Colin Valentis

Experience

Rex Medical — Conshohocken, PA
Project Leader & Senior Development Engineer — 2015-Current

- Leader of Rex Medical's Atherectomy Research & Development program with a staff of 5 engineers and technicians.
- Responsible for contributing to, and managing, all aspects of R&D from product conception to launch, including: CAD of all molded parts, non-clinical and clinical studies, regulatory submissions, and development of manufacturing equipment.
- Key contributor and developer of clinical study documents, in addition to management of the Atherectomy clinical research study, ensuring timelines and deliverables were met while performance goals remained on target.
- Developed and conducted a physician training program for proper use of the Atherectomy system during the clinical trial and provided case-support to cultivate future business/sales relationships.
- Sole regulatory contributor for the Atherectomy U.S. regulatory 510(k) submission and key contributor for CE mark.
- Monitored device performance and physician feedback during the clinical trial for implementation into the **G**en-**T**wo design, including enhanced performance efficiencies and changes for improved manufacturability and scale-up.
- Responsible for technical writing or review of test reports and implementation of risk-based sampling plans.
- Responsible for strategic planning, implementation, and distribution of the pre-allocated $5M R&D budget over the entirety of the 4-year development time frame.

Rex Medical — Conshohocken, PA
Development Engineer — 2012-2015

- Conceptualized and implemented design changes for currently marketed products and products still in development based on market and physician feedback leading to a reduction in MAUDE complaints.
- Responsible for 510(k) submissions for FDA review of newly developed medical devices and to expand *indications for use* for currently marketed devices.
- Instrumental in product line improvement contributions which lead to product line acquisition for >$150M.
- Designed circuitry to improve the functionality and safety of the thrombectomy and neuro-thrombectomy product lines.
- Utilized Pro Engineer/Creo and Eagle CAD to design mechanical and electrical components, assemblies, and schematics.
- Complied with all required FDA, ISO, ASTM, and other quality standards during the design, verification, and validation phases of product development.
- Created and conducted DOE for verification and validation testing to ensure design specifications were met.

Rex Medical — Conshohocken, PA
Medical Device R&D Intern — 2010-2012

- Worked directly with surgeons and veterinarians in GLP nonclinical studies for development of prototype medical devices.
- Designed and machined various testing and assembly fixtures for use with newly developed medical devices.
- Manufactured prototype medical devices in ISO certified cleanrooms for use in clinical trials and testing procedures.
- Developed testing protocols and methods for use with prototype device components on various testing equipment.

Kensey Nash Corporation — Exton, PA
Polymer Manufacturing Engineering Intern — 2008-2010

- Processed polymers using injection molding machines and pressing equipment to fabricate prototypes and test pieces.
- Performed mechanical & chemical testing, tabulated data, and prepared reports to summarize results and methods.
- Evaluated medical device designs and processes via Failure Mode and Effects Analysis (FMEA).
- Performed functional testing (shear, tensile, torque) of biomedical devices for both production and R&D applications.
- Experience in compliance of current GMP (Good Manufacturing Practices) guidelines.
- Created and maintained standard operating procedures utilized in the manufacturing of biomedical devices.

Education

Drexel University, School of Biomedical Engineering and Health Systems — Philadelphia, PA
Bachelor of Science in Biomedical Engineering — 2007-2012

Patents & Pending Patents

Granted: US Patent 10,159,556 (Method of inserting a vein filter)
US Patents 10,307,175; 10,433,868; 10,463,389 (Atherectomy Device)

Software

Microsoft Office Suite + Visio | MS Project | ProEngineer Wildfire & Creo | Minitab | LabView | Eagle CAD | Micro-Vu InSpec Metrology Software | Adobe Illustrator | Adobe Photoshop