|  |  |
| --- | --- |
| **Department** |  Validation |
| **Job Title** |  Validation Engineer | **FLSA Status** |  Exempt |
| **Role** |  N/A |
| **Sub Role (If any)** | N/A |
| **Reports To** |  Validation Manager |

**1. Role Purpose:**

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

|  |
| --- |
| * Support the development, execution, and maintenance of site commissioning, qualification, and validation programs for equipment, utilities, cleaning, processes, and assays in accordance with cGMP and regulatory requirements.
* Develop and execute validation documentation including User Requirements Specifications (URS), Installation Qualifications (IQ), Operational Qualifications (OQ), Performance Qualifications (PQ), and related protocols, reports, SOPs, change controls, deviations, and CAPAs.
* Ensure timely completion of validation deliverables to support production schedules and new equipment or process implementation.
* Maintain compliance with Penn Life Sciences Quality System requirements, site procedures, and applicable regulatory guidelines.
 |

**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)*

|  |
| --- |
| * Maintain company compliance with Penn Life Sciences Standard Operating Procedures (SOPs), specifications, and current Good Manufacturing Practices (cGMP).
* Write, execute, and coordinate commissioning, qualification, and validation protocol testing in support of site and regulatory expectations.
* Compile and analyze validation data, and generate summary reports that accurately document study results and conclusions.
* Support troubleshooting and perform impact assessments for atypical conditions identified during validation or qualification activities.
* Assist in maintaining and developing validation programs to ensure continued compliance with internal and external regulatory requirements.
* Provide technical rationale and scientific support for validation studies of new or modified GMP systems, equipment, and processes.
* Ensure all validation activities adhere to site and corporate procedures, safety requirements, and applicable training standards.
* Review validation deviations, errors, and discrepancies in coordination with user departments and Quality Assurance (QA) to ensure timely and compliant resolution.
* Manage assigned validation responsibilities and workload to ensure accuracy, documentation completeness, and on-time completion of all deliverables.
* Initiate and support change controls as required to facilitate validation activities in accordance with Quality Management System (QMS) procedures.
* Conduct investigations as required to support QMS deviations and CAPA processes.
* Implement corrective and preventive actions (CAPAs) that may require follow-up validation activities or documentation updates.
* Review completed validation, preventive maintenance (PM), and calibration documentation for technical accuracy, completeness, and GMP compliance.
* Comply with FDA guidelines, data integrity principles, and all site and corporate policies.
* Perform other duties as assigned to support validation and quality objectives.

  |

**3.Typical Supervisory Responsibility:**

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

|  |
| --- |
| This position does not have direct supervisory responsibility but will coordinate activities and provide technical guidance to peers and cross-functional team members during validation projects. |

**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.)*

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

|  |
| --- |
| **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*.)

|  |
| --- |
| * 0-4 years of validation experience in a GMP-regulated pharmaceutical or biopharmaceutical environment.
* Experience authoring, executing, and reviewing validation documentation including IQ/OQ/PQ protocols and reports.
* Prior exposure to commissioning, qualification, and validation of sterile manufacturing systems, utilities, or process equipment preferred.
* Demonstrated understanding of FDA, EMA, and ICH regulatory requirements related to validation and data integrity.
 |
| Number of Years (Minimum to Maximum) | 0-4 |

**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.)*

|  |  |
| --- | --- |
| Technical competencies | * Strong knowledge of cGMPs, GDPs, and validation lifecycle principles (IQ/OQ/PQ).
* Ability to plan, organize, and manage multiple validation projects simultaneously.
* Proficiency with Microsoft Word, Excel, PowerPoint, and statistical tools such as Minitab or JMP.
* Excellent analytical and problem-solving skills, with high attention to detail and documentation accuracy.
* Effective verbal and written communication skills and ability to work collaboratively in cross-functional teams.
* Commitment to quality, safety, and continuous improvement.
 |
| Certifications | N/A |
| 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:

|  |
| --- |
| * Walk, sit, and stand for extended periods during validation testing and facility activities.
* Use hands and fingers to handle tools, operate instruments, and enter data on computers.
* Reach with hands and arms; bend, stoop, crouch, or balance while inspecting or testing equipment.
* Lift, move, or carry materials and equipment weighing up to 20 pounds.
* Communicate effectively through verbal and written means in both office and manufacturing environments.
* Maintain adequate visual acuity for close work, distance viewing, color differentiation, and depth perception during inspections or documentation review.
 |

.

* 1. Work environment:

|  |
| --- |
| This role operates within a GMP-regulated pharmaceutical manufacturing facility that includes office, laboratory, cleanroom, and mechanical areas. Work may be performed in classified cleanroom environments requiring gowning, aseptic practices, and adherence to contamination control procedures. The position may involve exposure to steam, pressurized systems, sanitizing agents, and moderate noise levels. The incumbent is expected to maintain compliance with all site safety, gowning, and data integrity standards. |

**6.Compliance:**

|  |
| --- |
| * Comply with all Company codes, policies, and procedures concerning ethics, quality, and compliance, including compliance with applicable laws, rules and regulations, including the Food, Drug and Cosmetic Act and all associated regulations.
* Timely and satisfactory completion of all required training, including training related to ethics, compliance, quality, and position-specific requirements.
* Understand the compliance responsibilities of your role.
* Commit to the Company’s culture of ethics and compliance.
* 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 SOP-0015 (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** |