

Product Development Engineer I

Description: The purpose of the role Product Development Engineer I is to use existing and gain further technical knowledge to develop and implement product and process solutions and complete quality system documentation including but not limited to

- Develop and execute technical protocols and reports, including data analysis, for process development and validations,
- Complete technical and QMS documentation including engineering drawings, technical protocols and reports, and risk management activities,
- Manage and execute on assigned projects including resources, timelines, and budgets, and
- Build parts, conduct validations, develop verification methods, and complete testing as needed to execute engineering activities.

Qualifications:

- College degree in engineering or engineering technology
- Minimum 2-3 years' experience in a manufacturing environment under ISO 13485 and 21 CFR Part 820 regulations or other regulated environment
- Ability to identify and select appropriate equipment and suppliers
- Experience developing, overseeing, and conducting qualifications and validations
- Demonstrated ability to use hand tools and light or industrial equipment
- Demonstrated oral and written technical communication skills
- Demonstrated ability to manage more than one project at a time

Report To: Engineering Manager

Subordinates: N/A

Responsibilities:

- Assist with and lead some R & D process development.
- Assist with and lead sustaining activities for both newly released and existing products.
- Assist with writing and executing IQ, OQ, and PQ protocols, lead the qualification execution, and create the technical reports.
- Develop and validate test methods and develop technical documentation.
- Gain and apply understanding of welding, assembly, testing, and other product manufacturing capabilities to support engineering projects.
- Complete required Quality System activities including FAIs, risk management, CAPA, FMEA and other related activities.
- Create and modify CAD models and drawings using appropriate software such as AutoCAD and SolidWorks.
- Use time management skills to balance multiple projects and communicate estimated completion dates.
- Communicate with management, suppliers, team members, and customers regarding project requirements and status updates.
- Manage assigned project timelines, budgets, and work with other engineers and engineering technicians as necessary.
- Comply with safety and regulatory requirements.