



Title: Project Engineer

Division/Department: Engineering

Type of Position: Full Time

Summit Medical, an Innovia Medical Company

Eagan, Minnesota

August 2020

Innovia Medical combines the experience and expertise of Summit Medical, Shippert Medical, Network Medical, DTR and Eagle Labs to help our medical professional partners elevate the delivery of care to improve patient outcomes. We develop products not just for our customers, but with our customers. Our collaborative approach cultivates innovative medical solutions for the global health care industry. Through excellence in design, supply chain management, manufacturing and customer service we put quality at the forefront in all aspects of our business.

Job Summary

Provide engineering expertise for the support of existing manufacturing operations and improvements of existing medical disposable products. Regular support of manufacturing operations including IQ/OQ/PQ activities, risk management documentation, process development and training, LEAN implementation, and other associated activities as related to medical products manufacturing.

Essential Duties and Responsibilities

- Define and implement Verification and Validation activities.
- Meets required schedules.
- Facilitate project plans and reviews
- Facilitate risk analysis, and implements solutions to mitigate identified risks.
- Will design manufacturing jigs, fixtures and equipment
- Write work instructions
- Create internal label specifications
- Process document change orders (DCO's) promptly, accurately and completely.
- Support manufacturing, helping to produce products meeting Summit Medical quality standards, cost targets, and production schedules.
- Develop processes that are safe, mistake proofed, and easy to follow instructions using design for manufacturing principles.
- Support purchasing with complete documentation as required. Source, visit, and qualify vendors.

- Perform failure analysis, complete corrective actions and preventative actions as needed to support quality
- Provides cost and expense information as required to accounting.
- Other duties as assigned by manager

Desired Experience & Education

- Bachelor's Degree in Manufacturing or Process Engineering OR equivalent
- 3-5 yrs. medical device experience required
- Software proficiency
 - Microsoft Word, Excel, PowerPoint, Project, Solidworks, Minitab.
- Manufacturing process knowledge including:
 - Lean Manufacturing.
 - Packaging and labeling.
 - Clean room and sterilization processes
- Experience with small to large semi-automated equipment implementation including:
 - Working with outside equipment manufacturers for quotes
 - Design inputs
 - Validations (FAT, SAT, IQ, OQ, PQ)
- Materials selection knowledge including physical properties and biocompatibility (ISO10993)
- Product Design knowledge design for manufacturing, and drafting standards

FDA and ISO design control regulations

We offer a full complement of benefits including health, dental, vision, life insurance, AFLAC, 401(k) and generous PTO. Come work for a growing company that offers a fun, collaborative environment with work-family balance.

Qualified applicants should send their resume, cover letter and salary requirements to careers@innoviamedical.com.

EOE/Disabled/Veterans