.
- Conducted bioresearch inspections to include IRBs, clinical investigators, sponsor-monitors, and non-clinical laboratories.
- Certified as a level II medical device investigator beginning in 1999. Involved as a performance auditor for FDA and for the third party Accredited Person program. Selected as a district medical device specialist in October 2007.

01/1998 – 05/1994
The Upjohn Company, Kalamazoo, MI
Senior GMP Compliance Specialist
Duties:
- Performed domestic and off-shore cGMP audits of pharmaceutical and device operations for all dosage forms, APIs, biologics, clinical supplies, and sterile medical devices.
- Investigated product quality problems and worked as a team member for resolution.
- Helped coordinate regulatory agency inspections, including NDA pre-approvals.
- Worked with multi-function project teams for facility renovations, equipment upgrades, PAI preparations, and other projects, and consulted on cGMP issues. Provided written technical reports and audit reports to management.

01/1971 – 01/1974
U.S. Army
Duties:
- Served in the Medical Corps, Veterinary Department, Mort MacArthur, CA from August 1971 to January 1974. Performed quality control inspections in commercial firms for food destined for military personnel.

EDUCATION

09/1974 – 05/1976
University of Wisconsin – Platteville, Wisconsin
Masters – Teaching Program with science concentration.

09/1966 – 06/1970
Bachelors – Science Degree
Major: Biology, Minor: Chemistry

CERTIFICATIONS

- Biomedical Auditor, ASQ, 2015

ADDITIONAL TRAINING

- "Lead Assessor Certification" – (ISO 9000 Principles and General Auditing Techniques) – Stat-A-Matrix Institute, Chicago, IL, June 22-26, 1992.
- "Basic Industrial Course in the Preparation of Parenteral Medications" – University of Tennessee, Memphis, TN, June 10-15, 1990.
- Various medical device and pharmaceutical training courses sponsored by FDA, 1994 - 2006. This includes Industrial Sterilization, Medical Device Quality System Inspection Technique (QSIT), Computer Aided Inspections, Medical Device Process Validation, Medical Device Design Controls, Medical Device Performance Auditor, and Medical Device Quality Control.

SKILS AND STRENGTHS

- Knowledge of device Quality System, pharmaceutical, and biologic GMP regulations and principles. From 1994 through 2008 I specialized in medical device QS regulation and pharmaceutical cGMP inspections. Inspections have included evaluation of all systems and controls, including management/quality, design, corrective and preventive action, facilities/equipment, production/process, sterilization, materials, laboratory, and packaging/labeling.
- I have performed 12 cGMP inspections or audits of aseptic processing operations, at 8 manufacturing firms. One of these manufacturers processed injectable oncology products (cytarabine and irinotecan). Other facilities inspected or audited included special controls for containment of vaccine agents or potent drug ingredients. Two aseptic vaccine facilities were audited for compliance with cGMP requirements in June 2010 and November 2011, respectively.
- I was a member of the FDA foreign inspection cadre and made six trips to perform medical device inspections and five trips for pharmaceutical inspections in a total of eighteen countries. I am familiar with a variety of medical device and pharmaceutical technologies. Several inspections have uncovered significant deficiencies from the QS regulation, pharmaceutical cGMP, or biological cGMP requirements. Inspections required documenting evidence for regulatory action recommendations. I have also investigated medical device and pharmaceutical consumer and industry complaints involving deaths, injuries, defects, and other issues.
- Knowledge of bioresearch monitoring (IRB, clinical investigator, sponsor-monitor, non-clinical laboratory) regulations and principles.
- Ability to work as a team member and team leader. While with FDA I participated on several team compliance inspections for medical device, pharmaceutical, and biological firms. I served as the

district team leader on four occasions, with teams that included CDRH, CDER, or CBER personnel. I have made pharmaceutical and medical device training presentations for FDA personnel. While with the pharmaceutical industry I interacted with multiple department personnel as a team member.

AWARDS

- FDA Outstanding Achievement Award – June 2000
- Outstanding Federal Employee Award, Detroit Federal Executive Board – May 2003
- District Award for leadership role for inspection team in compliance inspection of a major medical device manufacturer – July 2006
- District Award for work performed related to an injunction action against a prescription drug manufacturer – September 1999