**Job Title:** Validation Manager

**Departments:** Quality Services

**Reports to:** Senior Director of Quality

**Date:**  January 2020

**Purpose:**

The Validation Manager will be directly responsible for the creation of Validation Strategy; preparation and execution of Installation Qualifications, Operational Qualifications, Performance Qualifications, Process Validation and Cleaning Validation which are harmonized with Tapemark corporate standards.

This position will be responsible for the development and execution of the requalification plan for the site.

This position will also be required to contribute to the development of Site Validation Master Plans, cleaning validation master plans and computer validation master plans. This position will implement and maintain computer systems in compliance with regulatory and company requirements and administer the Computer Validation Program.

**Principal Responsibilities:**

* Support all aspects of the Validation Life Cycle in Manufacturing from design through operation and improvement as required. Creates new validation approaches for new equipment; processes, or to align procedures and standards.
* Administer and create the Computer Validation Program for the site, including the author/review/approval of Computer Validation Master Plans, Process Control Installation/Operational Qualification protocols, and alarm acceptance testing protocols, computer acceptance protocols and maintenance of computer systems in accordance with corporate and departmental procedures.
* Provide key technical review with respect to SOP development and provide technical input for change control in order to assure that site needs are addressed, and compliance and industry standards are incorporated.
* Review or revise Standard Operating Procedures (SOP’s) as required.
* Responsible for developing the site requalification plan and strategy, execution and implementation.
* Streamline testing requirements while maintaining regulatory and corporate compliance.
* Responsible for the preparation of site validation documentation such as qualification protocols, validation master plans, risk assessments, periodic reviews.
* Maintain up to date knowledge of validation requirements, practices, and procedures and instruct other members of the site participating in validation studies.
* Participate on cross-functional teams, including value streams and site support groups to address specific problems, facilitate discussion and research and enable procedures to become more efficient. Build and enhance interdepartmental relationships. Implement improvement initiatives with filling/packaging and facility/utility qualification activities.
* As the site validation representative, present information or answer questions to regulatory agencies during the audit process regarding the validation program and specific validation studies.
* Perform all job responsibilities in compliance with applicable EHS and GMP regulations, guidelines, policies, and standard operating procedures.
* Manages and directs work of the Quality Engineers.

**Job Qualifications:**

* Minimum of BS degree in science or engineering (chemical or life sciences/biotechnology) or related field.
* Minimum of 5 years pharmaceutical experience in validation preferrably with knowledge of secondary process equipment.
* Prior experience interfacing with regulatory agencies, as well as exposure to the regulatory submission process.
* Prior experience preparing and executing equipment qualification documents (IQ/OQ/PQ) required.
* SME experience in any 3 of the following areas is required:
  + Process Validation
  + Cleaning Validation
  + Equipment Qualification
  + Packaging Equipment Qualification
  + Computer Systems Validation
  + Automation Qualification
  + HVAC, Smoke Studies and EM Qualification
  + Clean Utility Qualification
* Experience in preparing validation master plans.
* Familiarity with current Good Manufacturing Practices
* Must be able to provide leadership to generate options, resolve problems, prioritize solutions, select optimal solutions and implement decisions.
* Must have demonstrated self-direct work habits and strong communication skills.
* Must be a committed team player prepared to work in and embrace a team-based culture.
* Familiarity with regulatory expectations regarding electronic records and electronic signatures.
* Ability to work in a high complex matrix environment.
* Sense of urgency, flexibility and accountability.
* Ability to follow written procedures and document results in a neat and precise manner.
* Intermediate computer skills required.
* Stay current on developments in the field and Tapemark Standards.
* Maintain attention to detail, while completing multiple or repetitive tasks.
* Demonstrate a serious commitment to accuracy and quality while meeting goals or deadlines.
* Maintain a high level of integrity while balancing multiple priorities and responsibilities.

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