

JEAN K. BIGONEY

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MEDICAL DEVICE REGULATORY AFFAIRS

Four successful 510(k)s, Q-Subs for Class I and Class II devices, HCPCS Coding, Detained Entry, FDA Registration and Listing for US and non-US Manufacturers and Importers of medical devices and Tobacco Products. SOP auditing to 21 CFR 820, "Refuse to Accept" audits. Strong analytical problem-solving skills and cross-industry experience. Proven ability to succeed and drive improvement in ambiguous situations. Excellent at writing reports, building client relationships and giving oral presentations. Fluent German.

PROFESSIONAL EXPERIENCE

Guideline Medical, Amherst NY 2017 - present
Director of Regulatory And Scientific Affairs
Remote freelance assignments involving compliance for FDA-regulated products.

Key Achievements:

- Packaged client data for 1000 listings for newly deemed products in less than a month to bring client into compliance by FDA deadline

Nu-Device Consulting LLC, Newport NH / Murphy, NC 2011 - present
Managing Member
Established LLC to handle regulatory affairs consulting activities for startups, physician-entrepreneurs and potential importers of FDA-regulated products.

Key Achievements:

- Authored 510(k) submissions and Q-submissions to FDA on behalf of clients including teleconferences with FDA.
- Advised on regulatory strategy and requirements for clients planning to market medical devices in the review panels: anesthesiology, general and plastic surgery, and clinical chemistry
- Audited clients' 510(k) submissions against RTA criteria and assisted with replies to deficiency requests
- Acting as US Agent for foreign clients, including advising on compliance to FDA regulatory requirements.
- Audited quality system documents (SOPs) for compliance to 21 CFR 820 for startup

Springfield Metallurgical Services, Springfield, VT 2002 – 2014
Owner, President and Treasurer
Started company offering materials testing, analysis and consulting for local, regional, national and international clients. Medical device regulatory consulting was offered as a sideline. Primary customers were in industrial, automotive, consumer, sporting goods, medical device, aerospace, and fire protection systems.

Key Achievements:

- Supported customer's quality efforts by performing root cause failure analysis and product development in multiple industry sectors.
- Taught customized in-house failure analysis course for a client who "pushed the envelope" with a sophisticated engineering application of advanced materials.
- Recommended environmentally friendly and economical process to successfully re-work 150,000 purchased components which a large customer had been unable to utilize in production.
- Participated in design testing, gage R&R and data analysis in support of product development.
- Three successful 510(k) submissions for a therapeutic anesthesiology device involving biocompatibility (ISO 10993), basic safety and EMC (ISO 60601) on behalf of a non-US medical device manufacturer (K063645, K100749, K103176).
- Submitted HCPCS Level II coding requests and recommendations for reimbursement rates.
- Wrote Technical Manual for a non-US company to fulfill FDA labeling requirements.
- Translated Quality documents from German to English for a non-US client to fulfill GMP requirements.

Technische Universität München, Garching, Germany 1996 – 2002

Full Professor (Chair for Materials in Mechanical Engineering)

Directed materials research and coordinated materials curriculum within the faculty for Mechanical Engineering.

Key Achievements:

- Hired, trained and led group of about 25 people including visiting scholars, post-docs, seven graduate students, six interns and nine technicians.
- Transformed and updated materials engineering courses for mechanical and aerospace engineering students (over 600 freshmen) to the sequence: Materials Science, Materials Engineering, Materials Processing and Properties.
- Developed new course on Quality Management for biomedical engineering program including statistical methods, six sigma and kaizen.
- Mentored five graduate students to completion of PhDs
- Project initiation and management on residual stresses in titanium and high-strength spring steel, electronic packaging / soldering, mechanical behavior of notched titanium, aluminum and cast iron, and developing surface treatments for hip-implants.
- Helped launch national research program on the "Interface between Material and Biosystem."
- Planned and carried out joint research projects with orthopedic surgeons, maxillofacial, and cardiovascular specialists.

Martin-Luther-Universität Halle-Wittenberg, Merseburg, Germany 1995 –1996

Associate Professor (Metallic Materials)

Authored research grant proposals and taught courses pertaining to metallic materials within the department of Materials Science.

Key Achievements:

- Obtained grant funding for equipment and personnel to set up new laboratory for materials characterization and mechanical testing by writing proposals.
- Developed and taught courses on physical metallurgy, materials for electrical engineering, and metal working.
- Acted as liaison between Materials Science Department and Department of Dentistry.

EDUCATION AND CREDENTIALS

North Carolina State University, Jenkins Graduate School of Management, Raleigh, NC May 2020

Master of Business Administration (MBA), Innovation Management

Stanford University, Stanford, CA March 1983

PhD, Materials Science and Engineering

Stanford University, Stanford, CA March 1980

Master of Science, Materials Science and Engineering

Massachusetts Institute of Technology, Cambridge, MA September 1978

Bachelor of Science, Materials Science and Engineering

Certifications

Certified Quality Engineer, American Society for Quality December 2016

US Regulatory Affairs Certification, Regulatory Affairs Professional Society December 2014

International Certified Yellow Belt™ / International Association for Six Sigma Certification April 2015

Professional Development and Training

Analyzing and Visualizing Data with Excel

Essential Statistics for Data Analysis using Excel

ADDITIONAL INFORMATION

Awards

1997 DFG Gottfried-Wilhelm-Leibniz Research Award

Additional Skills

Microsoft Word, Excel, Power Point, web teleconferencing

Languages

Fluent German

Hobbies

Scuba Diving, Karate