

Colin Valentis

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Experience

Rex Medical

Project Leader & Senior Development Engineer

Conshohocken, PA
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 transfer to manufacturing.
- 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.
- Present for a majority of the study cases to provide case-support and 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 **Gen-Two** 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

Development Engineer

Conshohocken, PA
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

Medical Device R&D Intern

Conshohocken, PA
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

Polymer Manufacturing Engineering Intern

Exton, PA
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

Bachelor of Science in Biomedical Engineering

Philadelphia, PA
2007-2012

Patents & Pending Patents

Granted: US Patent 10,159,556 Method of inserting a vein filter, US Patent 10,307,175 Atherectomy Device
Pending: Publication Numbers – 20170273698, 20170071624, 20160183966 (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