Job Title: Director/Sr. Director Validation

Department: Penn Life Sciences Manufacturing

Reports To: VP & GM Sterile Operations

Position Summary

The Director of Validation is a manufacturing plant core team leader responsible for starting up, validating, managing, and continuously improving the facility, process equipment, and manufacturing processes at a newly constructed manufacturing site. The Director of Validation will be instrumental in leading the validation effort, establishing policy, procedures, and practices, implementing validation systems, coordinating new equipment validation, performing product lifecycle validation, and aligning with the product commissioning program as needed. Selected candidate will own, oversee, author, and implement all aspects of the Validation Master Plan for all GMP equipment and systems across the site which includes all 21CFR Part 11 and GAMP 5 compliance for computer based systems. The Director of Validation will participate in the writing and execution of Installation, Operational, and Process Qualification protocols (IQ/OQ/PQ) for equipment, instruments, utilities, and computer systems. The Validation of Director will work to establish, maintain, and defend validation strategies with regulatory agencies.

The selected candidate will also have responsible for leading Technical Services and Facilities & Engineering groups. Technical Services will qualify primary & secondary components, assess and improve equipment and process, and technically support significant investigations related to the production of generic aseptically manufactured products. The position will collaborate with a variety of management professionals from Manufacturing, Quality, Development, and Regulatory. Areas of validation leadership include bulk compounding, formulation, fill/finish, utilities, warehousing, and facility/engineering maintenance. Functional areas responsibilities will include Validation, Technical Services, and Facilities & Engineering.

Position Responsibilities

- Train, develop, and lead technical staff working in the areas of Validation, Technical Services, and F&E
- Develop and manage the Validation Master Plan for all GMP systems site wide including laboratory equipment
- Manage and prepare manufacturing operations, processes, and responses for FDA/EMA inspection
- Develop and manage a calibration program for all GMP equipment, instruments, and computer based systems
- Act as subject matter expert on all qualification validations activities including, risk assessments, protocols design reviews, factory acceptance testing, engineering studies, and investigations
- Participate and provide technical expertise for Validation and during FDA and other regulatory agency inspections
- Develop FDA inspection response strategies and coordinated response and gap analysis team
- Lead validation projects for packaging equipment, processes, facility, utilities, cleaning, and computer systems
- Cross-functionally provide expertise, education, and training on validation issues
- Serve as Subject Matter Expert on validation strategies, regulatory requirements, and technical advances
- Develop and implement of process validations, review and authorize process validation protocols and reports
- Develop, train staff and implement impact/risk assessment methodologies and/or strategies site wide
- Provide oversight of process, cleaning, and shipping validation in support of GMP product manufacturing
- Identify opportunities for continuous improvement and implement improvement projects
- Support authoring and/or reviewing of various compliance documentation such as deviations, CAPAs, change controls, and technical study protocols
- Provide leadership and coaching to the team that will develop and implement high quality, robust and scalable manufacturing processes that drive a high-performance culture while accommodating dynamic growth
- Collaborate with Facilities, Engineering, Technical Services, Validation and QA/QC to ensure facilities and equipment are properly maintained in a continuous validated/compliant state of operation
- Facilitate an environment of collaboration among QA/QC, Manufacturing, F&E, and Development to accomplish the goals of the company while maintaining the highest quality and compliance standards
- Ensure validation documentation is clear, concise, and accurate with respect to processes & industry standards
- Work closely with the Regulatory team to ensure successful development of submissions, compliance with those submissions and regulatory commitments/inquiries
- Lead/mentor staff, set expectations, write performance reviews, annual goals, hold one-on-ones
- Develop an adaptable organization to handle new technologies resulting from alliances with partnering companies

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Specific program management leadership responsibilities:

- Impact/Risk Management Program
- Equipment and Instrumentation Qualification
- Facility and Utility Qualification Program
- Manufacturing Process Validation Program
- Packaging Process Validation Program
- Computer Validation Program
- Cleaning Validation Program
- Cleaning Verification Program
- Calibration Program
- Shipping Validation Program

Minimum Requirements/Qualifications

- Fifteen (15) years of proven experience in biopharmaceutical manufacturing & development
- B.S degree in biochemistry, chemical engineering, bioengineering, biology or related technical field.
- Advance degree in related field a plus
- Experience in leading and/or managing validation activities a must
- Previous work experience should include exposure to a broad range of biopharmaceutical validation activities such as document control, information technology, production record review, cGMP Compliance, Computerize System Supplier Assessment, validation, change control, etc.
- Direct experience with process development, technology transfer, and laboratory functions a strong plus
- Excellent oral and written English communications skills with ability to pass proficiency assessment
- Proven working knowledge of cGMPs and FDA & EMA biopharmaceutical regulations
- Experience in communicating directly with regulatory agencies
- Well-developed interpersonal and problem-solving skills
- High degree of knowledge of cGMP operational requirements and experience documenting, writing, editing, evidenced based documentation content within biopharmaceutical compliance industry standards
- Ability to motivate and mentor peers, staff, foster a culture of continuous improvement and operational excellence.
- Excellent oral and written English communication. Ability to demonstrate proficiency

Other Position Requirements

- Position requires no travel
- Position and plant are located in Bucks County, PA