FDA Field Investigator, GS-13 & GS-12 Device Specialist

AREAS OF EXPERTISE

- **Lead investigator, medical device and drug seizure recommendation, 2002**
- **Lead investigator, medical device recall and seizure recommendation, 2002**
- **FDA Class II Certified Medical Device Auditor**
- **Member of the Quality System Inspection Technique (QSIT) Reengineering Team**
- **Trained European Union auditors in Denmark on conducting FDA QSIT inspections**
- **ISO, Lead Auditor Certified**

INTRODUCTION

As a regulatory compliance consultant, Consultant performs quality assurance audits for medical device companies, Good Clinical Practice (GCP) audits Good Laboratory Practice (GLP) audit, Principal Investigator audits, IRB audits and Sponsor audits, dietary supplement and pharmaceutical audits. Consultant conducts training, create and implement quality systems and clinical investigator systems and provides guidance on quality, regulatory and compliance issues throughout the world. This includes companies that have received a Warning Letter from the FDA, are currently under an FDA injunction or have had product seized by the FDA.

Assist Medical Device companies with Gap Analysis including GMP training, SOP preparation, FDA Readiness Training, FDA Compliance Training, Adverse Event Reporting, GMP regulation interpretation in addition to other services.

Assist Principal Investigators, IRBs and Sponsors with GCP and GLP mock FDA audits to ensure clinical trials are conducted per FDA regulations and ICH Guidance. Perform mock FDA audits in all areas of clinical trials, provide training to regulations and FDA inspection preparation.

WORK EXPERIENCE

06/2003 – Present
Industry Consultant

1996 – 2003
FDA, Denver District Office, Office of Regulatory Affairs, Denver, Colorado
FDA Field Investigator, GS-13 Device Specialist
Duties:

- As a GS-13 Investigator/Medical Device Specialist in the Denver District Office, Consultant conducted quality assurance audits to assure compliance with medical device, clinical investigator, sponsor, IRB, pharmaceutical, dietary supplement and food regulations.
- Member of the Quality System Inspection Technique (QSIT) Reengineering Team. Assisted in creating QSIT Training CD-ROM and QSIT CD Exam. Received Vice President Gore's Government Hammer Award.

- Assisted in developing QSIT Training for FDA managers and compliance officers. Was a presenter on the 7/00 LIVE video downlink that trained FDA managers and compliance officers nationwide.
- 40% of workload focused on clinical investigator, IRB, sponsor, GCP and GLP audits. Performed these audit both domestically and internationally.
- Member of the Medical Device EIR Workgroup brought together to harmonize FDA's inspectional reports with the Mutual Recognition Agreement (MRA).
- Trained European Union auditors in Denmark on conducting FDA QSIT inspections. Training was in conjunction with MRA global harmonization task force.
- Provided classroom training to FDA, Clinical Principal Investigators, IRBs, Sponsors, Pharmaceutical and medical device industry and trade groups, Regulatory Affairs Professional Society (RAPS), Colorado Medical Device Association (CMDA), and the American Society for Quality (ASQ) on QSIT inspection techniques and quality system regulation.
- Provided classroom training as an American Association of Medical Instrumentation (AAMI) instructor to the medical device industry on the quality system regulation.
- Performed complex inspections of medical device, clinical investigator, IRB, sponsor, dietary supplement, manufacturers and distributors both domestically and internationally (Japan, France, Italy, Switzerland, Austria, Sweden, Denmark, England and Canada). While with the FDA Denver District I was involved with inspecting some of the nation's largest pharmaceutical and medical device manufacturers.
- Lead investigator, medical device and drug seizure recommendation, 2002
- Lead investigator, medical device recall and seizure recommendation, 2002
- FDA Class II Certified Medical Device Auditor.
- Trained State of Colorado, Department of Health and Environment inspectors on conducting clinical investigator, IRB, sponsor, pharmaceutical and medical device inspections in the Denver area.
- Provided technical assistance within the Denver District and outside the district to state, local and other federal agencies.
- Denver District Medical Device Program Monitor for the Medical Device Pilot (pre-announcing inspections and annotating FDA-483's).
- Acting Supervisory Investigator (Manager) for various supervisors including a three (3) month Supervisory Detail.
- Open line of communication with Denver District Compliance Branch.

1990 – 1996
FDA, Seattle District Office, Office of Regulatory Affairs, Bothell, Washington
FDA Field Investigator, GS-12 Device Specialist
Duties:

- As a GS-12 Medical Device Specialist in the Seattle District Office, Consultant conducted inspections to assure compliance with medical device, clinical investigator, IRB, sponsor, GCP and GCP, pharmaceutical, dietary supplement, biologic and food regulations. My focus included auditing companies domestically and internationally. Some of the activities I was involved in as a field investigator included:
- Lead investigator for medical device inspection in 1994 that resulted in a consent decree of permanent injunction.
- 30% workload focused on clinical investigator, sponsor, IRB, GCG, GLP inspections.
- Lead investigator Pharmaceutical inspection 1993 that resulted in a recommendation for injunction. Litigation during the case included my deposition to testify to the facts of the case.
- 75% of all inspections I conducted resulted in the issuance of a Warning Letter.
- Provided classroom training to new hire FDA employees on pharmaceutical and medical device regulations.

- Performed complex inspections of pharmaceutical and medical device manufacturers and distributors both domestically and internationally. Was involved with inspecting some of the nation's largest pharmaceutical and medical device manufacturers.
- Provided technical assistance within the Seattle District and outside the district to state, local and other federal agencies.
- Seattle District Medical Device Registration Monitor.
- Acting Supervisory Investigator in the medical device program area approximately four (4) weeks each calendar year.
- Provided classroom and field training to Seattle District Laboratory personnel on how to conduct medical device inspections.

EDUCATION

Colorado State University, Fort Collins, Colorado
Bachelor – Consumer Economics

ADDITIONAL TRAINING

Numerous FDA courses including: law, compliance, medical device, bioresearch monitoring, clinical investigator, IRB, sponsor, GCP, GLP, pharmaceutical, process validation, computer system validation, sterilization, good manufacturing practices, quality system regulation, design controls, QSIT, statistics and risk analysis, dietary supplement.

06/2009
ISO, Lead Auditor – Certified Lead Auditor

MDD 93 42 EEC – Labeling Review, Product Registration Post Market Surveillance, Product Classification, Vigilance, Language Requirements, General Guidance Directives.

PROFESSIONAL AFFILIATIONS AND AWARDS

- Regulatory Affairs Professional Society
- American Society for Quality
- Numerous FDA commendations and awards including Vice President Gore's Hammer Award

PRESENTATIONS (Since January 1999 only)

- FDA Readiness Training – classroom training various companies 2005-2015
- Clinical Investigator, Sponsor, IRB – face to face and classroom training 2006-2015
- Founder Rocky Mountain Dietary Supplement Forum, Boulder, CO 2012 and 2013
- Compliance Online, Managing Your FDA Inspection Training 2012, 2013 and 2015 (Classroom Training)
- Medical Device GMP Training 2010-2015 (routine)
- Dietary Supplement GMP Training 2010-2015 (routine)
- FDA Law and Inspections, presented to private firm 2010 and 2014
- FDA inspections, UNPA, October 2009

- RAPS, FDA Inspections, Lakewood, CO, August 2009
- Managing your FDA Inspection, UNPA, September 2008
- FDA Compliance Training, private firm May 2008
- FDA Inspections, private firm, May 2008
- Adverse Event Reporting Training, 2007
- Dietary Supplement Compliance Training 2006, 2007
- Dietary Supplement GMP Training 2004, 2005, 2007
- Dietary Supplement Preparedness, 2005, 2006, 2007
- FDA Readiness Training, Nationwide, 2006
- Medical Device Company Compliance Training, Nationwide 2006
- Medical Device and Pharmaceutical Training, Italy, 2005
- Pharmaceutical Manufacturer, Denver, Colorado, Comprehensive GMP Training, 2005
- OTC Drug Manufacturer, Highland Ranch, Colorado, GMP and Compliance Training, 2003, 2004, 2006
- Pharmaceutical BioScience, Boulder, Colorado GMP Training, April 2003
- Medical Device Company, Stockholm, Sweden, GMP Training, December 2004
- Medical Device Company, Indianapolis, IN, FDA Readiness Training, November 2004
- Medical Device Company, Houston, TX, GMP/QSIT Presentation, July 2004
- Dietary Supplement Company, St. George, Utah, New Dietary Supplement Regulations, May 2004
- Dietary Supplement Company, Farmington, Utah, New Dietary Supplement Regulations, April 2004
- Dietary Supplement Company, Provo, Utah, New Dietary Supplement Regulations, March 2004
- Pharmaceutical Company, Chicago, IL, GMP Presentation, March 2004
- Medical Device Company, Denver, CO, Process Validation Training Course, January 2004
- Pharmaceutical Company, Seattle, WA, Process Validation Presentation, January 2004
- Medical Device Company, Billings, MT, Process Validation Presentation, November 2003
- Medical Device Company, Vancouver BC, FDA Readiness Training, August 2003
- Medical Device Company, Salt Lake City Utah, FDA Readiness Training, June 2003
- Colorado Department of Health and Environment, Conducting FDA Inspections, Denver, Colorado, March 2003
- FDA New Hire Training – Medical Devices, Denver, Colorado, April 2002
- QSIT Compliance Officer and Manager Training, LIVE Video Downlink, Rockville, Maryland, July 2000
- AAMI Design Control Requirements and Industry Practice, Denver, Colorado, May 2000
- ASQ FDA Update Meeting, FDA and Industry Updates, Denver, Colorado, April 2000
- Regulatory Affairs Professionals Society, New FDA Policies, Denver, Colorado July 1999
- Regulatory Affairs Professional Society, What is QSIT, Denver, Colorado, May 1999
- Colorado Medical Device Association, QSIT and the FDA, Boulder, Colorado, April 1999
- International Society of Pharmaceutical Engineers, QSIT and the Quality System Regulation, Denver, Colorado, February 1999