Senior Regulatory Affairs Specialist

AREAS OF EXPERTISE

- **21 years of medical device experience in Product Development, Regulatory Compliance, Quality Assurance, and Clinical Affairs**
- **Company representative for interactions with FDA, Health Canada (HC), and EU Competent Authorities**
- **Experienced with all stages of a product's life cycle – from cradle to grave**
- **Class I, II, and III devices – clinical trials, registrations, approvals/clearances, and post-market compliance in the U.S., Canada, Europe, and Rest of World (ROW)**
- **Skilled in investigations for Corrective and Preventative Actions (CAPAs) and complaints**
- **Writing various pre-market and post-market regulatory submissions**

INTRODUCTION

My lifelong goal has been "to help doctors and nurses help people." As a biomedical engineer and quality & regulatory professional, I have been privileged to develop and support many safe and effective medical devices. I now enjoy using my expertise to assist medical companies as they develop their products, prepare regulatory strategies, obtain device approvals/clearances, address quality issues, and achieve and maintain compliance.

WORK EXPERIENCE

06/2013 – Present
Industry Consultant
Duties:

- Preparing regulatory submissions.
- Mentoring and advising RA personnel.
- Providing partial or full RA/QA services (e.g., determining regulatory pathways, developing Quality System, preparing product documentation and labeling, helping plan usability studies, performing audits, providing document control, supporting clinical trials, completing FDA registration and device listings).
- Supporting company communications with FDA including Q-Sub meetings and responses to AI (Additional Information) requests.
- Developing regulatory strategies for medical device registrations with FDA, EU, HC, and ROW.
- Writing various pre-market submissions including Q-Sub requests and 510(k)s.
- Preparing post-market regulatory submissions such as Premarket Approval Annual Reports, Post-Approval Study Reports, and requests for expanded Indications for Use.
- Authoring Clinical Evaluation Plans and Reports, including Literature Search Plans and Reports.
- Creating clinical trial documents including protocols, investigator's brochures, informed consent forms, data-gathering forms / case report forms, patient information leaflets, and trial reports.
- Writing or reviewing product requirements & specifications, risk management documents, Operator's Manuals / Instructions for Use, other device labeling, and training plans.

- Providing regulatory guidance and support to small companies developing drugs and cosmetics.
- Performing Quality System internal audits for medical device companies.

06/2002 – 12/2012

Olympic Medical Corp / Natus Medical Incorporated, Seattle, WA

Senior Regulatory Affairs Specialist, (12/2012 – 12/2012)

Quality Assurance / Regulatory Affairs Specialist, (12/2007 – 12/2010)

Duties:

- Processed ~165 complaints per month as Complaint Coordinator for 40 medical device product lines; managed investigations, opened Corrective Actions, and submitted FDA Medical Device Reports.
- Chaired cross-functional Failure Review Board to address product failures and other quality concerns.
- Reviewed all labeling and design changes for company's products with focus on regulatory impact.
- Managed regulatory aspects of two Field Corrective Actions and one Field Safety Notice for two devices; prepared mandatory reports to FDA, Health Canada (HC), and European (EU) Authorities.
- Submitted FDA & HC annual registrations, license renewals, and device & establishment listings.
- Wrote numerous Premarket Approval (PMA) Annual Reports, PMA Post-Approval Study (Registry) Reports, and PMA Supplements (for design changes) for review by FDA.
- Authored FDA 510(k) and HC Class III Medical Device Application for neoBLUE blanket LED Phototherapy System (device for treatment of neonatal hyperbilirubinemia).
- Prepared Essential Requirements Checklists, CE Technical Files, and Declarations of Conformity.
- Researched and wrote Clinical Evaluation Reports and Post-Market Surveillance Reports.
- Supported ROW device registrations submitted by Natus headquarters.
- Requested Certificate to Foreign Government (CFG); addressed device import issues / product holds.
- Maintained the division's regulatory-related and complaint-related procedures.
- Assisted with Quality System and PMA inspections by FDA and Notified Body (for EU and HC).
- Served as Lead Auditor for annual internal audits on various aspects of the Quality System.

Product Development Manager, (07/2005 – 12/2007)

Duties:

- Project Manager for translation (13 languages) and new features for Olympic Cool-Cap® System and Olympic Cerebral Function Monitor®; these are medical devices for the treatment and detection of neonatal hypoxic-ischemic encephalopathy, respectively.
- Managed 12-site Continued Access Clinical Trial; prepared reports for FDA, HC, and IRBs.
- Performed first Cool-Cap in-service and trained Clinical Consultants how to perform them.
- Provided initial Technical Service for Cool-Cap customers prior to training Technical Service staff.
- Managed discussions with FDA for Cool-Cap's product labeling and Post-Approval Registry Plan.
- Participated in Natus Medical's due diligence meetings prior to acquisition of Olympic Medical Corp.

Product Development Specialist, (06/2002 – 06/2005)

Duties:

- Worked with engineers, doctors, and nurses to develop commercial version of Cool-Cap device; designed and performed usability tests. Also tested software for the Cool-Cap sales simulator.
- Wrote PMA; planned and organized company's presentation at FDA's Advisory Panel Meeting.
- Lead presenter for Pre-PMA, 100-Day, and Real-Time Labeling Review Meetings at FDA.
- Wrote Clinical Evaluation Report in support of Cool-Cap device's CE Mark approval.
- Evaluated all new product ideas under consideration by Olympic Medical Corp.

- As member of International Electrotechnical Commission (IEC) Working Group, rewrote five international standards for infant medical equipment for alignment with 3rd Edition of 60601-1: radiant warmers, incubators, transport incubators, phototherapy devices, and heated mattresses.

07/1997 – 05/2002
LifeSpex, Inc., Kirkland & Bothell, WA
Manager of Advanced Development, (11/2001 – 05/2002)
Duties:
- Managed all aspects of five-week clinical trial in South Africa for Cerviscan™ (device for detecting precervical cancer). Also managed Clinical Affairs for feasibility trial at six clinical sites.
- Promoted to lead the company's technical efforts to expand into other areas of cancer detection.

Program Manager & Senior Scientist, (03/2001 – 10/2001)
Duties:
- Managed Hardware Team's building, testing, and characterization of seven Cerviscan devices.
- Oversaw the Team's installations, upgrades, and repairs of all field units.
- Supervised Quality Assurance Specialist, Manufacturing Engineer, and two Research Scientists.

Senior Scientist, (04/2000 – 02/2001)
Staff Scientist, (05/1999 – 03/2000)
Research & Development Engineer, (07/1997 – 04/1999)
Duties:
- Designed and performed experiments to characterize the Cerviscan; also analyzed clinical trial data.
- Participated in FDA Pre-IDE Meeting and prepared written communications.
- Worked with Engineering Team and gynecologists to design disposable probe.
- Selected lens material for disposable probe after testing a variety of plastics and glasses.
- Developed Customer Requirements, Product Performance Specifications, and Project Plans.

09/1991 – 06/1997
University of Washington, Seattle, WA
Research Assistant
- Developed a Raman spectroscopy-based polymeric sensor for general anesthetics.
- Designed, built, and tested anesthetic vapor delivery system and flow cell for monitoring absorption of general anesthetics into silicone waveguides using Raman spectroscopy; fabricated and characterized waveguides.
- Applied data preprocessing schemes to correct additive and multiplicative variations in spectra.
- Applied chemometric techniques to predict individual anesthetic levels in anesthetic mixtures.
- Performed statistical analysis to assess detection limit and response time for Raman-based sensor.
- Assisted in development of a cardiac enzyme electrochemical sensor.
- Designed, fabricated, and tested prototypes for silicon-processed oxygen/glucose sensor.
- Assisted with experiments using oxygen sensor and glucose oxidase to monitor glucose.
- Assisted in preparing National Institutes of Health (NIH) grant proposal and performing preliminary experiments for cardiac enzyme sensor.
- Analyzed use of Raman spectroscopy for breast cancer detection.
- Researched use of Raman and fluorescence spectroscopies to detect various cancers, cataracts, atherosclerosis, and ruptured silicone breast implants with an emphasis on breast cancer detection.
- Created NIH grant proposal using Shifted Excitation Raman Difference Spectroscopy to reject fluorescence in tissue samples of breast cancer grown in rats. Emphasis was on testing for statistically significant differences in lipid and β-carotene Raman band intensities for normal and

cancerous tissue.

06/1991 – 08/1991
Los Alamos National Laboratories, Los Alamos, NM
Graduate Research Assistant

- Used acoustic resonance spectroscopy for military and civilian applications
- Designed, built, and tested numerous electronic circuits for acoustic resonance experiments.
- Generated user-friendly, QuickBASIC computer programs to acquire data from spectrum analyzer.
- Performed acoustic resonance experiments for military use.

08/1987 – 05/1991
University of New Mexico, Albuquerque, NM
Teaching Assistant, (03/1991 – 05/1991)
Duties:

- Taught weekly electronics laboratory course and graded lab reports.

Recitation Instructor, (08/1987 – 12/1988)
Duties:

- Lectured weekly for FORTRAN 77 course; administered and graded programs and exams.

EDUCATION

09/1991 – 06/1997
University of Washington
Ph.D.: Bioengineering

08/1986 – 05/1991
University of New Mexico
Bachelor of Science: Electrical Engineering with electives in electronic circuit design
Additional coursework in Anatomy & Physiology, Organic Chemistry, and Biology