Former FDA Medical Device Specialist; Former FDA Consumer Safety Officer; QSR Specialist

AREAS OF EXPERTISE

- **A member of the FDA Design Control Team that provided training to FDA field personnel and industry representatives regarding Design Control Regulations of the QSR**
- **Expert knowledge of FDA device registration and listing requirements**
- **Vast knowledge of FDA policies, procedures and actions, relating to medical devices**
- **Conducted FDA inspections as part of the FDA international Inspectional cadre, ensuring that imported medical devices were in compliance with FDA regulations**
- **Conducted mock FDA audits to assist regulated firms with QSR and other FDA laws and regulations**
- **Member of FDA training cadre for medical devices, providing instructions and guidance to FDA personnel**

INTRODUCTION

Consultant has 31 years of experience with the U.S. Food and Drug Administration (FDA) as a field investigator (Consumer Safety Officer, CSO) in the Detroit District Office. Consultant was the District Medical Device Specialist for 11 years.

Consultant was the District Medical Device Specialist, conducting the most complex medical device inspections, evaluating the manufacturing facility's compliance with the Quality System Regulation (QSR) and other laws and regulations. Consultant also conducted evaluations of the manufacturing sections of PreMarket and 510(k) submissions for firms within the District boundaries. Consultant also conducted special investigations, complaint follow-ups and other aspects of medical device regulation.

Currently, Consultant acts as regulatory consultant, providing expertise regarding the FDA Quality System Regulation, International Standards for Medical Devices and regulatory mediation. Consultant conducts mock FDA QSIT audits, training for the FDA Regulations and works with clients that may have potential for FDA regulatory actions.

WORK EXPERIENCE

2007 –Present
Industry Consultant

10/1974 – 07/2003
US Food & Drug Administration, Detroit, MI
Medical Device Specialist
Duties:

- Conducted inspections of risk- based Class II and Class III medical devices nationally and internationally. Also conducted evaluations of 510(k) and PMA submissions.
- Attained Certified Level 2 Investigator status for the Medical Device Program.
- Selected as a Performance Auditor for the Medical Device Investigator Certification Program – evaluated other investigators seeking certification.

- Trainer, FDA Medical Device courses.
- Trainer, AAMI QSR Compliance for Quality Systems courses.
- Member FDA Design Control Team- conducted workshops for FDA personnel and industry representatives regarding design control regulations.
- Team leader FDA Detroit District Medical Device Team-established work priorities, reviewed peer reports, and delegated work assignments.

Consumer Safety Officer

Duties:

- Conducted scheduled inspections and investigations of majority of commodities regulated by the Food & Drug Administration
- Received promotion and award for acting as lead investigator for breast implant investigation at Dow-Corning, Hemlock, MI.

EDUCATION

Michigan State University, E. Lansing, MI
Bachelor in Science: Zoology

ADDITIONAL TRAINING

- Industrial Sterilization of Drugs and Medical Devices
- Process Validation
- Computer Software Validation
- Plastics and Latex Technology
- Advanced Pharmaceuticals and Pharmacology

REGULATORY AND QUALITY EXPERTISE

- Medical Devices: Electro-mechanical, orthopedic, latex, textile, durable, single use disposable devices, reprocessed, implantable, sterile, combination products
- Quality System Regulation (QSR), FDA inspectional procedures, FDA 483, Inspectional Observations, Warning Letter correspondence. Quality Assurance, Quality management, Quality System Establishment and Evaluation, Consulting

TECHNICAL EXPERTISE

- Process and Production Control, Corrective and Preventive Actions (CAPA), Special Investigations, FDA inspections, mock FDA audits
- Clinical Investigation Evaluation Clinical investigator inspections, Sponsor/Monitor activities, Institutional Review Board (IRB) evaluation
- Conducted approximately 550 inspections. This includes FDA inspections and special investigations, mock FDA audits and contract supply audits. The product ranges from Class l to Class lll medical devices, PreMarket Applications (PMA's) and 510(k) submissions, component and contract manufacturing operations