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INTRODUCTION:

Over 20 years of FDA experience encompassing virtually all of the FDA field positions. Also eighteen years of industry experience as a mid-level manager and senior executive in clinical, regulatory, and quality in the medical device industry. 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, 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 routinely serves as an Expert Witness in the area of FDA regulation of medical devices.

WORK EXPERIENCE:

One Way Consultants, LLC, September 2011 – Present

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. I am a professional public speaker who can train persons on all aspects of FDA requirements, and practical and successful solutions to FDA problems.

Completed writing 510(k) submissions for electronic devices utilizing laser energy.

I also had a project to assist a foreign firm in obtaining an FDA PMA for a class 3 implantable cardiovascular device. The first step in this process was to prepare an FDA "Pre Sub" IDE meeting request. The meeting request was accepted by FDA for an in-person meeting to finalize pre-clinical testing and the future clinical evaluation requirements for an IDE for the device. The meeting was held at CDRH with ODE and CDER staff, and at the meeting, I assisted the client. The FDA response was favorable and the next step is the preparation of the IDE and another meeting with FDA to discuss the final clinical trial design.

Completed a project to 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 included a recommendation on reorganization needed to meet FDA QSR requirements. In addition, the firm requested two additional audits to determine effectiveness of corrective actions. Recently met with the FDA District Office District Director with the firm to discuss corrective actions taken to resolve the letter. The meeting was successful in FDA saying they would close the Warning Letter.

I have performed audits of quality systems performed upon request to assess compliance multiple International regulatory systems. A matrix has been developed that covers FDA Quality System Regulation,

21 CFR Part 820; European Standards for Medical Device Sections, European Standard ISO 13485:2016 Medical Devices; Canadian rules Medical Devices Regulations SOR/98-282; and Japan's MHLW Ministerial Ordinance No. 169 Medical Device Manufacturing. This is more complex audit than an FDA QSR audit, and entails more time to create the written report, but the firm received a report addressing all 4 international requirements.

I 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.

Performed multiple audits for two "Virtual" firms developing combination products. Audited contract firms for design controls, quality systems, and clinical studies, for both the drug component and the device component of the final products.

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,

I regularly perform webinars, and also serve as a guest speaker at Regulatory and Quality Conferences (See the resume section on Presentations.)

I have been an Expert Witness for over 20 court cases involving the FDA regulation of medical device firms. My services have included preparing an expert report, being deposed, and testifying in open court.

UNITED STATES FOOD & DRUG ADMINISTRATION, November 2000 - September 2011.

Supervisory Investigator, FDA Saint Louis Office, March 2009 – September, 2011

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, September 2008 – March 2009

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, November 2003 to September 2008

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, June 2002 - November 2003

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, November 2000 – June 2002

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

President/Founder, March 1997- November 2000
MEDICAL DEVICE DEVELOPMENT CORPORATION, Fullerton, CA

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.

Vice President, Regulatory Affairs, Clinical Research, and Quality Assurance, 1995 -1997
CORDIS WEBSTER, INC. a Johnson & Johnson Company, Baldwin Park, CA 91706

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.

Vice President, Regulatory Affairs, Clinical Research, and Quality Assurance, 1994 – 1995
CARDIMA CORPORATION, Fremont, CA 94538

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.

Vice President, Regulatory Affairs/Quality Assurance, 1993 - 1994
CARDIAC PATHWAYS CORPORATION, Sunnyvale, CA 94086

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.

Vice President, Regulatory Affairs, Clinical Research, and Quality Assurance, 1990 - 1993
BAXTER HEALTHCARE CORPORATION, Edwards LIS Division, Irvine, CA 92714

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)

Vice President, Regulatory Affairs, Clinical Research and Quality Assurance 1986 - 1990
RETROPERFUSION SYSTEMS, INC., Costa Mesa, CA

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.

Manager, Regulatory Affairs, 1984 - 1986
UNITEK CORPORATION, Subsidiary of Bristol-Myers Company, Monrovia, CA

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.

Manager, Regulatory and Clinical Affairs 1982 - 1984
HEYER SCHULTE DIVISION, American Hospital Supply Corporation, Goleta, CA

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.

EARLY FDA EXPERIENCE, 1972-1982

U. S. Food and Drug Administration, Los Angeles, CA
Small Business Representative, July 1979- March 1982

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. Trained by FDA on all aspects of the 1976 Medical Device Law and regulations. 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.

U. S. Food and Drug Administration, Los Angeles, CA
Consumer Affairs Officer, September 1975- June 1979

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.

U. S. Food and Drug Administration, Los Angeles, CA
Consumer Safety Officer (Investigator) June 1972 - August 1975

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

California State University, Fullerton, Bachelor of Arts, 1970. Biological Sciences

Golden Gate University, Santa Barbara, CA, MBA Program: One year Completed; 1982-83

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

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. August, 2011 to present

Industry Representative, FDA Circulatory Systems Advisory Panel, FDA Center for Devices and Radiological Health, four-year term, ending June 1993.

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

PUBLICATIONS

Abel, J., Stevens JL. What to Expect When You are Inspected. Endovascular Today, 2004 Jan; 3(1):58-60

Stevens JL. Practical Aspects of the Clinical Evaluation of a Medical Device. Medical Device & Diagnostic Industry. 1985 Apr: 7(4):71-75.10/15/2015

Stevens JL. Design Verification. Medical Device & Diagnostic Industry. 1994 Jan:93-97

Stevens JL. Are your internal quality system auditors overlooking deficiencies of FDA significance? Self-published on LinkedIn (2015 Oct. 15)

Stevens JL. Don't use FDA to Rate Your Quality System. Self-published on LinkedIn (2016 Feb. 24) 08/01/2016

Stevens JL. How Do I Know if My Personal Training Program Meets FDA's Expectations? Self-published on LinkedIn (2016 Aug. 1)

Stevens JL. What is happening with FDA's 510(k) Refuse to Accept Policy> Self-published on LinkedIn (2015 Oct. 29).

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, 2013

"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

"FDA cGMP for Pharmaceuticals – 2104 Expectations" cGMP 2013 Conference, Utrecht, The Netherlands, December, 2013

"FDA and Medical Device Advertising in the 21st Century" One Hour Webinar for Biopractice.com, July 2014

"FDA Requirements for Good Clinical Practice's and efficient and effective clinical trial" One Hour Webinar for Biopractice.com, September 2016

"Effective Management Reviews for FDA and Management" One Hour Webinar for Biopractice.com, November 2016

"Protecting Patient Privacy" One Hour Webinar for Biopractice.com, February 2017

"Good Clinical Practice and More!" One Hour Webinar for Biopractice.com, September 2017

Premarket and Postmarket Data Collection - A Faster FDA Approval for Medical Devices One Hour Webinar for Biopractice.com, February 2018

"UDI and GUDID - The Unique Device Identification and the Global Unique Device Identification Database : The FDA Plan and Your Requirements", One Hour Webinar for Biopractice.com, April 2018

"Medical Imaging Latest Regulatory, Compliance and Quality Developments" 90 Minute Webinar for FDA News, March 2019.

AFFILIATIONS

Regulatory Affairs Professionals Society, Member 1982 - Present,
President, Western Section, 1985 - 1986

American Society for Quality, Member 1976 – Present

FDA Alumni Association, Member 2013-Present