Former FDA Investigator

AREAS OF EXPERTISE

- **US FDA Investigator**
- **Pre-Approval Inspections**
- **cGMP Compliance/Audit**
- **cGMP and Documentation Training**
- **Electronic Records / Electronic Signatures**
- **Pharmaceutical and Medical Device Inspections**
- **Quality System Development & Implementation**
- **21 CFR Part 11**

INTRODUCTION

Consultant has more than 37 years of experience as a US Food & Drug Administration Investigator. His FDA experience includes device manufacturing, repacking, and compliance. He has broad experience in blood banking, plasma operations, clinical investigators, food, dietary supplements, and cosmetic inspections. He specializes in Medical Device Quality System Inspections, Drug cGMP, and clinical investigator inspections.

WORK EXPERIENCE

1999 – Present
Industry Consultant
Duties:

- Training of Quality Assurance and Quality Control Laboratory Personnel – GMP Training, FDA Inspectional Procedures
- Pre-approval Inspections, Due-diligence Audits, Validity Assessments (Data Integrity), manufacturing Operations and Quality Control Laboratory Auditing
- Audits of Medical Device and In-vitro Diagnostic Manufacturing Facilities
- Simulated FDA Pre/post-approval Inspections
- cGMP Inspections and development of responses to FDA Notices of Observations and Warning Letters
- Medical device and pharmaceutical industries consultant
- Performed medical device QSR and ISO audits
- Conducted training / prepared pharmaceutical and medical device facilities for FDA inspections
- Served as Acting Director of Quality Assurance at a medical device firm; reviewed and approved corrective and preventive action reports, document control records, non-conformance reports, laboratory investigations, failure analysis reports, and customer complaints
- Conducted assessments of client studies, procedures and programs to determine compliance
- Assisted with development and implementation of quality systems for pharmaceutical and medical device companies to comply with QSR and ISO requirements
- Developed and implemented corrective action plans to address deficiencies
- Conducted GMP audits and mock FDA inspections

- Conducted GMP, GLP, and mock FDA inspection audits of A.P.I. manufacturers, Drug manufacturers, Device manufacturers, laser, infant formula (thermally processed and aseptically filled) manufacturers, and glucose monitoring devices
- Conducted "FDA-interface" type training sessions
- Performed due diligence audits of contract Drug and A.P.I. manufacturing sites; reviewed Quality Systems processes: product/process validation, vendor approval / qualification, batch record review, and operating procedures
- Worked at IVD manufacturer under Consent Decree; involved in Quality Systems development and product and process validations using a risk-based approach
- Conducted "FDA-interface" type training sessions
- Performed due diligence audits of contract manufacturing sites for coronary stents manufacturer; reviewed Quality Systems processes: product/process validation, vendor approval / qualification, design control, batch record review, and operating procedures

1962 – 1999
FDA

Senior Investigator
District and Regional Health Fraud Coordinator
Investigator
Resident-In-Charge

Duties:

- Conducted regulatory investigations of medical devices, compressed medical gases, clinical research investigators, GLPs, institutional review boards, dietary supplement manufacturers, source plasma centers, cosmetic manufacturers, and food processors
- As member of Foreign Cadre, conducted international investigations of medical device manufacturers who produced endoscopes ultrasound machines, anesthesia trolleys, cochlear ear implants, pacemaker leads, spinal implants, syringes, blood collection sets, drug sets, dialysis filtration systems, and respiratory monitoring systems
- Conducted plant inspections, sample collections, and special investigations; areas of specialization included acidified and low acid food processing, drug repackaging, and veterinary drug manufacturing
- Prepared work plan and schedules of inspections of numerous FDA-regulated firms engaged in acidified and low acid food processing, medical devices, bulk pharmaceuticals, GLPs, clinical investigations, plasma collection, blood collection / processing, veterinary drugs, and fish processors.
- Conducted plant inspections, sample collections and special investigations including for acidified and low acid food processors, dairy processing plants, and fish processors.

PRESENTATIONS

04/2001
AVIRON
Logistics of an FDA inspection

03/2002
CLEAN ROOM EAST
FDA inspections made easy

06/2004
MDM EAST JUNE
QSR applied to product development

05/2001
MDM EAST
FDA inspections made easy

08/2002
MDM MINNEAPOLIS
QSR applied to product development

RECOGNITION AND AWARDS:

- Numerous "Outstanding" Performance Ratings
- Commissioner's Commendable Service Award for work performance and training employees
- Many "Group Performance Awards"
- Cash Awards for "Individual Accomplishments"

TRAINING AND EDUCATION:

- Basic Bacteriology Course
- Basic Drug Manufacturing Course
- Evidence Development Course
- Basic Food and Drug Law Course
- Low Acid and Acidified Foods Course
- Pharmacology and Experimental Therapeutic Course
- Basic Blood Banking Course
- Medical Device Basic Course
- Updated Food and Drug Law and Evidence Development Course
- The Reid Technique of Specialized Interviews Course
- Bachelor's Degree in Fish & Wildlife Management Iowa State University Ames, IA