FDA Supervisory Investigator; FDA Compliance Officer

AREAS OF EXPERTISE

- **Medical Device Expert (21 years with FDA, 18 years in the device industry)**
- **Planning, implementing, and managing Quality Systems**
- **Regulatory Affairs Certified by the Regulatory Affairs Professionals Society (RAPS)**
- **Internal Medical Device Quality System Requirements**
- **Establishing Design Controls**
- **Establishing Quality Indicators for Management Review regulations**
- **Mock FDA pre-PMA Inspections**
- **Former Industry Representative, FDA Circulatory Systems Advisory Panel, FDA Center for Device and Radiological Health**
- **Training on FDA Requirements (QSR, IDF, IRB, Design Control)**
- **Clinical Protocol Development**
- **Mock FDA BIMO Audits**
- **Designing Clinical Studies**
- **Expert Witness for FDA Regulation of Medical Devices**
- **Webinar presenter on FDA Issues.**

INTRODUCTION:

Consultant has over 20 years of FDA experience encompassing virtually all of the FDA field positions. Consultant also has 18 years of industry experience as a mid-level manager and senior executive in clinical, regulatory, and quality in the medical device industry. Consultant has personally designed quality systems, prepared regulatory submissions (510(k), IDE and PMA) and managed 7 multi-center clinical trials for class 3 medical devices. From 1989-1993, Consultant was the Industry Representative on the FDA Circulatory Systems panel. Additionally, a seasoned educator/speaker with over 250 public presentations to audiences ranging from senior executives, physicians, technical personnel, other medical personnel, major media, and the general public. Holds regular Webinars on FDA Issues, and serves as an Expert Witness in the area of FDA regulation of medical devices.

WORK EXPERIENCE:

09/2011 – Present
Industry Consultant
Duties:

- Services offered to FDA regulated businesses include regulatory guidance on 510(k), IDE and PMA submissions. Also planning, creating, and auditing quality systems to USA and international standards. Creation of clinical plans including protocol development, case report form development, implementing and managing clinical trials. Also, assistance with Design Control to meet FDA requirements and representing clients in FDA meetings. A professional public speaker who can train persons on all aspects of FDA requirements, and practical and successful solutions to FDA problems.
- Consulting work completed writing several 510(k)s. I also created an FDA "Pre Sub" IDE meeting request accepted by FDA for an in person meeting to finalize requirements for an IDE for a class III device. Currently serving as the FDA liaison for a foreign client on a pending IDE for a class III device.

- Successfully lead a company in resolving quality issues raised in an FDA Warning Letter. The project involved a review of the issues raised in the Warning Letter and a complete review of the company's organizational structure and resource allocations for Quality Systems. The final report will include a recommendation on reorganization needed to meet FDA QSR requirements.
- Regularly perform audits of quality systems performed upon request to assess compliance multiple International regulatory systems.
- Worked with a major medical device firm to perform RA/QA/CA due diligence for potential acquisition. This required more than an FDA audit as it involved detailed analysis of all international regulatory actions, as well as interviewing all key officials and reporting on their background relative to the roles they played in the firm.
- Completed a 3-month assignment at a major U. S. based, class 3 medical device manufacturer. Operating under an FDA supervised Voluntary Injunction. Assessed remediation plans, and audited progress. Met regularly with company management to apprise them of progress and advise on additional compliance issues.
- Performed vendor audits for a major manufacturer of a combination product as mock FDA PAI inspections. This included audits of facilities in England and Germany

11/2000 – 09/2011
United States Food & Drug Administration

Supervisory Investigator, FDA Saint Louis Office, (04/2009 – 09/2011)
Duties:

- Directed all of the FDA operations at the Saint Louis, MO office for FDA. This included work planning for investigators, training of investigators, reviewing inspection and investigation reports for technical and legal requirements. Received an FDA commendation for development of newly hired investigators. Trained on Incident Command Systems (ICS) to serve as a leader in multiagency response to national incidents.

Acting Director of Compliance, FDA Los Angeles District, (09/2008 – 03/2009)
Duties:

- Directed the activities of 7 Compliance Officers. Monitored all on-going projects, and assured adequate resources to assure timely and accurate review of violative inspections, investigations, and sample collections. Negotiated with FDA Centers, Office of Chief Counsel, and Office of Enforcement regarding legal cases. Chaired meetings with regulated firms regarding requirements necessary to meet FDA legal requirements.

Director, Import Operations Branch, FDA Los Angeles District, (11/2003 – 09/2008)
Duties:

- Responsible for managing the operations of over 100 FDA employees located at offices in San Pedro, Carson, Long Beach, Ontario, and Los Angeles International Airport. It was the responsibility of these employees to review all FDA regulated products offered for entry and sale into the United States from foreign sources through the Ports of Long Beach and Los Angeles, and Ontario and Los Angeles International Airports. Successfully reorganized the branch to optimize personnel efficiencies, regularly chaired Import Broker meetings to gain feedback on their perception of FDA Import Operations. Received a special award from FDA's Office of Criminal Investigation for support the Import Branch provided for development of criminal cases. Acted as the FDA Los Angeles District Director, during the Director's absence.

Compliance Officer, FDA Los Angeles District, (06/2002 – 11/2003)

Duties:

- Perform technical reviews of inspection reports and sample analyses and determine the potential need for further regulatory action by FDA. Work assignments were almost exclusively complex medical device and pharmaceutical inspections and require both risk and legal assessments to formulate regulatory enforcement plans. In my first six months in this position, I authored six Warning Letters. The Warning Letters involved four pharmaceutical, and two medical device firms. Charges cited in the letters ranged from cGMP (QSR), to unapproved new drugs, failure to comply with an OTC Monograph, and failure to submit a 510(k) Premarket Notification. Also chaired meetings requested by companies to discuss their regulatory status. The meetings involved both Corporate and Private Counsel and senior executives for major device firms.

Investigator (Medical Device Specialist), FDA Los Angeles District, (11/2000 – 06/2002)

Duties:

- Served as a technical specialist in the Los Angeles District for all aspects of Medical Device regulatory compliance. Performed inspections of manufacturers of high-risk medical device firms for both GMP/QSR compliance, as well as sponsor/monitor and clinical investigator inspections for IDE, IRB, and Informed Consent compliance. Certified in the QSIT Approach, and certified for knowledge of the Quality System Regulation. In a 15-month period had two warning letters issued for QSIT inspections, and one recall initiated as a result of a QSIT inspection. Served as a trainer for less experienced investigators for QSIT inspections, Bio-Research Monitoring inspections, food sampling, and recall initiation and monitoring. Selected in January 2002, as the New Hire Training Coordinator for the Los Angeles District Domestic Investigations Branch.

INDUSTRY EXPERIENCE

03/1997 – 11/2000

Medical Device Development Corporation, Fullerton, CA

President/Founder

Duties:

- Founded this consulting firm to advise medical device manufacturers of management responsibility, organizational structures, processes, procedures, and requirements to take a medical device concept to the market. Clients were primarily start-up companies who engaged the services of the firm to provide strategic guidance in the areas of clinical studies, design development, quality systems development, product liability issues, and government approvals (both U.S. and international). Successfully developed strategic plans, and designed and implemented program planning. Services also included preparation of complex regulatory submissions (IDE, 510(k), PMA, Product Dossiers, Product Technical Files). When requested represented the client before FDA, Notified Bodies, Physicians, Investors, Corporate Partners, and Boards of Directors.

1995 – 1997

Cordis Webster, Inc., a Johnson & Johnson Company, Baldwin Park, CA 91706

Vice President, Regulatory Affairs, Clinical Research, and Quality Assurance

Duties:

- Joined the senior staff of the company shortly after the acquisition of Webster Laboratories by Cordis Corporation. Cordis Webster was a mature company manufacturing and developing Class 2 and 3 products for the cardiac electrophysiology market. Successfully reorganized the Clinical and regulatory departments, and developed systems to assure that all clinical studies and regulatory submissions efficiently met development schedules. Developed a strategic plan that allowed the company to amend a PMA to assure that FDA would approve it. Oversaw quality systems

development and management that led to a successful FDA PMA inspection and to ISO-9001 certification and CE Marking. Designed and implemented an innovative clinical protocol that was used to support a PMA product that was approved for a $100-million-dollar market.

1994 – 1995
Cardima Corporation, Fremont, CA 94538
Vice President, Regulatory Affairs, Clinical Research, and Quality Assurance
Duties:

- Key member of the senior staff of this early stage company developing products for the electrophysiology market. Utilizing team-building efforts, lead the company in a reassessment of priorities allowing for more focus and program accountability. Successfully negotiated with FDA over a complex IDE, to obtain an approval in 30 days. Set up all procedures and plans for a multi-center clinical study. Interacted with venture capital company representatives in efforts to secure additional financing. Lead the company's ISO/GMP program, and development of management systems to assure efficient operations in an environment of total employee involvement.

1993 – 1994
Cardiac Pathways Corporation, Sunnyvale, CA 94086
Vice President, Regulatory Affairs/Quality Assurance
Duties:

- As member of the senior management team of this start-up company, developed strategic programs in the development of an integrated system for diagnosis and treatment of cardiac arrhythmias. Directed the implementation of a clinical program to comply with U.S. FDA and European Union requirements. Responsible for overseeing R&D efforts to assure adequate documentation of design control. Prepared all regulatory submissions for both U.S. and international clinical evaluation and marketing approval of various cardiovascular catheters and diagnostic systems. Personally wrote one 510(k) and two IDE's.

1990 – 1993
Baxter Healthcare Corporation, Edwards LIS Division, Irvine, CA 92714
Vice President, Regulatory Affairs, Clinical Research, and Quality Assurance
Duties:

- Senior management position responsible for directing all of the quality assurance programs, clinical evaluation programs, and preparation of government regulatory submissions required for marketing medical devices in the United States and throughout the world. Edwards LIS Division was a fully integrated manufacturer of medical devices for vascular surgery and interventional cardiology. Directed implementation of a preproduction quality assurance program significantly improving the product development cycle and product reliability. Effectively reorganized Quality, Regulatory, and Clinical departments to facilitate a company-wide Total Quality Assurance approach. Established an International RA function and established plans for obtaining the "CE" mark in Europe. Certified by Baxter Healthcare Corporation as an examiner for the Baldrige (Baxter) Quality Award. Attended all FDA Circulatory Systems Advisory Panel meetings as the Industry Representative (four-year appointment by FDA 1989-1993)

1986 – 1990
Retroperfusion Systems, Inc., Costa Mesa, CA
Vice President, Regulatory Affairs, Clinical Research and Quality Assurance
Duties:

- Joined the start-up company team to develop an innovative electromechanical medical device to be utilized in interventional cardiology in the treatment of coronary artery disease. Interfaced with design engineers and physicians and oversaw pre-clinical research. Prepared the original

Investigational Device Exemption (IDE) application that was approved by FDA in 30 days from the first submission. Set up the clinical evaluation program, implemented and managed an international multicenter clinical evaluation and prepared the Premarket Approval Application (PMA) which was accepted by FDA for filing in 45 days from the original submission. Obtained international approvals for export. Organized and staffed the Quality Assurance department, established pre-production QA functions and created procedures to meet Good Manufacturing Practices (GMP) regulations.

1984 – 1986
Unitek Corporation, Subsidiary of Bristol-Myers Company, Monrovia, CA
Manager, Regulatory Affairs
Duties:

- Responsible for all of the regulatory requirements for this large fully integrated manufacturer of mechanical, electronic and chemical medical devices and pharmaceuticals. Managed the company employee safety program, the environmental health program, product complaint department and internal GMP Audit program. Prepared all regulatory submissions (510(k), IDE, Product Registrations). Member of the strategic planning committee for the company and a key member of all product development teams.

1982 – 1984
Heyer Schulte Division, American Hospital Supply Corporation, Goleta, CA
Manager, Regulatory and Clinical Affairs
Duties:

- Responsible for the regulatory and clinical programs for this medium sized manufacturer of implantable silicone devices utilized in neurology, cardiology, orthopedics, and plastic surgery. A member of the project teams that successfully developed and introduced to the market new class II and class III products. Managed the clinical evaluation of two class III devices and the preparation of all regulatory submissions (510(k), IDE, PMA). Performed internal GMP audits and was the liaison with corporate GMP and GLP auditors, and state and federal inspectors.

1972 – 1982
U. S. Food and Drug Administration (FDA), Los Angeles, CA
Small Business Representative, (07/1979 – 03/1982)
Duties:

- Established the first West Coast office in the Small Business Assistance program, and served as a representative of the CDRH, Division of Small Manufacturers Assistance. Provided regulatory guidance to developers of new medical devices. Performed on-site visits at manufacturing locations and advised on procedures necessary to meet GMP and IDE requirements. Met with Institutional Review Board representatives to advise them of regulatory requirements. Served as an FDA spokesperson at numerous government and industry meetings, presenting regulatory requirements for medical device manufacturers.

Consumer Affairs Officer, (09/1975 – 06/1979)
Duties:

- Directed the consumer, industry, and press information programs for the Los Angeles District.
- Prepared and implemented professional education programs for teachers, health educators, nurses, and physicians. Primary public spokesperson in Los Angeles for all FDA related matters.

Consumer Safety Officer (Investigator), (06/1972 – 08/1975)
Duties:

- Performed inspections and investigations of all product areas regulated by FDA. Specialties included sterilization and injury/illness investigations. Trained other investigators. Awarded the FDA Commendable Service Award in 1974 for outstanding performance as an investigator

EDUCATION

1982 – 1983
Golden Gate University, Santa Barbara, CA
MBA Program – One year completed

1970
California State University, Fullerton, CA
Bachelor of Arts – Biological Sciences

AWARDS

- FDA Commendable Service Award, 1974
- FDA Special Achievement Award, FDA Office of Criminal Investigations, 2009

CERTIFICATIONS

- Certified in Regulatory Affairs (RAC) by the Regulatory Affairs Professionals Society, 1991

APPOINTMENTS

08/2011 – Present
Member, Board of Directors, National Alliance on Medical Illness, Southern Illinois Division, a non-profit organization offering assistance to persons or families dealing with mental illness, and advocating on their behalf.

06/1989 – 06/1993
Industry Representative, FDA Circulatory Systems Advisory Panel, FDA Center for Devices and Radiological Health.

1994 – 2000
Instructor, Design Control Seminars, Noblitt & Rueland

PUBLICATIONS

- “What to Expect When You Are Inspected”, Endovascular Today Magazine, January 2004
- "Design Verification", Medical Devices and Diagnostics Industry. Vol. 16, No. 1, January, 1994
- "Practical Aspects of the Clinical Evaluation of a Medical Device", Medical Devices and Diagnostics Industry. Vol. 7, No. 4, April, 1985

PRESENTATIONS

- **"**Establishing Quality Indicators to Assure GMP/GCP Compliance" lecture, GMP-GCP 2012, GMP & GCP USA, Europe, Japan, Asia Pacific, OMICS Group Conferences, Philadelphia, PA December, 2012
- "Conducting Successful FDA Meetings" One Hour Webinar for Biopractice.com., May 2013
- "Using Quality Indicators for Successful FDA QSR Management Reviews" One Hour Webinar for Biopractice.com, September, 2014
- "Navigating FDA Import Requirements for all FDA Regulated Products" One Hour Webinar for Biopractice.com, July, 2015
- "Understanding the Mindset of an FDA Employee" One Hour Webinar for Biopractice.com, October, 2013

AFFILIATIONS

- 1982 – Present, Regulatory Affairs Professionals Society, Member
- 1985 – 1986, President, Western Section
- 1976 – Present, American Society for Quality, Member
- 2013 – Present FDA Alumni Association, Member