



Job Title:	Process Validation Engineer	Job Code:	PRVLDENG
Department:	Manufacturing Engineering (MFG O/H)	Division:	Ithaca, NY
Reports to:	Manufacturing Engineering Manager	FLSA Status:	Exempt
Hours:	Full-time – 40 Hrs/week	Rev Date:	03-08-2019

Primary Function

This position will be responsible for manufacturing process validation and verification. Design and develop protocols and standard operating procedures for equipment and processes to produce products meeting internal and external regulatory, safety, and quality requirements.

I. Duties and Responsibilities

- Study product and/or customer requirements and review with management to determine process validation objectives.
- Review applicable validation documentation such as product requirements specification, engineering change notices, schematics, or drawings.
- Review, modify or create Work Instructions related to production processes.
- Create installation, operation, and performance qualification plans for new or modified manufacturing equipment, processes, or systems.
- Develop process flow diagrams and process failure modes and effects analysis reports.
- Coordinate validation test activities with affected departments and personnel.
- Conduct validation, verification and/or qualification tests of new or existing equipment, processes or software in accordance with internal protocols or external standards.
- Resolve testing problems by modifying test methods or revising test objectives and standards.
- Identify deviations from established product or process standards and provide recommendations for resolving them.
- Identify root causes of production problems and recommend improvements.
- Create and maintain databases for tracking validation activities and test results.
- Analyze test data to determine whether equipment, processes or systems have met the validation criteria
- Prepare detailed validation reports or design statements based on test results.
- Communicate test results with applicable departments including Engineering, Production, Quality, and Regulatory.
- Procure or devise manual and/or automated test stations or other test fixtures and equipment as needed.
- Assist in training equipment operators or other staff on validation protocols and standard operating procedures.
- Provide guidance and expert advice to management or other groups on technical, systems-, or process-related topics.



Job Title: Process Validation Engineer	Job Code: PRVLDENG
Department: Manufacturing Engineering (MFG O/H)	Division: Ithaca, NY

II. Working Relationships

- Work with and develop successful working relationships within Manufacturing Engineering, Engineering, Manufacturing, R&D, Quality and Regulatory Affairs department personnel including all levels of Management
- Interact and communicate effectively with quality, regulatory and audit agencies

III. Education and Experience

- BS in Engineering or relevant field
- 5-7 years Progressive Manufacturing experience (Medical Device preferred)
- Proven process validation and verification hands-on experience
- Certified Manufacturing Engineer (CMfgE) Certification is a plus

IV. Knowledge, Skills and Abilities

- Strong interpersonal skills
- Must have the ability to effectively and accurately teach, convey information and train personnel to properly implement standard operating procedures and validation processes
- Excellent written and verbal communication required
- The ability to apply general rules to specific problems to produce answers that make sense through deductive reasoning is essential
- Ability to have a fluency and flexibility of ideas for developing solutions to complex processes while maintaining regulatory and quality standards (internal and external)
- Effective time management skills are essential
- Must be willing and able to handle multiple projects and successfully analyze and prioritize critical needs
- Communicate with Management in a timely manner and effectively explain needs and requirements of validation and verification processes and projects
- Exceptional computer, technical and mechanical skills are a must

V. Supervisory Responsibilities

- No Direct Reports

VI. Physical Demands

- Frequently required to sit, stand, bend at the knees and waist, and walk
- Regularly required to use computers, keyboards and other office equipment
- Essential tasks include ability to type, handle objects and paperwork, talk, hear and use close vision with ability to focus



Job Title: Process Validation Engineer	Job Code: PRVLDENG
Department: Manufacturing Engineering (MFG O/H)	Division: Ithaca, NY

VII. Work Environment

- Office and Manufacturing environment
- Occasional exposure to elements such as odor, noise, dust, heat and cold and chemicals
- Use of Personal Protective Equipment (PPE) as required
- Occasional travel may be required

Disclaimer: This Job Description is not intended to be all-inclusive and may be subject to change to include new responsibilities and tasks or change existing ones as management deems necessary to meet the ongoing needs of the company.