

Job Summary

This Process Development Engineer works cross-functionally to lead the process development of complex medical devices and ensures effective transfer of designs into production.

Essential Functions

- Works with project teams to develop the processes used to manufacture component, sub-assemblies, and FG devices to bring the product to a commercialized state.
- Acts as the liaison between development and operations
- Advocates for the process to ensure they are repeatable, and the process can capably produce product that meets the design requirements
- Prepares and presents detailed plans necessary to complete assigned projects.
- Develops schedule milestones, coordinates manpower, facility and equipment for assigned projects
- Assists in improving the system of production controls, standard operating procedures, safety, quality control and training.
- Prepares and maintains detailed layouts of buildings and equipment.
- Coordinates the manufacturing launch of new/revised products including establishing goals, training team members and evaluating results.
- Designs, develops and tests as well as sources various tools, machinery and equipment for recommended manufacturing methods while providing ROI analysis.
- Performs product/process analysis for production and quality metrics.
- Write engineering change orders to process changes to manufacturing documents, drawing, and Bill of Materials
- Support company finance, accounting, human resources, quality, regulatory, and clinical departments as necessary to ensure compliance with requirements.

Education, Experience, Required Skills

- Bachelor's degree in engineering or related field (equivalent work experience may be considered)
- 1-5 years related experience
- Demonstrated ability to develop medical device manufacturing processes from concept to production
- Experience with medical device Design for Manufacturing, design control, quality systems and product development phases
- Strong oral and written communication skills
- Strong problem-solving skills to identify, gather, and analyze information develop solutions and resolve problems in a timely manner
- Demonstrated cross functional teamwork
- Ability to work in a fast-paced, constantly changing environment.
- Ability to travel to support projects and customer requirements (10%)
- MS Office Proficiency
- Lead and IPG experience a plus

Physical Requirements

- Prolonged periods of sitting at a desk and working on a computer.
- Must be able to lift up to 25 pounds at times.
- Must have excellent hand-eye coordination.
- Ability to differentiate between colored wires, tabs, and electronic components.
- Must wear gown, gloves, and ear protection if applicable.

Authority and Responsibility

Accountable for their performance and will have authority as delegated to complete their tasks and objectives.