Senior Regulatory Affairs Specialist

AREAS OF EXPERTISE

- **Biomedical Engineering**
- **Cell Culture**
- **Matlab**
- **Clinical Research**
- **Life Sciences**
- **Engineering**
- **AAMI - Quality Systems**
- **Microbiology**
- **FDA**
- **Medical Devices**
- **Cardiology**
- **Regulatory Affairs**
- **Research**
- **Data Analysis**
- **Thermodynamics**
- **Cell**

INTRODUCTION

Consultant is an accomplished biomedical engineer with extensive knowledge of FDA regulations. Concentrates in cardiology and pediatrics. Currently working with a regulatory group attempting to launch innovative vascular interventional products in the US Market. Previously, examined pre-market submissions for cardiac medical devices, specifically devices that are inserted into the coronary arteries and the devices used in the interventional procedure. Drug eluting stents, atherectomy systems, percutaneous transluminal coronary angioplasty balloons, guide catheters, and embolectomy catheters are just a few of the devices that consultant is responsible for reviewing. Previously, reviewed dental devices such as implants, abutments, bone-grafting materials, bone plates, and trans-mandibular joint implants.

WORK EXPERIENCE

11/2016 – Present
Industry Consultant
Duties:

- Review and restructure the device portions of a combination product NDA submission
- Preliminary regulatory assessments for: a prostate biopsy device, an absorbable dental device, biomarker diagnostic, and a prosthetic nipple.
- Pre-submission meetings for a dura mater substitute and an anti-sleep apnea device
- Draft a 510(k) for an oral rinse
- 30 Day Notice for a cardiovascular device
- Promotional labeling reviews for conferences
- Draft and review of responses to 510(k) deficiencies
- Participate in RAPS discussions
- Business development for a regulatory firm

06/2015 – 10/2016
Biotronik, Inc.
Senior Regulatory Affairs Specialist
Duties:

- Authored and submitted an original PMA which received approval in less than 9 months
- Authored and submitted an original 510(k) which received approval in less than 6 months
- Developed strategy, authored, and submitted IDE and pre-submissions for combination products such as drug eluting stents and absorbable scaffolds
- Developed overall RA strategies and authored/submitted pre-IDE, 510(k), HDE, IDE and original PMA submissions to FDA for many cardiovascular device systems.
- Provided RA and engineering/technical guidance to project teams in Switzerland and Germany for GLP non-clinical engineering tests, biocompatibility tests, and animal studies.
- Provided guidance to clinical study group to ensure clinical studies meet FDA requirements.
- Developed change assessment SOPs to ensure proper regulatory notifications and internal documentation.
- Led and participated in multinational teams to bring BIOTRONIK's medical devices to the US Market.
- Completed training in ISO 13485:2016 and Six Sigma: Yellow Belt

11/2009 – 5/2015
Food and Drug Administration
Biomedical Engineer and Scientific Reviewer
Center of Devices and Radiological Health
Office of the Commissioner, Policy Analyst (Detail), (01/2015 – 05/2015)
Office of Device Evaluation, Interventional Cardiology Devices Branch, (11/2010 – 05/2015)
Office of Device Evaluation, Dental Devices Branch, (11/2009 – 12/2011)
Duties:

- Examined pre-market submissions for cardiac medical devices, specifically devices that are inserted into the coronary arteries and the devices used in the interventional procedure.
- Drug eluting stents, atherectomy systems, percutaneous transluminal coronary angioplasty balloons, guide catheters, and embolectomy catheters.
- Also, reviewed dental devices such as implants, abutments, bone-grafting materials, bone plates, and trans-mandibular joint implants.
- As a policy analyst, worked on a guidance to encourage enrollment of minorities and diverse age groups in medical device trials.
- Reviewed well over 100 medical device pre-market submissions (IDEs, 510(k)s, PMAs, and HDEs) to determine if devices were safe and effective.
- Included are many pre-market approval applications, and original clinical trial applications, known as investigational device exemption submissions (IDEs).
- Lead reviewer of these large projects involved using engineering and biological knowledge to take a global view of the project, as well as leadership skills to coordinate teams of clinicians, statisticians, engineers, chemists, pharmacologists, and industry sponsors.
- Evaluated engineering and clinical study design issues in complex IDEs and worked with sponsors to resolve problems to allow initiation of trials in humans in the United States and guided sponsor-investigators through regulatory requirements for conducting significant risk clinical trials which impact the practice of medicine.
- Helped lead groups of newer reviewers and sponsor companies through the current MDUFA and FDASIA legislative changes.
- As lead reviewer, I participated in several other projects, working groups and committees.

- Awarded $145,000 to fund a project to determine the failure mode of dental hand pieces which have been shown to overheat during use causing severe burns to the patient's mouth. The project is still ongoing.
- Leader in the Pediatric Devices Working Group in the Division of Cardiac Devices.
- Presented pediatric issues within the Center numerous times, and provided expertise for engineering issues with pediatric interventional devices.
- Worked with Cross-Center signal review teams to develop resolution strategies for potential public health issues related to cardiovascular devices. Current signal teams deal with hydrophilic coating integrity and pre-mature failure of bioprosthetic heart valves in pediatric patients.
- Participant in the Center Pediatric Steering Committee commenting on pediatric issues throughout the Center and relaying information from the DCD pediatric group.
- Leader of branch rounds for the Interventional Cardiology Devices Branch.
- Developed a Memorandum of Understanding between the FDA and National Institute of Health to facilitated interaction between the two agencies. This led to grant collaboration for new companies and a network of experts for panel-track PMA submissions.
- Participant in the Heart Valve Rounds within the division using my graduate student expertise in heart valve mechanics and cellular make up to consult others in reviews specific to artificial valves and I provided comment during guidance document development.
- Participated, as member, in the computational modeling group in ODE to develop new guidance to develop regulatory procedures for the submission and review of computational modeling data.
- Assisted in development of a Reviewer Certification Program for the Office of Device Evaluation providing comments from my experience as a member of the pilot group. The RCP program is now used as a training program throughout the office for all new hires.
- Established a sound relationship between FDA and American Association of Pediatric Dentistry which has allowed the agency to seek advice and allowed the AAPD to provide needed expert opinions on pediatric issues within dental devices such as amalgam (silver fillings) use.
- Organized clinical visits to Walter Reed Medical Center to view live dental cases.
- Member of the Nitinol working group in ODE which is examining the nickel toxicity levels of Nitinol devices (2011-2013).
- Combined Federal Campaign Charity organizer for the Division of Anesthesiology, General Hospital, Infection Control and Dental Devices (2010 and 2011), organizing fundraising events, collecting moneys and answering questions related to donations.
- Mentor to several new engineers in both the Dental Devices Branch and Interventional Cardiology Devices Branch. Mentoring involves teaching new reviewers all the pertinent laws and regulations; teaching the review process; supervising sponsor interaction and more.
- Acted as branch chief for periods of time (up to 3 weeks) when the current branch chief was unavailable, using my expertise to give a final assessment on the medical device review recommendations of other lead reviewers.

EDUCATION

2007 – 2009
University of Alabama at Birmingham
Masters of Science: Biomedical Engineering

2003 – 2007
University of Pittsburgh, Pittsburgh, PA
Bachelor of Science: Bioengineering, Summa cum Laude

2005
University of Newcastle - Newcastle, Australia
Visiting Scholar

HONORS AND AWARDS

- 06/2012 – 06/2013 Center Leadership Readiness Program Among a small group of participants throughout CDRH selected to participate in this program. The program is designed to produce potential supervisory candidates with well- developed management competencies who have confidence in their leadership style, and are prepared to effectively transition into a management position. The program works to develop competencies developed for CDRH managers and supervisors and it includes 180 hours of professional development courses. Through the program worked with a group of four to update the "Device Advice" website to include all the MDUFA and FDASIA legislation and procedures.
- 06/2012 Quality Step Increase Awarded a quality step increase due to my excellent work within both the Dental Devices Branch and Interventional Cardiac Devices Branch during FY2011.
- 10/2011 Completed the Reviewer Certification Program as a founding member

PUBLICATIONS

- "Heart valve mechanobiology", Mechanobiology Handbook, ed. by Jiro Nagatomi, March 2011.

CONFERENCE PRESENTATIONS

- "Hyper-physiologic strain activates TGF-β1 in the aortic valve interstitial cell", Biomedical Engineering Society (BMES) Annual Fall Meeting, St. Louis, MO, 2008.
- "Mechanical Strain of Aortic Valve Interstitial Cells Regulates TGF-β1 Activity", 3rd Biennial Heart Valve Biology and Tissue Engineering, London, UK, 2008.
- "Strain-Dependent TGF-β1 Synthesis and Activation by Aortic Valve Interstitial Cells", Proceedings in Bioengineering (ASME), Marco Island, FL, 2008.
- "Strain-Dependent TGF-β1 Synthesis and Activation by Aortic Valve Interstitial Cells", UAB Graduate Research, Birmingham, AL, 2008.
- "Volumetric Airflow Gauge", Senior Biomedical Research Symposium, Pittsburgh, PA, 2007.
- "Design and Development of a Micro-Biaxial Mechanical Soft Tissue Testing Device", Pittsburgh Tissue Engineering Initiative Undergraduate Summer Internship Scientific Poster Session, Pittsburgh, PA, 2006.