

Company: Medical Device Manufacturing
Job Position: Full time
Job Location: Fremont, CA

We're seeking for a full time _____ .

Job Summary:

The production engineer is an experienced person within the medical device industry with extensive knowledge performing their function with the Food & Drug Administration (FDA) Quality System Regulations (QSRs), International Organization of Standardization (ISO) 13485, Medical Device Directive (MDD) 93/42/EEC, and ISO 14971. The position entails working closely with design engineers, manufacturing personnel, and the quality department to support the manufacturing of current and next generation ROBODOC systems. General responsibilities include managing production personnel, completing and managing deliverables in the areas of manufacturing, packaging, graphics, and production tolling associated with the development, and commercialization of the ROBODOC systems.

Travel Requirements:

This position may require less than 5% travel.

Job Responsibilities:

- Manage production personnel providing guidance and ensuring production schedules and deliverables are met.
- Work closely in the Product Development team to translate device designs into manufacturing specifications using design output documents.
- Involve in a variety of development projects including design, fabrication, and processing.
- Develop test procedures and testing modules for manufacturing validations.
- Troubleshooting, fabricating, and repairing machines, mechanical assemblies, and related CAD drawings.
- Perform both product and process failure investigations.
- Develop test protocols for failure investigation on products or components, as required.
- Develop and maintain the documentation necessary to ensure the consistent manufacturing of products (processes, drawings, etc.)
- Design and evaluate new and existing fixtures and equipment, test methods, specifications, layouts, and standards supporting a manufacturing environment.
- Direct support of daily manufacturing production as the operations technical expert from line start up through product transfer to production.
- Responsible for the development and maintenance of pFMEA.
- Identify and recommend manufacturing technologies to strategically develop business objectives and potential opportunities.
- Participate on project teams to support new process/product development and the successful transfer of product into manufacturing.

- Comply with applicable FDA and international regulatory laws/standards.
- Adhere to and enforce the company code of conduct, policies and practices in the production floor.
- Other duties or special projects as required in order to meeting company's objectives.

Qualifications:

- 8+ years experience in manufacturing and process engineering in the medical device industry.
- Four-year, accredited degree in Engineering.
- Able to read, evaluate, and draft mechanical drawings; understand technical product specifications
- Familiar with basic mechanical tools and their use in fabrication, measurement and assembly.
- Familiar with current mechanical design, analysis, verification and validation techniques.
- Must have effective verbal and written communication skills, including the use of MS Word and Excel.
- Experience with 3D modeling software, math software, and CAM software.
- Knowledge of statistical and analytical methods such as SPC, SQC, and DOE.
- Knowledge of electrical workmanship standards: IPC 610E, ANSI ESDS 20:20
- Experience with medical instrument development (FDA design controls and ISO standards).

We offer a fast-paced work environment, and a very competitive compensation, medical and 401K retirement plan benefits available

We are an equal opportunity employer and encourage diversity.

To apply: Please submit resume and Cover Letter to HR dept at jobs@robodoc.com

Company Overview:

The Company is a pioneer in medical robotics and world leader in image-directed, robotic products for orthopedic applications. The Company's product allows surgeons to pre-operatively plan their surgery in a 3-D virtual space and then execute the surgery in the operating room, exactly as planned.