



Job Description

Job Title: Process Development Engineer I

Department: Engineering

Supervisor: Engineering Manager

FLSA Status: Non-Exempt

Summary

The purpose of the role Process 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

Essential Duties and Responsibilities include the following. Other duties may be assigned.

- 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.

Supervisory Responsibilities

This job has no supervisory responsibilities.

Competencies

To perform the job successfully, an individual should demonstrate the following competencies:

Use of Technology - Demonstrates required skills; adapts to new technologies; troubleshoots technological problems; uses technology to increase productivity; keeps technical skills up to date.

Problem Solving - Identifies and resolves problems in a timely manner; gathers and analyzes information skillfully; develops alternative solutions; works well in group problem solving situations; uses reason even when dealing with emotional topics.

Customer Service - Manages difficult or emotional customer situations; responds promptly to customer needs; solicits customer feedback to improve service; responds to requests for service and assistance; meets commitments.

Teamwork - Balances team and individual responsibilities; exhibits objectivity and openness to others' views; gives and welcomes feedback; contributes to building a positive team spirit; puts success of team above own interests; able to build morale and group commitments to goals and objectives; supports everyone's efforts to succeed.

Written Communication - Writes clearly and informatively; edits work for spelling and grammar; varies writing style to meet needs; presents numerical data effectively; able to read and interpret written information.

Ethics - Treats people with respect; keeps commitments; inspires the trust of others; works with integrity and principles; upholds organizational values.

Adaptability - Adapts to changes in the work environment; manages competing demands; changes approach or method to best fit the situation; able to deal with frequent change, delays, or unexpected events.

Attendance/Punctuality - Is consistently at work and on time; ensures work responsibilities are covered when absent; arrives at meetings and appointments on time.

Innovation - Displays original thinking and creativity; meets challenges with resourcefulness; generates suggestions for improving work; develops innovative approaches and ideas; presents ideas and information in a manner that gets others' attention.

Planning/Organizing - Prioritizes and plans work activities; uses time efficiently; plans for additional resources; sets goals and objectives; organizes or schedules other people and their tasks; develops realistic action plans.

Quality - Demonstrates accuracy and thoroughness; looks for ways to improve and promote quality; applies feedback to improve performance; monitors own work to ensure quality.

Safety and Security - Observes safety and security procedures; determines appropriate action beyond guidelines; reports potentially unsafe conditions; uses equipment and materials properly.

Qualifications

To perform this job successfully, an individual must be able to perform each essential duty satisfactorily. The requirements listed below are representative of the knowledge, skill, and/or ability required. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

Education and Experience

- 4-year degree in engineering discipline such as electrical, mechanical, or biomedical
- 2-3 years' experience in a manufacturing environment under ISO 13485 and 21 CFR Part 820 regulations or other regulated environment

Training:

Computer Skills

Microsoft Office (Word, Excel, Powerpoint, Access, Publisher, Outlook, Internet Explorer); Proficient with SolidWorks or similar, AutoCAD or similar. Familiar with data analysis tools such as Minitab, R, JMP, Matlab. Working ability with 3D printing.

Language Skills

Ability to read and comprehend simple instructions, short correspondence, and memos. Ability to write simple correspondence. Ability to effectively present information in one-on-one and small group situations to customers, clients, and other employees of the organization. Ability to speak Spanish is a plus, but not required.

Other Skills:

Mathematical Skills

Ability to add and subtract two digit numbers and to multiply and divide with 10's and 100's. Ability to perform these operations using units of American money and weight measurement, volume, and distance.

Reasoning Ability

Ability to apply common sense understanding to carry out simple one- or two-step instructions. Ability to deal with standardized situations with only occasional or no variables.

Physical Demands

The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

While performing the duties of this Job, the employee is regularly required to stoop, kneel, crouch, or crawl and talk or hear. The employee is frequently required to stand; walk; use hands to finger, handle, or feel and reach with hands and arms. The employee is occasionally required to sit. The employee must occasionally lift and/or move up to 25 pounds. Specific vision abilities required by this job include close vision, distance vision and color vision.

Work Environment

The work environment characteristics described here are representative of those an employee encounters while performing the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions. The noise level in the work environment is usually moderate.

The above job description is not intended to be an all-inclusive list of duties and standards of the position. Incumbents will follow any other instructions, and perform any other related duties, as assigned by their supervisor.