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Overview

- 30 years of experience in medical device regulatory affairs and quality assurance
- History of leadership, collaboration, and innovation
- Track record of bringing innovative devices to market through the 510(k) pathway
- Breadth of experience includes work in regulatory-adjacent functional areas including clinical, quality assurance, and operations
- History of successful interactions with FDA and notified bodies
- Demonstrated ability to lead a team within a large organizational structure
- Able to manage large and complex workload

Experience

Regulatory Affairs Director, Lung Health and Visualization, November 2020 – Present

- Overall site lead for the Lung Health and Visualization RA team, based in Minnesota and Israel. Accomplishments include successful Breakthrough Device Designation and 510(k) submission to expand indications for use of the near-IR visualization system.
- Engagement with FDA on clinical and regulatory strategy for the breakthrough device. Provide overall strategic direction to the RA team.
- Provide strategic advice on artificial intelligence product development and RA strategies.
- Responsible for team development and organizational health.
- Establish resource needs for the site.
- Provide RA input to the leadership team and portfolio management team.
- Represented RA in diligence projects.
- Review submissions and regulatory strategies to ensure that they are compliant and high quality.
- Provide leadership on ongoing process improvements.
- Establish EU MDR certification strategies.

Regulatory Affairs Director, Surgical Energy and Safety, Medtronic, April 2018 – November 2020

- Overall site lead for the Boulder Surgical Innovations Regulatory Affairs team. Accomplishments include successful 510(k) submissions for ultrasonic surgical devices, multi-function electrosurgical generators, and vessel sealing devices and successful EU MDR submissions; major sustaining projects including changes of sterilization sites and major manufacturing site transfers.
- Provide direction to the RA team at the Ribeirao Preto site.
- Provide overall strategic direction to the RA team.

- Responsible for team development and organizational health.
- Establish resource needs for the site.
- Provide RA input to site-level governing boards (PDT, FET, ASCEND) and to the site management review meetings.
- Review submissions and regulatory strategies to ensure that they are compliant and high quality.
- Provide leadership on ongoing process improvements.
- Facilitate cross-functional communication within the department and with other departments at the site.
- Participate in regulatory advocacy activities.
- Provide guidance on specific regulatory questions.
- Help team to establish priorities and navigate potential conflicts.
- Functional leader for Medtronic RA Transformation Global Submissions workstream

Regulatory Affairs Manager, Medtronic, July 2016 – April 2018

- Managed team of regulatory specialists with responsibilities for new product development and state of the art activities while remaining a core team member on a complex product development project
- Provided coaching and mentoring to team members to further develop both technical and personal skills and to help them meet career aspirations
- Participated in site-wide management processes including product development oversight (PDT/FET) and quality system management review
    - Worked with RA team to submit seven successful 510(k)s through collaboration on regulatory strategy, discussion of test evidence, and content of 510(k) submissions
    - Supported team seeking new pediatric indication, including work on clinical strategy, IDE review, and participation in FDA meetings
- Regular involvement in advocacy activities to help shape the regulatory environment
- Formal and informal collaboration with other functional groups to meet business goals
- Advertising and promotion regulatory review for most sectors of the business
- Prepared 510(k) for complex multi-component device system
- Supported international regulatory submissions including key renewals in China and Brazil
- Continued to lead and implement processes and initiatives begun in previous role

Principal Regulatory Affairs Specialist, Medtronic/Covidien, Sept. 2013 – July 2016

- Multiple successful submissions to support launch of new energy platform: submissions on legacy products to remove regulatory obstacles and review risks; major contributions to architecture and content of the energy platform 510(k)
- Regulatory core team member on project to introduce RFID technology
- Successful 510(k) to add ENT indication to ultrasonic surgical device without clinical data
- Provided mentoring and guidance to a direct report and other department members
- Assisted with responses to challenging review questions to 510(k)s submitted by other Surgical Innovations sites
- Regulatory representative on risk management board

- Established formal process for prospective evaluation and implementation of standards used to support CE marking; served as team leader of cross-functional group
- Provided support and guidance to RA team that developed a streamlined method for creating and managing electronic technical files
- Regulatory core team member for complex ultrasonic surgical system
- Engaged advocacy work:
    - Analyzed and submitted comments to FDA draft guidance documents that could have significant site impact
    - Contributed significantly to Medtronic team that engaged with FDA on the update to the modifications guidance documents
    - Company representative for AdvaMed 510(k) Working Group

Director, Regulatory Affairs and Quality Assurance, Evergreen Research, Inc., Sept. 2004 – Aug. 2013

- Worked with executive management to establish flexible and compliant quality system for contract design, development, and manufacturing of medical devices; management representative for the quality system
- Established or significantly modified several operational systems including design controls, design transfer, CAPA, and training systems
- Implemented quality system requirements and supervised work of internal auditors
- Primary contact with BSI auditors
- Played major role in on-boarding new employees and mentored employees on regulatory agency expectations and quality system requirements
- Worked with clients to establish and implement regulatory strategies, including identification of testing needed to support desired marketing claims
- Authored or contributed to successful 510(k)s for multiple products
- Oversaw completion of significant risk clinical studies, including required reports to FDA
- Worked with clients to achieve or maintain the CE mark for Class IIa, Class IIb, and Class III devices as notified body expectations and oversight evolved
- Guided new product development teams to help them understand and fulfill design control, risk management, and regulatory requirements

President, RDD Consultants, Inc., July 1995 – Dec. 2004

- Principal in small consulting firm that specialized in scientific/technical communications, including regulatory affairs services for medical devices
- Worked with executive management and marketing personnel at a local medical device company to establish and implement a successful clinical and regulatory strategy for an innovative method to treat recurrent pleural effusion, which became the standard of care
- Authored or contributed to multiple 510(k) and IDE submissions for a range of device types
- Served as one of six FDA-recognized Third-Party reviewers during the initial year of the pilot program; reviewed and cleared 510(k)s for *in vitro* diagnostic devices
- Obtained initial CE marking for legacy devices, including interface with notified body reviewers
- Made financial, purchasing, and compensation decisions for the company; ensured that tax filings and other regulatory obligations were met on time

- Prepared and submitted proposals to clients
- Science/Technical writing and press relations for scientific, governmental, and non-profit organizations

Account Executive, Porterfield Enterprises, Jan. 1991 – Sept. 1995

- Services for the medical device industry, including 510(k) submissions, quality system audits, and quality system development.

Technical Writer and Regulatory Affairs Specialist, BioStar Medical Products, Aug. 1988 – Sept. 1990

- Series of successful 510(k) submissions for innovative diagnostic products used in the diagnosis and management of autoimmune disorders
- Identified regulatory and clinical strategy for first-of-type anti-cardiolipin assay; presented to FDA for alignment prior to submission

Education

- M.A. in Molecular, Cellular, and Developmental Biology, 1985. University of Colorado, Boulder
- B.A. in Biology, *magna cum laude*, B.A. in French, 1983. Washington University in St. Louis
- RAC through Regulatory Affairs Certification Board
- Continuing Education through industry publications, participation in FDA teleconferences and Regulatory Affairs Professional Society meetings
- Graduate-level work in biostatistics and epidemiology at level required for Masters' of Public Health (UCHSC)

Honors and Awards

- Phi Beta Kappa
- National Science Foundation Pre-Doctoral Fellowship

Seminars and Presentations

- Presentation and panel discussion on change analysis and documentation of no-file decisions, 2015, Regulatory Affairs Professional Society Regulatory Convergence Conference
- Rocky Mountain Regulatory Affairs presentations on design controls, 510(k)s, and quality system training, 2006-2009
- Risk Management for Medical Device Clinical Studies, June 2002, Colorado Medical Device Association
- Changes to Cleared Devices, September 2002, Regulatory Affairs Professional Society Audioconference
- Designing Medical Device Clinical Studies to Meet Your Strategic Goals, August 2000, Rocky Mountain RAPS