Sr. Validation Engineer

Job Type: Full-time
Schedule: 8-hour shift, Monday to Friday
Office Location: Wyomissing, PA.
Salary: Commensurate with experience

Job Description

This position resides in a department whose responsibility is the commissioning / qualification of facilities, utilities and equipment and the validation of manufacturing, packaging and cleaning / sanitization processes used in the production of OTC drugs and cosmetics and pharmaceuticals.

Company Benefits

- Excellent work-life balance and flexible work week
- Hybrid work environment/ability to work from home
- Growth opportunities within the organization
- Paid overtime, time off and sick days
- 401(k) matching
- Insurance plans

Education/Experience

- BS degree in Engineering or other appropriate technical discipline is required. Continuing education in pharmaceutical technology and / or cGMP is preferred.
- Ten (10) plus years of related experience in Validation / Quality / Engineering in an FDA/cGMP compliant manufacturing environment is required.

Tasks, Responsibilities, & Utilized Skills

- Train on Site Validation Master Plans. Maintain Site Validation Master Plans to reflect evolving regulatory and corporate requirements.
- Train on Validation Department and related SOPs. Maintain an on-time training record of 95+%. Maintain Validation Department SOPs. Provide Department SOP training on an as-needed basis.
- Create and maintain Commissioning / Qualification / Validation (C/Q/V) protocol and report templates.
- Serve as Core Team / Extended Team member to FPX Project Teams. Provide design review of equipment / processes. Provide C/Q/V strategy to Project Team. Track project validation schedule. Provide project deliverables via FPX Project Team / Core Team Member. Prepare quotations for

validation services and forward to Project Manager. Draft Capital Authorization Requests for validation resources and track through the approval process.

- Develop C/Q/V protocols from their reference documentation and administer their approval. Execute protocols. Perform any sampling / testing / inspection required. Compile results. Perform statistical analysis as required by the protocol. Identify and resolve deviations, with input from Project Team. Issue interim and final reports. Coordinate resources / schedule as required.
- Develop cleaning / sanitization methodology and criteria.
- Draft / review / approve site cleaning SOPs. Train Operations on cleaning SOPs on an as-needed basis.
- Provide SME input to Site Change Control Committee. Revalidate as required.
- Interact with auditors on an as-needed basis. Provide response to audit observations. Define, manage, and execute projects designed to remediate audit observations.
- Subscribe to the JNJ Safety Culture by maintaining a 100% training quotient and demonstrated safe behavior.
- Excellent interpersonal and communication skills, both verbal and written, are required. Special emphases on technical writing, requiring no edits.
- Proven track record of meeting project objectives required. Successfully planning, tracking, and executing validation projects with respect to scope, quality, time, and cost.
- Ability to manage multiple conflicting priorities required.
- Superior engineering aptitude required. Demonstrated ability to cross the validation disciplines (i.e., equipment, automation, manufacturing, packaging, cleaning) with subject matter expertise.
- Expert knowledge of the code of Federal Regulations and cGMPs relating to the field of validation.
- Demonstrate ability to lead. Perform all duties unsupervised.
- Quantify resource requirements in area of responsibility for purposes of capital appropriation. Build culture of proactive quality. Provide ad hoc counsel to department staffers.
- Perform the above-listed Duties and Responsibilities in accordance with all Company policy and Lititz Standard Operating Procedures.

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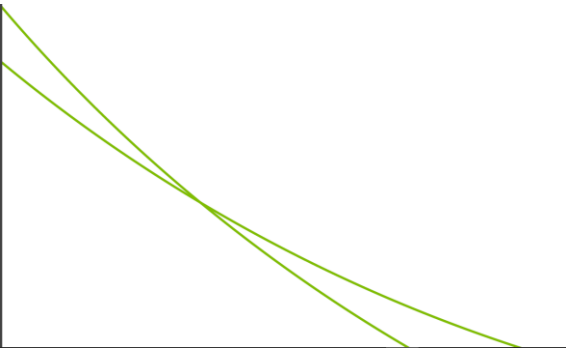

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