Validation Specialist

Full Time
Mt. Laurel, NJ
Requisition ID: 1448

FLSA Status
Non-exempt

Job Summary
The Validation Specialist is responsible for commissioning, qualifying, and validation activities associated with equipment and processes related to cGMP operations.

Essential Duties and Responsibilities include the following. Other duties may be assigned.

- Developing and/or approving all validation/qualification (IQ/OQ/PQ) documentation for new and existing equipment.
- Performs temperature mapping for autoclave(s), depyrogenation oven(s), incubator(s), stability chamber(s), and other related equipment.
- Performs sterilization validations for autoclave and depyrogenation cycles.
- Assist sterilization cycle development and hold-time studies.
- Develop and execute cleaning validations for relevant manufacturing equipment.
- Develop or review URS and FDS documentation for relevant projects.
- Assist in maintaining all equipment, facilities, and utilities, in the relevant compliant state, during changes and routine review as related to activities. This includes summary reports and/or periodic review that must be documented for each piece of equipment and utility.
- Maintain equipment database to tracking routine and non-routine maintenance/calibration activities.
- Assist in change control management for relevant validation/qualifications.
- Assist in the implementation of new and revised policies/procedures.
- Maintain compliance with company policies, regulatory requirements, quality specifications, safety standards, and sanitation practices.
- Perform quality review of related validation/qualification documentation and processes for other departments.

Required Education and Experience

- Bachelor's Degree in Biological Science, Chemistry, Biomedical Engineering, or relevant field
- Minimum 3 years of experience in pharmaceutical/cosmetic manufacturing environment or related field
- Familiar with GMPs, FDA, ICH, OSHA requirements
- Familiar with 21 CFR Part 11, 210, 211, and 820
- Familiar with ICH Q7, Q8, Q9, and Q10
- Experience using Minitab, Excel, and/or relevant applications
- Must have knowledge of basic principles, theories and laws, policies and procedures that pertain to compounding
- Must have strong organizational skills and exceptional attention to detail

- Must exhibit punctuality and low absenteeism
- Able to work independently, as well as part of a team
- Able to sit, stand, squat, kneel, reach and walk for prolonged periods of time
- May need to lift up to twenty-five (25) pounds on occasion

Eligibility Qualifications

- Must be capable of wearing all protective wear as required by State Board of Pharmacy. This includes, but is not limited to, mask, gloves, gown, hairnet, safety goggles, etc.
- Must be able to work with chemicals used in the preparation of compounds following any special safety precautions as required.

Competencies

- Communication Proficiency
- Decision Making
- Detail Oriented
- Time Management
- Problem Solving/Analysis
- Quality Driven
- Results Driven
- Technical Capacity

Supervisory Responsibility

This position has no supervisory responsibilities.

Work Environment

This job operates primarily in an office and a controlled laboratory environment. This position requires the use of standard office equipment, and frequent standing and walking.

Physical Demands

The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of this job.

- Able to sit and/or stand 8-10 hours or more per day as needed
- May sit, stand, stoop, bend and walk intermittently during the day; may be necessary to work extended hours as needed
- Finger dexterity to operate office equipment required
- Ability to lift up to twenty-five (25) pounds on occasion

Position Type and Expected Hours of Work

This is a full-time position. Because of the nature of the business, work schedules may vary at times.

Travel

No travel is expected for this position.

Disclaimer

The above job description is intended to describe the general nature and level of work being performed by employees assigned to this job. It is not designed to capture or illustrate a comprehensive list of all responsibilities, duties, and skills required of employees assigned to this job.

AAP/EEO Statement

Stokes Healthcare is an Equal Employment Opportunity and Affirmative Action Employer.