Jevon Nyemscek

Biomaterials Senior Project Engineer with extensive R&D, project management, production, quality, and regulatory experience.

Brookhaven, PA - Email me on Indeed: indeed.com/r/Jevon-Nyemscek/da76ea87f9b089af

I've been involved in medical device development (resorbable polymer bone grafts) from concept to launch on multiple projects including feasibility, production development from bench to scale up, process and equipment validation, quality control test development, regulatory approvals including 510k, IDE, and CE. and product management following launch including forecasting, marketing material development, sales training, and surgeon feedback.

I'm looking for an opportunity to apply my engineering and project management skills, knowledge, and experience to the design and development of medical devices. I have an extensive knowledge of bone graft implants and resorbable polymers. My main interests are in resorbable polymers,bone grafts, and cardiovascular devices.

WORK EXPERIENCE

Biomaterials Senior Project Engineer

Globus Medical - Audubon, PA - December 2010 to Present

• Project Leader for MicroFuse (Novel resorbable polymer technology) Structural Spacers (Cervical and Lumbar)
o Launch in US and EU including
* Design of Implant system: Implant, Packaging, and Instrumentation
* Design and Qualification of Mold tooling
* Leading process, sterilization, and shipping validations
* Involvement on Regulatory Submission (510k, IDE, and CE Marking)
* Development and Support of entire Manufacturing Process
* Design History File creation and maintenance
* Oversaw all verification testing including static/dynamic mechanical testing, chemical analysis, degradation studies, animal studies.
* Marketing Involvement including development of technique guides and product brochures, forecasting, and sales/surgeon training.
* Writing of all production documentation including product specifications, manufacturing procedures, test methods,

Biomaterials Project Engineer

Globus Medical - Audubon, PA - 2007 to December 2010

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• Project Leader for MicroFuse ST Granules (Bone Graft)
o Launch in US including, in addition to the responsibilities listed above: * Oversaw Gas Chromatograph (GC) installation, qualification, and test method development for quality control release testing.
* Involvement in clinical study protocol writing and development.

• Project Leader for MicroFuse ST MIS (Minimally Invasive delivered Bone Graft)

o Launch in US including, in addition to the responsibilities listed above: * Thermoformed tray design and development
* Full Instrument set design and development (10 instruments)
* Graphic Case Design and Development
* Pressure Sensor studies to determine delivery forces.
* Development of cantilever bend test for quality control testing.

• Project Engineer for MicroFuse Putty (Granules in a moldable carrier) - Secondary Responsibility
o Support on all engineering functions for the launch of the product.

Biomaterials Associate Project Engineer

Globus Medical - Audubon, PA - September 2005 to 2007

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• Project Leader for development of microsphere manufacturing process
o Developed 6 mobile generators capable of scaling up 100:1 (lab process) for the production of resorbable micospheres.
* Including pump and flow system, air driven valve system, customized polymer delivery system, customized hardware, solvent sensing and reduction system, ventilation system, and drainage
o Developed remainder of microsphere production procedure including ancillary equipment and customized tooling.
o Optimized production parameters for highest process yields.
o Validated entire process for 3 different polymer types

• Project Leader for the initial development of the MicroFuse product line - Basic Science
o Conducted basic science studies including degradation studies, animal studies, porosity studies, molecular weight studies, sterilization studies, shelf life studies, etc.
o Oversaw installation, qualification, and calibration of gel permeation chromatograph (GPC).
* Developed and validated test method for quality control release.

Research and Development Lab Technician

Bristol Myers Squibb - Skillman, NJ - November 2004 to September 2005

- Conducted physical property tests (tensile strength, fluid uptake, tearing force, etc) for quality assurance and development purposes
- Wrote comprehensive reports on testing results and conducted statistical analysis of data.
- Assisted in programming and development of new laboratory testing methods

Daily monitoring and troubleshooting of temperature recorders and stability chambers

EDUCATION

B.S. in Biomedical Engineering

Drexel University - Philadelphia, PA
January 1999 to January 2004

MS in Biomedical Engineering

Drexel University - Philadelphia, PA
January 1999 to January 2004

SKILLS

QUALIFICATIONS

ADDITIONAL INFORMATION

QUALIFICATIONS

- Experience in taking 5 projects (4 as the lead) from concept to launch
- Extensive involvement in all phases of project development including:
- Research, Design, Development, Packaging, Sterilization, Quality Control Testing, Manufacturing Engineering, Manufacturing Support, Regulatory, Marketing, and Design Control Practices.
- Expertise in the science and capabilities of resorbable polymers and techniques
- Experience and knowledge with collagen products, ceramics, other synthetics, bone based grafts and demineralized bone matrices, cell based products, etc.
- Proficiency in CAD (ProE)
- Proficiency with Microsoft Word, Excel, Project, and Publisher
- Excellent interpersonal, communication, and teamwork skills.