MARK LOAR
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- Over thirty years regulatory, clinical, quality and R&D experience in the medical device industry
- Managed, prepared and submitted original marketing application for active implantable medical device and received US FDA approval
- Obtained product approvals in several international markets including the EU, Canada, Japan, South Korea, Taiwan, Saudi Arabia and Russia.
- Gained US FDA clearances for numerous 510(k)s for Class II and Class III ophthalmic, cardiovascular, and orthopaedic devices
- Obtained US IDE approval for Class III active implantable devices
- Managed QSR and notified body inspections, leading to approval of manufacturing facilities and CE marking
- Developed and managed departmental budgets and operations
- Directed and managed departmental staff as well as internal and international project teams
- Developed regulatory strategies that met business objectives and were consistent with state, federal, and international regulatory requirements

PROFESSIONAL EXPERIENCE:

2005 – 2018 **SECOND SIGHT MEDICAL PRODUCTS, INC.**
Sr. Director, Regulatory Affairs

Responsible for regulatory submission and compliance activities for start-up with novel Class III active implantable ophthalmic device. Regulatory staff of three reported into this position.

- Authored original marketing application for Class III retinal prosthesis that successfully received US FDA approval
- Prepared design dossiers and registrations applications that gained approval for company to market devices in several international jurisdictions including the European Economic Area (CE mark), Canada, Taiwan, South Korea, Turkey, Saudi Arabia, and Russia
- Authored IDE applications that gained requisite approvals for company to conduct clinical studies of Class III retinal prosthesis and cortical implant in the US
- Obtained in-country approvals to conduct clinical study of retinal prosthesis in select EU member states including UK, Germany, France, and Switzerland
- Managed inspections by regulatory bodies
- Prepared product labeling (labels, physicians and patient manuals) that met US and international regulations
- Performed regulatory review of device documents including standard operating procedures, pre-clinical and bench verification studies, software validations, and device specifications
- Authored numerous marketing supplements and notifications to gain approval of revised products
- Prepared grant that successfully gained funding of clinical activities through FDA's Orphan Product Grant program
- Instituted complaint handling / vigilance program and oversaw its activities

2003 – 2005 **INTERPORE CROSS INTERNATIONAL, INC.**
Manager, Regulatory & Clinical Affairs

Responsible for managing all regulatory strategy/submissions, clinical research and regulatory compliance for worldwide markets of orthopaedic products that includes spinal implants, bone allograft, blood processing devices, and surgical instruments. Product lines encompass Class I – III in the US, Canada, EU and Australia. Department obtains approvals/clearances in Japan, Mexico, South America, China and other worldwide markets. Regulatory staff of five reported into this position. Total department budget of $2 million.

- Gained FDA clearance of multiple 510(k) notifications for Class II implantable devices
- Received EU approval on design dossier for resorbable Class III spinal implant
- Developed clinical protocols and managed clinical studies to demonstrate clinical evidence of safe/effective use of Interpore Cross products. This included studies in the US (IDE) and Australia.
- Hired, trained, and supervised regulatory and clinical staff and prepared / managed departmental budget
- Responsible for the development of a Quality System compliant with FDA (QSR), MDD (ISO 13485) and Canada (CMDCAS)
- Directed complaint handling / MDR activities and conducted two formal FDA product recalls
- Performed regulatory review of all device documents including labeling, standard operating procedure changes, software/process validations, and device specification changes
- Directed FDA GMP inspections and European/Canadian ISO 13485/9001/46001 quality inspections as well as inspections by state licensing agencies for human tissue products
- Reviewed all design changes to develop innovative regulatory strategies for gaining marketing clearance

2000 – 2003 EDWARDS LIFESCIENCES, INC.

2001 – 2003 Regulatory and Product Development Consultant

Served European division of company by providing regulatory and product development consulting for Class III (EU) renal products. Activities included process and design validation protocol development, product realization activities, and preparation of regulatory submissions.

- Prepared project charter detailing scope of project and the deliverables
- Developed and updated project timelines detailing resources, work breakdown structures, and budgets
- Prepared design input/output requirement documents that addressed the performance characteristics, safety, reliability, sterility and manufacturability of the devices
- Prepared validation protocols and reports (design, process, IQ/OQ, FMECA) facilitating the clinical release of catheters, hemofilters, and hemofiltration tubing sets containing biocompatible coating
- Developed manufacturing processes for applying biocompatible coatings to the devices and documented in standard operating procedures
- Set-up manufacturing equipment in European facility and trained employees on its use
- Provided guidance to Regulatory/Clinical in developing strategies to minimize regulatory hurdles to the US and Canadian markets
- Assisted Regulatory in preparation of design dossier and 510(k) submissions for renal devices

2000 – 2001 Research Scientist, Research & Development

Responsible for managing biomaterial research and new product development of cardiovascular devices. Technical support staff of two reported into this position.

- Interacted with cardiovascular surgeons and clinical perfusionists to determine clinical needs / evaluate prototypes and translated these clinical requirements into viable products
- Successfully led cardiopulmonary device development program for venous reservoir that accounted for $11 million dollars in annual sales
- Managed design control activities for development programs to assure compliance with company procedures and QSR/ISO 13485/9001/46001 requirements
- Researched, evaluated and implemented environmentally friendly cleaning solvents that replaced CFC's in existing manufacturing operations. Resulted in company savings of over $5 million.
- Prepared agendas and minutes and facilitated project meetings that allowed for clear understanding of objectives and accountabilities
- Assisted Regulatory in developing regulatory strategies and preparing 510(k) submissions for cardiovascular devices
- Authored and edited articles for publication in scientific journals that documented investigational studies performed on cardiovascular devices

1985 – 2000 BAXTER HEALTHCARE CORPORATION, CARDIOVASCULAR DIVISION

1998 – 2000 Sr. Regulatory Affairs Specialist

Responsible for submission requirements with state, federal and international regulatory authorities, including licensing, registrations, technical files, design dossiers, premarket notifications, IDE's, post market surveillance, and annual reports. Also responsible for clinical data management and clinical monitoring of investigational studies. Product lines encompassed Class II and Class III cardiovascular devices in the US, Canada, and EU.

- Planned, coordinated and prepared domestic regulatory submissions, including 510(k)'s, IDE's and internal "letters to file"
- Prepared CE technical files and design dossiers for Class II and Class III medical devices
- Prepared clinical protocols and case report forms (CRF) to obtain clinical data for IDE study to gain information to support 510(k) and market preference studies
- Authored written responses to inquiries from FDA and international regulatory agencies facilitating market release of devices
- Reviewed and approved test protocols and reports to support regulatory submissions
- Reviewed and advised on labeling claims to ensure compliance with regulations
- Performed literature searches to compile clinical information to support regulatory submissions
- Provided support during FDA / notified body inspections of company's manufacturing operations

1994 – 1998 Sr. Project Scientist, Research & Development

Responsible for managing all phases of product development programs for Class II and Class III cardiopulmonary devices. Technical staff of three reported into this position.

- Successfully gained FDA market clearance for centrifugal pump and hemofiltration system
- Organized and coordinated international teams representing R&D, QA, Marketing and Manufacturing operations in California, Puerto Rico, Japan and the Netherlands
- Designed animal study to evaluate the safety and efficacy of newly developed oxygenator
- Developed and validated sterilization methods compatible with temperature sensitive devices
- Prepared IDE submission to gain FDA approval of clinical study for infant oxygenator
- Prepared technical documentation including process and design qualification protocols/reports
- Presented key accomplishments and progress reports to senior technical and business management

1987 – 1994 Project Scientist, Research & Development

Responsible for research and development of new biomaterials and the processes for integrating them into medical devices.

- Developed biocompatible coatings for medical devices that rendered them more blood compatible. Biocompatible coatings accounted for over $15 million in annual sales
- Invented patented manufacturing processes for applying coatings to oxygenators, venous reservoirs, filters and catheters
- Prepared detailed technical protocols and reports for internal documentation of medical devices and white papers for external use
- Prepared 510(k) regulatory submissions for devices containing biocompatible coatings and responded to inquiries from FDA

1985 – 1987 AMERICAN HOSPITAL SUPPLY, INC.
Chemist, Research & Development

Provided technical support to engineering staff for product development and product improvement activities.

- Formulated adhesives used in bonding critical components of medical devices that assured their safety and effectiveness
- Performed analytical testing (gas and liquid chromatography, IR spectrophotometry, and biological assays) on various polymeric materials of medical devices to ensure that they met specifications
- Prepared detailed technical reports of investigative findings
- Developed methods for evaluating materials and documented methods in company procedures

EDUCATION / AFFILIATIONS

Member of Regulatory Affairs Professional Society (RAPS)
Certification (RAC) 2002

Medical Device Development Program, University of California, Irvine
Certification 2003

BS Biological Sciences, University of California, Irvine (1985)
BS Chemistry, University of California, Irvine (1985)