Former FDA Investigator; Clinical, Quality and Regulatory Manager

AREAS OF EXPERTISE

- **Strong knowledge of regulations, requirements and practices necessary for developing, manufacturing and marketing medical devices**
- **Knowledge of medical device sterilization methods (steam, gamma, e-beam, EtO, gas plasma)**
- **Proven ability to remediate quality systems records to bring customers into compliance**
- **Exceptional written/verbal communication skills**
- **Skilled at translating regulatory requirements into successful policies and procedures**
- **Detailed and thorough quality systems auditor**
- **Knowledge of process and equipment validation**
- **Experienced and effective trainer.**
- **Strong computer skills with experience on multiple systems**

INTRODUCTION

Manager of regulatory and clinical affairs with over eighteen years' experience within the medical device industry. He specializes in Mock FDA Audits, FDA audit readiness training, as well as quality system auditing. Furthermore, he has a great deal of experience with supplier audits, supplier qualifications, and remediation of quality problems.

WORK EXPERIENCE

02/2007 – Present
Industry Consultant

- Regulatory consultant to the biotech and medical device industry.
- Contract auditor for mock FDA inspections, supplier audits and qualification, facility qualification, and constructive review of quality systems to bring customers into compliance.
- Remediation of quality systems in preparation for FDA inspection. Projects include CAPA systems, complaint and MDR systems, corrections and removals, nonconforming product management, design controls, and validation records remediation.
- Instructor in quality systems for medical device manufacturers, quality auditing, and preparing for FDA and ISO audits.

01/2006 – 02/2007
Manager, Regulatory and Clinical Affairs

- Created and maintained entire quality system for a start-up medical device company
- Worked as part of the clinical team: designed clinical trial, performed safety analysis of prototype device, obtained IRB approval, recruited experimental subjects, and collected, analyzed and reported clinical trial data for 50+ experimental subjects.

05/2003 – 09/2005
Industry Consultant
Regulatory Affairs Manager

- Managed regulatory contacts with US FDA, US Fish and Wildlife Service, USDA, California Food and Drug Branch, Health Canada, EU Notified Bodies, and other US and foreign governmental agencies.
- Successfully audited and licensed by California Food and Drug Branch after facility move.
- Interviewed and selected ISO Registrar for company. Successfully audited and subsequently certified to ISO 13485-1996 and Canadian Medical Devices Regulations. Successfully re-audited and transitioned to ISO 13485-2003.
- Responsible for review and sign-off on all SOPs, Quality Manual, label proofs, house specifications, training files, validation protocols, and other quality documents.
- Managed Validation Department: one employee directly reporting, up to 20 additional employees assigned as needed.
- Created or revised standard operating procedures: internal audits, supplier audits, design controls, risk management, corrective and preventive actions, validations, management review, medical device reporting, etc.
- Responsible for all internal and supplier audit functions. Trained and managed team of 10 auditors from multiple disciplines. Wrote and/or reviewed all internal and supplier audit reports. Coordinated corrective actions for audit findings.
- Conducted companywide training sessions on quality, regulatory, and management topics.
- Conducted targeted training sessions for individual departments, new hires, management, etc.

09/1997 – 05/2003
US Food and Drug Administration
Investigator

- Conducted inspections of medical device manufacturers for adherence to Quality Systems Regulations. Documented inspectional findings in written reports.
- Investigated complaints, product recalls and provided customer service to regulated industry.
- Coordinated all premarket approval (PMA) and 510(k) inspection assignments for Los Angeles District for three years.
- Selected as one of twelve FDA personnel nationwide to pilot test Quality System Inspection Technique (QSIT), since adopted as the FDA standard.
- Selected as one of six FDA personnel nationwide to pilot test TurboEIR software through three versions of software development.
- Chosen as only FDA Investigator from Pacific Region to act as National Trainer in TurboEIR roll out.
- Member of International Inspection Cadre.
- Trained new hire employees in medical device inspection techniques.

CONSULTING EXPERIENCE
Consulting experience. Note: For purposes of client confidentiality, the names of clients have not been revealed. Only large clients or long term projects are listed.

- September 2012 to June 2013. Worked as a contractor at the headquarters of a multinational orthopedic device manufacturer for CAPA remediation and FDA audit preparation.
- September 2012 to June 2013. Worked as a contractor at the headquarters of a multinational orthopedic device manufacturer for CAPA remediation and FDA audit preparation.
- February 2012 to September 2012. Conducted corporate compliance audits of a multinational medical device manufacturer at multiple manufacturing, distribution and warehousing sites worldwide.

- June 2011 to November 2011. In the wake of an FDA audit where a multinational medical device manufacturer had been cited for failing to file MDR reports, worked as part of a team on a large scale MDR remediation project. Filed upwards of 2,500 MDRs that had previously been determined to be delinquent.
- December 2010 to May 2011. Worked as a contractor fulfilling the role of a Quality Director within a multinational medical device manufacturer. Reviewed complaints and adverse event reports to ensure that they were completed correctly. Approved complaints for closure.
- June 2010 to November 2010. In the wake of an FDA audit, worked as part of a team of consultants at a cardiovascular device manufacturer to assess the firm's complaint handling system, identify deficiencies in the complaint handling process and individual complaint records, review service records to identify complaint issues that were not recorded as complaints, draft procedures to correct the deficiencies in the process, advised firm's personnel in correcting the deficiencies in the complaint and service records, provided training to the employees, and worked on a project to reduce the number of open complaint files to manageable levels.
- March 2010 to Present. Working as a contractor fulfilling the role of part-time Quality Manager for an OEM medical device manufacturer. Handled entire quality system including CAPA, complaints, non-conforming product, change control, and acting as the site Management Representative. Updated entire quality system to improve ease of use. Have been successfully audited by the OEM's clients.
- January 2009 to December 2009. In the wake of an FDA audit and facility shut down of a major medical device manufacturer, reviewed the entire quality system and communications with the FDA to determine areas of weakness. Advised facility management on the remediation of the quality system. Conducted mock audits and spot checks of the efficacy of the remediated quality system. Conducted numerous training sessions and mock audit role playing exercises to prepare subject matter experts and site personnel for the impending FDA re-audit of the facility.
- September 2008 to December 2008. Worked as part of a team of consultants at a sterilization systems manufacturer to review over 37,000 complaint files for unreported MDR events. Performed all data management, analysis, and reporting for this project.
- July 2008, September 2009 and December 2009. Conducted quality systems audits at four separate facilities of a multinational medical device manufacturer.
- March 2008 to Present. Conducted periodic mock FDA audits of manufacturing facilities in the US, Europe and Asia for an orthopedics, trauma, dental implant, and sports medicine device manufacturer.
- November 2007 to March 2008. Headed team of consultants tasked with CAPA system remediation at one facility of a multinational medical device manufacturer. Conducted training sessions and mock audits at this same facility to prepare subject matter experts and site personnel for an impending FDA audit.
- July 2007 to October 2007. Worked as part of a team of consultants to audit medical device manufacturing facilities for a multinational medical device manufacturer. Worked in the management office of this consulting group to edit, polish and publish audit reports to ensure consistency in the finished product. Performed data analysis of audit findings in support of project reports to corporate client.

EDUCATION

May 1994
University of California, San Diego, La Jolla, California
Bachelor of Science: Bioengineering; Minor in Writing

TRAINING COURSES ATTENDED

- AQS "RABQSA Certified Lead Auditor (ISO 13485:2003) – 36-hour training course" (December 2012)
- AQS "Canadian Medical Device Regulation (CMDR) overview" (December 2012)
- AQS "EU Medical Device Directive (MDD) overview" (December 2012)
- PTi International "Conducting Internal Audits" (July 2005)
- Noblitt & Rueland "Auditing Quality Systems: FDA GMP/QSR & ISO 13485:2003" (July 2004)
- San Diego Regulatory Affairs Network (SDRAN) "What you need to know about new medical device regulations" (October 2003)
- FDA "Conducting International Inspections" (June 2002)
- FDA "Verbal Judo" (April 2002)
- FDA "Industrial Sterilization for Drugs and Medical Devices" (May 2000)
- FDA "Process Validation: Concepts and Applications" (February 2000)
- FDA "Turbo EIR Train the Trainer" (1999)
- FDA "Quality Systems Inspection Technique (QSIT)" (1999)
- AAMI "Design Control Requirements & Industry Practice" (November 1998)
- FDA "Basic Medical Device" (June 1999)
- FDA "Basic Investigator / Food and Drug Law" (August 1998)
- FDA "The FDA Review Process for New Product Applications" (July 1998)
- FDA "New Hire Training (Food, Drugs, Devices, Biologics, Veterinary Medicine, Import Operations) (1997 to 1998)