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| **Department** | Validation | | |
| **Job Title** | Validation Manager | **FLSA Status** | Exempt |
| **Role** | N/A | | |
| **Sub Role (If any)** | N/A | | |
| **Reports To** | VP, Technical Services | | |

**1. Role Purpose:**

*(Provide a summary of the primary purpose of this role)*

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| * Manage and execute the site’s validation strategy under the direction of senior site leadership, ensuring all validation programs for equipment, processes, and facilities comply with cGMP and regulatory standards. * Direct and oversee all validation activities for facilities, utilities, equipment, processes, cleaning, and computerized systems to ensure a state of validation readiness. * Develop and implement risk-based validation and commissioning/qualification (C&Q) programs leveraging commissioning data to minimize redundant qualification testing. * Author, review, and approve validation documentation including URS, FRS, DQ, IQ, OQ, PQ, and associated protocols, reports, SOPs, change controls, deviations, and CAPAs. * Plan and coordinate the timely execution of validation deliverables for new installations, process changes, and routine requalifications to support uninterrupted sterile manufacturing operations. * Foster a culture of technical excellence, regulatory compliance, and continuous improvement across the validation function through staff mentorship, structured training, and performance management. |

**2. Key Duties & Responsibilities:**

*(Briefly describe the essential activities that are performed by this role including key duties/responsibilities. Each statement should start with a verb. Additionally, indicate how frequently it is performed)*

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| * Lead, train, and mentor validation engineers and specialists to ensure consistent technical execution, documentation quality, and professional development. * Establish and maintain validation master plans (VMPs) aligned with site and corporate quality objectives. * Develop annual validation schedules and staffing plans to support new equipment qualifications, requalification cycles, and production timelines. * Implement and sustain risk-based approaches to commissioning and qualification, leveraging commissioning test data to streamline qualification requirements. * Oversee and approve all validation deliverables for critical sterile manufacturing systems (e.g., autoclaves, depyrogenation tunnels, lyophilizers, terminal sterilization systems, and cleanroom/HEPA environments). * Ensure all validation protocols and reports include clear acceptance criteria, deviations, and statistical data analysis to support data integrity and regulatory expectations. * Review, approve, and trend validation deviations, non-conformances, and change controls to ensure timely closure and CAPA effectiveness. * Provide technical input during equipment and process design reviews to ensure validation and compliance considerations are integrated early in the lifecycle. * Lead investigations into atypical validation results, impact assessments, and requalification justification through equivalency studies. * Coordinate cross-functional collaboration with Quality Assurance, Engineering, Production, and Regulatory Affairs to ensure validation alignment with production readiness. * Represent the Validation function during regulatory inspections, internal audits, and customer visits. * Ensure adherence to FDA, EU Annex 15, ICH Q7/Q9/Q10, and internal data integrity standards. * Perform other duties as assigned to support site quality and compliance initiatives. |

**3.Typical Supervisory Responsibility:**

*(Identify any responsibilities the role has for supervising others)*

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| * Direct and oversee the day-to-day work of Validation Department personnel, ensuring all activities are performed safely, compliantly, and in alignment with site objectives. * Establish departmental goals, priorities, and workload distribution, ensuring adequate staffing and efficient execution of validation projects. * Provide coaching, performance feedback, and professional development through regular one-on-one meetings, training plans, and evaluations. * Coordinate cross-functional communication and reporting, serving as the primary validation point-of-contact with Quality Assurance, Engineering, and Production management. |

**4. Education & Experience:**

*(Describe the education required for this role, including specifications, if any. If equivalent experience or knowledge can be substituted for the educational requirements, A combination of Education and experience shall be considered.)*

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| **Education Requirement** | **Specialization (If any)** |
| * Bachelor’s degree in Engineering, Life Sciences, or a related technical discipline required. * Advanced degree (MS) preferred. |  |

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| **Experience Requirement** |

*(Describe the experience required for this role. Identify the type of experience, number of years, and any additional comments on the experience and education requirements for the role. Also, include any geography specific requirement that differs from experience*.)

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| * 7+ yearsof progressive validation experience in a GMP-regulated pharmaceutical or biopharmaceutical environment, with a strong focus on sterile manufacturing operations. * 2+ years of supervisory or project leadership experience managing validation staff, schedules, or major qualification activities. * Demonstrated expertise in commissioning and qualification (C&Q), equipment and process validation, and regulatory inspection support. * Hands-on experience with autoclave qualification required; tunnel, terminal sterilization, and lyophilization experience preferred. * Experience developing and executing validation master plans, risk assessments, and lifecycle documentation in accordance with FDA, EMA, and ICH guidance. | |
| Number of Years  (Minimum to Maximum) | 7+ years in a cGMP pharmaceutical or biopharmaceutical manufacturing environment. |

**Technical competencies/ Certifications/ Licenses**:

*(Briefly describe the required competencies such as skill, ability, and knowledge an individual must possess to perform the role. Also, identify any certification or licenses required to perform the role.)*

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| Technical competencies | * Comprehensive knowledge of validation principles (IQ/OQ/PQ), process validation, cleaning validation, and equipment validation. * Strong understanding of 21 CFR Parts 210/211/11, EU Annex 15, and GAMP 5 guidance. * Demonstrated proficiency in risk assessment, root-cause analysis, and statistical tools (e.g., Minitab, Excel). * Proficient in Microsoft Office 365 suite; experience with electronic Quality Systems (e.g., TrackWise, MasterControl) preferred. * Excellent analytical, organizational, and documentation skills with meticulous attention to detail. * Exceptional verbal and written communication skills; ability to collaborate across departments. * Ability to manage and prioritize multiple projects in a dynamic, regulated environment. |
| Certifications | * ASQ Certified Quality Engineer (CQE) or equivalent validation certification preferred but not required. * GAMP 5, Six Sigma, or Risk Management training desirable. |
| Licenses | * N/A |
| Other | * N/A |

**5.Physical demand and Work environment:**

*(Provide details regarding the physical demands and work environment that are essential to the role)*

* 1. Physical demands:

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| * Walk, sit, and stand for extended periods during routine work and facility walkthroughs. * Use hands and fingers to handle tools, operate equipment, and enter data on computers. * Reach with hands and arms; bend, stoop, crouch, or balance when inspecting equipment or systems. * Lift, move, or carry materials and equipment weighing up to 20 pounds. * Maintain adequate visual acuity for close work, distance viewing, color differentiation, and depth perception when reviewing documentation or conducting inspections. |

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* 1. Work environment:

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| This role operates within a GMP-regulated pharmaceutical manufacturing facility encompassing office, laboratory, cleanroom, and mechanical areas. Work may be performed in classified cleanroom environments that require gowning, adherence to aseptic techniques, and strict contamination control procedures. The position may involve periodic exposure to steam, pressurized systems, sanitizing agents, or moderate noise during equipment qualification or utility verification activities. |

**6.Compliance:**

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| * Foster a culture of ethics and compliance with the law, including compliance with the Food, Drug and Cosmetic Act and all associated regulations (the “FDCA”), in the Company’s day-to-day operations at all levels of the Company. * Personally comply with all Company codes, policies, and procedures concerning ethics, corporate governance, quality, and compliance, including compliance with the FDCA and all other applicable laws, rules and regulations. * Provide strong, visible support and commitment to the Company’s policies against violations of the law, including the FDCA, and the Company’s codes, policies and procedures. * Reinforce these standards and encourage employees under your supervision to abide by them. * As properly authorized by the Company’s Board, President, Chief Executive Officer, General Counsel, the Quality Council, Investigation Review Board, or otherwise by the Company’s policies and procedures, support quality and compliance-related continuous improvement plans and initiatives, quality investigations, and investigations concerning possible violations of the FDCA, its associated regulations, and Company codes, policies, and procedures concerning ethics, quality, and compliance. * As appropriately authorized by the Company’s Board, President, Chief Executive Officer, General Counsel, the Quality Council, Investigation Review Board, or otherwise by the Company’s policies and procedures, support the Company’s continuous improvement plans and initiatives related to ethics, quality, and compliance, including compliance with the FDCA and associated regulations, and projects related to such plans and initiatives. * Timely and satisfactory completion of all required training, including training related to ethics, compliance, quality, and position-specific requirements. * Ensure that all Company personnel under your supervision timely and satisfactorily complete all required training, including training related to ethics, compliance, quality, and position-specific requirements. * Understand and fulfill the compliance responsibilities of your role. * Understand the compliance responsibilities of the employees under your supervision and take reasonable steps to ensure that those employees are aware of, and fulfill, their responsibilities. * Report all known or potential violations of Company codes, policies, and procedures, or of applicable laws, rules and regulations, to the Company as contemplated by the Company’s policies and procedures, including PLS-SOP-0187 (Escalation to Management on Critical Matters Pertaining to Quality and Regulatory Compliance), or through the Company’s FaceUp portal, available by telephone or online (details below).   **Compliance Hotline # (205) 354-2405**  [**www.faceup.com**](http://www.faceup.com)  **Download Faceup App using the**  **Passcode # PLSxxxx1842**  **Or scan QR Code below** |