Sharon Starowicz

Professional Background Summary

Overview

Regulatory Affairs professional with 30+ years of experience in medical devices, including Regulatory Compliance, Quality Systems and Clinical Affairs leadership responsibilities

22 years with Johnson & Johnson- 3 different operating companies- Franchise and Management Board experience

Previous FDA experience (Center for Devices and Radiological Health, Office of Device Evaluation)

Global Regulatory Affairs experience and organizational responsibility

Knowledgeable and experienced in many diverse areas of Regulatory Affairs

- **Class I, II and III US submissions to support FDA approvals/clearances for new products**
- **EU Technical Files, Dossiers and CERs to support CE marking of products in the EU**
- **Technical support and legal documentation required for international product registrations**
- **Japanese regulatory process- led an innovative cross-functional team to accelerate product approvals in Japan that are aligned with marketing priorities**
- **Health Authority inspections- have served as primary point of contact and liaison with HAs for site inspections (FDA, TUV and BSI)**
- **Class III products and clinical trials experience**
- **FDA Advisory Committee panel meetings**
- **Device reclassification petitions**
- **Manufacturing site approvals and transfers**
- **Product promotion compliance- advertising and promotional materials review and approval**
- **Complaints, MDRs, MDVs, Recalls**
- **Due diligence for assessment of new business development opportunities and L&A**
- **Business integration and process harmonization**
- **Global strategic regulatory guidance and expertise in support of product development efforts**

Appointed as Industry Representative to the FDA Orthopaedic and Rehabilitation Devices Advisory Panel in 2017

Education

Master of Science in Engineering Mechanics/ Biomedical Engineering- Virginia Polytechnic Institute and State University (Virginia Tech)
Bachelor of Science in Engineering Science and Mechanics- Virginia Polytechnic Institute and State University (Virginia Tech)

External Environment- Shaping and Advocacy

President of the Orthopedic Surgical Manufacturers Association (OSMA)- industry trade association- October 2011- December 2018
Active member of MassMEDIC FDA working group
Johnson & Johnson representative to the AdvaMed PMA Working Group
Member of the Medical Device Innovation Consortium (MDIC) Computer Modeling and Simulation (CM&S) Steering Committee
Leadership role in AAOS Orthopaedic Device Forum (industry representative)- Collaborate with stakeholder representatives (surgeons, FDA, ASTM, CMS, and research societies) to foster an environment of open communication among the scientific community, government and related industry
NASS Spine Forum (industry representative)
Engagement with EU Notified Bodies and other international regulators

Leadership and Team Development

Over 25 years of experience in building, leading, developing and mentoring teams

- **Promoted numerous associates, expanding job responsibilities and opportunities for career growth**
- **Hired associates from other functional areas interested in pursuing a regulatory career and developed them to take on increasing levels of responsibility within Regulatory Affairs**
- **Provide ongoing guidance and mentoring for junior-level regulatory associates**
- **Frequently consulted for regulatory guidance and expertise across the organization**

Strategic Thinking

With external environment focus, engage in shaping and influencing the evolving regulatory policies that impact our industry- through continued monitoring and understanding of the evolving regulatory landscape, and collaboration and partnership with regulators, business leaders, industry colleagues and cross-functional and cross-Franchise business partners
Provide strategic regulatory guidance and expertise to product development efforts, assessment of new business development and L&A opportunities (due diligence), evidence generation planning and product strategy
Provide strategic regulatory guidance and expertise to cross-functional business partners

Government/Legislative Experience

As representative of MassMEDIC, presented to legislative staff and senior FDA management
Participated in Capitol Hill Fly-Ins
Worked with industry Government Affairs partners to develop proposed language as part of FDASIA legislation
Frequent engagement with FDA management and staff

Credo and Collaboration

Developed an extensive network of colleagues both within and external to J&J
Fostered and maintained strong working relationships, including those with regulators
Maintain strong collaborative working relationships with cross-functional leaders and business partners
Employ a Credo and risk-based approach to decision-making, able to effectively tap in to extensive network of subject matter experts and present options that will benefit the patient, customer, business and industry

Summary of Work History

INDEPENDENT REGULATORY CONSULTANT
July 2019- present

JOHNSON & JOHNSON
Raynham, MA

Director of Regulatory Policy Innovation, Global Orthopaedics
November 2015- July, 2019

Responsible for providing strategic regulatory guidance and expertise and, with a focus on the external environment, shaping the evolving regulatory policies that impact our industry to achieve an environment that fosters accelerated delivery of healthcare technology to patients and maintains sustainable business growth in compliance with existing and future regulation.

DEPUY SYNTHES Companies of Johnson & Johnson
Raynham, MA

Director of Regulatory Affairs- Franchise External Environment
July 2014- November 2015

Provide strategic regulatory guidance and expertise and, with a focus on the external environment, engage in shaping and influencing the evolving regulatory policies that impact our industry.

DEPUY SPINE, INC./ DEPUY SYNTHES SPINE, A Johnson & Johnson Company
Raynham, MA

Director of Regulatory Strategy
February 2011- July 2014

Lead the DePuy Spine and JJKK (Japan) Collaboration Team to drive timely product approvals in Japan and accountable to the DePuy Global Management Board, DePuy Spine Board and JJKK Board for successful completion of team milestones and for the development of a process that could be leveraged across the Franchise to accelerate product approvals in Japan.

Provide global strategic regulatory guidance and expertise to front-end (concept and feasibility stages) product development efforts and product strategy and portfolio input to Board level project activations.

Support DePuy Synthes integration efforts, including the development of a harmonized process for the review and approval of advertising and promotional materials.

Director of Regulatory Affairs
January 2004 – January 2011

Responsible for the direction and management of day-to-day regulatory affairs activities, including the development and execution of strategies for attaining approval of new products in the US and worldwide and ensuring compliance with all postmarket requirements.

DEPUY ORTHOPAEDICS, INC., A Johnson & Johnson Company
Warsaw, Indiana

Director of Regulatory Compliance
November 2001- December 2003

Responsible for the direction and management of regulatory compliance activities for DePuy Orthopaedics, Inc., a Johnson & Johnson company specializing in implantable devices for total joint replacement, trauma, OR and casting products. Specific responsibilities included the facilitation of third party inspections (i.e., FDA and BSI), as well as management of the Company's internal audit program. Additional responsibilities included management of the product complaint system, failure investigations, medical device reporting (MDR) and medical device vigilance (MDV) systems, product recalls, and facilitation of product liability claims.

Director of Regulatory Affairs
January 2001- November 2001

Responsible for the direction and management of regulatory affairs activities, including FDA regulatory submissions (510(k)s, PMAs and PMA supplements), international product registrations for Canada and Latin America, technical files/dossiers for products marketed in the European Union and labeling development and approval for Class II and III products. Additional responsibilities included the review and approval of marketing and promotional materials, evaluation of the regulatory impact of product and process changes, support for product recalls and facilitation of all third-party inspections.

INDIGO MEDICAL, INC., a Johnson & Johnson Company
Cincinnati, Ohio

Director of Regulatory, Clinical and Quality Systems
Member of Management Board
January 1997- January 2001

Responsible for the direction and management of Regulatory Affairs, Clinical Affairs and Quality Systems functions for Indigo Medical, Inc., a Johnson and Johnson company specializing in the field of urology (benign prostatic

hyperplasia, prostate cancer and incontinence). Provided strategic and tactical guidance and direction to quality systems design and implementation, global regulatory approval/ clearance of new and modified products, regulatory compliance, implementation of clinical strategies to facilitate regulatory approvals and to support sales and marketing objectives, input to due diligence process for potential license and acquisition activities and professional development of staff.

ELECTRO-BIOLOGY, INC. (a division of Biomet, Inc.)
Parsippany, New Jersey

Director of Regulatory Affairs
February 1991- December 1996

Directed corporate regulatory functions, including the following areas of responsibility:

- **Provided regulatory input and strategy to meet corporate objectives and priorities**
- **Prepared 510(k), IDE, and PMA submissions to FDA for Class III implantable and noninvasive electrical bone growth stimulation/orthopedic devices to support new product approvals and product enhancements, and initiated clinical trials for investigational devices**
- **Served as FDA liaison regarding correspondence relative to FDA submissions**
- **Provided regulatory input regarding new product development and testing**
- **Served as primary company representative during FDA inspections**
- **Oversaw activities relating to product recall and corrective action**
- **Reviewed and approved all product labeling and promotional material prior to distribution to ensure compliance with FDA regulations**
- **Prepared information necessary to support FDA and foreign government approval to export products**
- **Oversaw device complaint reporting system**

IMPLANT TECHNOLOGY, INC.
Secaucus, New Jersey

Manager of Regulatory Affairs
July 1989 - February 1991

Responsible for the development and implementation of a Clinical and Regulatory Affairs department for a start-up company that included the following areas of responsibility:

- **Preparation of 510(k) and IDE submissions relative to orthopedic implants**
- **Establishment of a program for effectively monitoring IDE clinical studies (i.e., data retrieval, data organization, patient follow-up, and serving as a liaison between company and clinical investigators)**
- **Development and maintenance of an effective manufacturing compliance program (i.e., understanding and interpreting GMP regulations, setting up appropriate QC protocol, maintaining necessary documentation and files and ensuring compliance with applicable regulations)**
- **Fulfillment of requirements for foreign export**
- **Consultation regarding new product development and testing required for FDA clearance**

U.S. FOOD AND DRUG ADMINISTRATION
Center for Devices and Radiological Health
Division of Surgical and Rehabilitative Devices
Rehabilitation Devices Branch
Orthopedic Devices Section
Silver Spring, Maryland

Biomedical Engineer/Scientific Reviewer
August 1985 - June 1989

- **Reviewed scientific (i.e., engineering and clinical) data submitted in support of a variety of medical device actions (including premarket approval applications, applications for investigational device exemptions, premarket notification of intent to market a device, and establishment inspection reports)**

- **Summarized scientific data provided in support of medical device actions, directed the review of regulatory submissions by functioning as task leader, reviewed the recommendations of support level scientists, as appropriate, and made recommendations concerning data and final action taken**

- **Interacted with the medical and scientific experts who serve as panel members on FDA advisory committees, including discussion of device actions and recommendations concerning the adequacy of proposed data, and preparing material for presentation to committee members**

- **Developed, modified and evaluated guidelines concerning data required in device actions submitted to the Agency. Participated as a member of a team of experts to develop general Agency-wide guidelines applicable to the regulation of medical devices**

- **Developed and modified existing guidelines and protocols for testing specific types of devices**

- **Presented reviews, conclusions, opinions and recommendations to appropriate scientific review panels on PMAs, petitions for reclassification, etc., in which key issues pertaining to safety and effectiveness were outlined for approval or disapproval of the device or submission**

- **Provided scientific information and consultation to industry, academic, and private laboratory scientists conducting research on the safety and effectiveness of materials used in the manufacture of medical devices, and provided information on Agency guidelines and regulatory requirements concerning medical devices**

- **Collaborated with other scientists in order to obtain a greater understanding of problems associated with medical devices and keep abreast of current events and findings in the field, as well as changes in the law and regulations affecting medical devices by review of scientific and legislative literature, personal contact with authorities in the field, and attendance at scientific meetings**