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POSITION TITLE: Validation Engineer	**DEPARTMENT: Validation**	
REPORTS TO: Validation Supervisor	**FLSA DESIGNATION: Exempt**	
DATE WRITTEN/REVISED:	**HR APPROVAL/DATE:** **QA APPROVAL/DATE:**	

JOB SUMMARY:

Responsible for ensuring equipment is suitable for its intended use through the development and execution of qualification documentation to support the System Life Cycle, including facilities, utilities, equipment, and automation. Responsible for ensuring compliance by following government regulations including but not limited to, FDA (21 CFR 210/211 and Part 11), HC, EMA and company policies.
The Validation Engineer is responsible for interaction with regulatory agencies, certifying bodies, management, and critical customers.

CORE DUTIES AND RESPONSIBILITIES:

1. Areas of responsibility include the *Project Phase* of the System Life Cycle approach to qualification as follows:
   - The development of User / Functional requirement Specifications (UR/FS), Verification Plans, Commissioning protocols (FAT/SAT, Hardware & Software Tests), Area Qualification protocols (ISO 7 & 8), Installation / Operation Qualification protocols, Performance Qualification protocols, associated summary reports and Traceability Matrices.
   - The preparing of specifications for the purchasing of materials or equipment.
   - The execution of commissioning and qualification protocols for GMP Areas, Utilities, manufacturing and packaging equipment.
   - Instrumentation qualification including Installation Qualification, Operational Qualification, and Performance Qualification, as applicable.
   - Systems qualification including automation and computerized systems.
2. Areas of responsibility include the *Retirement Phase* of the System Life Cycle approach to qualifications as follows:
   - Decommissioning of facility, utility, and equipment including computerized systems.
   - Migration, archival and destruction requirements for historic data and records.
   - Ensuring the equipment calibration status prior to decommissioning.
   - Decommissioning impact assessment regarding the decommissioning plan.
   - Ensuring the obsoletion of associated documentation such as SOPs, PMs, and calibration procedures.

3. Areas of responsibility include the execution & data compilation of qualification protocols:
    - Inspecting completed installations and observe operations to ensure conformance to design and equipment specifications and compliance with operational, safety, or environmental standards.
    - Ability to clearly describe qualification deviations, provide evaluation of impact and to propose resolutions and corrective actions.
    - Provide graphical representation of collected data, and the ability to use data to identify and correct system problems.
    - Analyzing validation test data to determine whether systems or processes have met predefined acceptance criteria.
    - Operating computer-assisted engineering equipment to perform engineering tasks.
    - Performing detailed calculations to compute and ensure manufacturing, construction, or installation standards or specifications.
    - Responsible for field work and interaction with various departments in connection with validation studies which may include validation project oversight, auditing, sampling, protocol execution, or data acquisition as required.
    - Perform temperature and humidity mapping studies and engineering studies such as design of experiments and range finding studies.
    - Creating, populating, and maintaining databases for tracking validation activities, test results, or validated systems.
4. Areas of responsibility include providing documentation required to support document control, change control, and validation activities:
    - Responsible for Hazard Analysis/Component Design FMEA (Failure Mode Effective Analysis)/review. Process FMEA/Risk management and provide inputs to Design team directing validation activities.
    - Develops supporting documentation such as process flow diagrams, material specifications, and standard operating procedures.
    - Participates in the development of Risk Assessments as part of the Verification Plans relevant to equipment, and responsible for updating and maintaining relevant Verification Plans.
    - Preparing/review of technical drawings, specifications of electrical systems, and topographical maps to ensure that installation and operations conform to standards and customer requirements.
    - Provide documented evidence to support the release of facilities, utilities and equipment for their intended use.
    - Create statistically significant sampling plans, when applicable, to support the qualification approach to achieving fitness for use.
    - Responsible for performing gap analysis of different manufacturing systems by reviewing Standard Operating Procedures (SOPs) and Work Instructions (WIs) and ensuring the verification of the closure of any identified gaps.

5. Areas of responsibility include the ability to work as part of a team in order to meet company objectives:
    - Consulting with engineers, customers, or others to discuss existing or potential engineering projects or products.
    - Coordinating the implementation or scheduling of validation testing with affected departments and personnel.
    - Assisting project production efforts to assure projects are completed on time.
    - Directing or coordinating manufacturing, construction, installation, maintenance, support, documentation, or testing activities to ensure compliance with specifications, codes, or customer requirements.
    - Perform relevant training to operators or other staff on qualification protocols and standard operating procedures.

SUPPORTIVE FUNCTIONS

In addition to performance of the essential functions, this position may be required to perform a combination of the following supportive functions, with the percentage of time performing each function to be solely determined by management based upon the particular requirements of the plant:

1. Team member for problem solving to resolve production and quality issues.
2. Responsible for participation in internal plant audits.
3. Participates in cross-training in Engineering areas of responsibility.
4. Promotes safe operating and working procedures.
5. Provides support for process improvement teams and capital projects.
6. Responsible for statistical analysis of data, including Process Capability Studies.
7. Responsible for Vendor Audits for critical processes.
8. Participate in internal or external training programs to maintain knowledge of validation principles, industry trends, or novel technologies.

SPECIFIC JOB KNOWLEDGE, SKILLS AND ABILITIES

The individual must possess the following knowledge, skills and abilities and be able to explain and demonstrate that he or she can perform the essential functions of the job, with or without reasonable accommodation, using some other combination of knowledge, skills, and abilities:

- Knowledge of the practical application of engineering science and technology. This includes applying principles, techniques, procedures, and equipment to the design and production of various goods and services.
- Knowledge of arithmetic, algebra, geometry, calculus, statistics and their application.
- Knowledge of circuit boards, processors, chips, electronic equipment, and computer hardware and software.

- Possesses broad comprehensive knowledge of technologies in pharmaceutical, dietary supplement, and consumer product manufacturing and packaging industries.
- Must have excellent verbal and written communication skills.
- Must be able to effectively communicate with large groups and work collaboratively.
- Must be familiar with best practices systems such as Total Quality Management, Good Manufacturing Practices, and Lean Manufacturing.
- Must have legible handwriting, and the ability to perform good doc practices and maintain data integrity.
- Must be detail oriented, capable of following instructions precisely, and capable of accurately transcribing detailed information.
- Must be capable of accurately performing mathematical operations and routinely making numerical entries without errors.
- Must be organized and have the ability to ability to coordinate multiple activities.
- Must be able to work in a methodical and organized fashion and maintain mental focus to ensure efficient and accurate completion of individual tasks.
- Proficiency in computer skills including data entry, report writing, and data analysis using Microsoft Excel, and Microsoft Word is required.

PHYSICAL DEMANDS

- Must be flexible in terms of working hours to meet requirements of position.
- Must be able to fit and wear respiratory, hearing, gowning and other personal protection as required for entry and work in Unipharma facilities.
- Must be able to sit, walk, and/or stand for a minimum of 12 hours per day.
- Must be able to exert well-paced ability in limited space and to reach other locations of the plant on a timely basis.
- Must have the manual dexterity to install and operate sensors, devices and instruments as required to perform duties and assignments of the position.
- Vision occurs continuously with the most common visual functions being those of near and color vision and depth perception.
- Must be able to speak clearly on the telephone.
- Ability to sit at a desk and work on a computer as needed.
- Must be able to bend, stoop, squat and stretch to fulfill maintenance and cleaning tasks.
- Must be able to lift up to 50 pounds.

CRITICAL TASKS

- **Write qualification documentation**
- **Execute qualification protocols and summarize results**

QUALIFICATION STANDARDS

Education: This Position involves Performance of complex duties that normally requires at least a Bachelor's degree in Computers, Science, Math, Engineering or equivalent experience.

Experience: Five years of validation experience in Food/OTC or other FDA Regulated manufacturing environment.

Grooming: All employees must maintain a neat, clean and well-groomed appearance per Unipharma standards.

Relevant position titles:
Computer System Validation Engineer
Quality Engineer
Validation Associate
Validation Scientist
Validation Specialist

This job description is not an exclusive or exhaustive list of all job functions that an employee in this position may be asked to perform from time to time.