

R&D & Manufacturing Engineer

Post date: April 10, 2024

Spino Modulation Inc. · Montreal, QC

On-site - Full-time - Intermediate level

Spino Modulation is a privately held company founded in 2010 and based in downtown Montreal, Quebec, Canada. Its core expertise revolves around the design, development, evaluation, and manufacturing of medical devices for orthopedics and spine applications in children and adults. Our goal is to provide patients with innovative, performant, and safe spinal care solutions.

Job Description

Spino Modulation is looking for a R&D and Manufacturing Engineer to add to its existing team. Our ideal applicant would be a multi-tooled, versatile and experienced engineer. The applicant should be well-versed in medical devices engineering, design controls, risk management and manufacturing. The applicant should also be able to interact with various stakeholders (CMOs, testing labs, end-users). Finally, the applicant should also be comfortable with quality management systems (ISO 13485). The minimal experience requirement is 5 years in the medical devices field. Spino Modulation is only looking for bilingual (French and English) people who are positive, hard-working, autonomous, motivated, articulated, team-oriented, resourceful and that take initiative.

Role and Responsibilities

As part of the Research and Development team, the roles and responsibilities of the R&D & Manufacturing Engineer include, but are not limited to, the following:

- Participate or run brainstorming initiatives with respect to design concepts, product development and optimization of new and existing devices.
- Lead assigned projects including budgeting and planning, and report progress and status on a timely basis.
- Build and maintain Design History Files, including user needs capture, design inputs determination, design outputs (3D modeling using Solidworks + design for manufacturing principle), verification and validation activities planning and execution (in-house or subcontracted), design reviews, design transfer, design changes.
- Conduct Risk Management activities in accordance with ISO 14971
- Experience in Finite Element Analysis.
- Build and maintain Device Master Records including all specifications needed to manufacture the devices (drawings, packaging, labeling...).
- Build and maintain Device History Files including all manufacturing records.
- Participate in in-house manufacturing activities and inventory log maintenance.
- Qualify and manage current or new suppliers for prototypes and devices manufacturing.
- Participate in non-conformity, customer complaint and CAPA processes.
- Provide all internal departments and, on a need basis, OR team with technical support
- Collaborate in continuous improvement processes

Required Profile

- Bachelor's degree or higher in Mechanical or Biomedical Engineering
- 5-10 years of experience in mechanical design (orthopedic mechanical design preferred)
- Work experience in medical devices industry is a must
- Regulatory (FDA, HC, CE) and Quality System (ISO 13485) knowledge preferred
- Working knowledge of musculo-skeletal anatomy from an orthopedic standpoint preferred
- Knowledge and proficiency in 3D modeling – Solidworks experience desired
- Proficiency in geometric dimensioning and tolerancing (GD&T)
- Requires proficiency with MS Word, Excel, Project, Adobe
- Knowledge of CAPA process is an asset
- Ability to work on multiple tasks at the same time
- Autonomous, responsible, and resourceful
- Effective collaboration in a team environment
- Good interpersonal, project management and presentation skills, with the ability to clearly present recommendations and ideas and to summarize complex issues.
- Must be eligible to work in Canada at time of application
- Requires a valid OIQ permit and driver's license
- Proficiency in French and English (spoken and written)
- Small company mindset

Compensation Package

- Industry standard compensation
- Enterprise retirement plan (RRSP matching) & stock options plan.
- Flexible hours & work-life balance
- Health, dental, and wellness packages
- 3 weeks vacation + 5 flexible days

Please submit your application to HR@spinologics.com