

Analytical Chemist



Department: Analytical Research and Development

FLSA Status: Exempt

Reports to: Manager

Location: 110 Terry Drive

BASIC FUNCTION: Perform analytical testing of raw materials, in-process materials, stability samples, finished products and product development products using different analytical techniques.

JOB RESPONSIBILITIES:

- Operation, Calibration, Qualification, Preventive maintenance and routine trouble shooting of analytical instruments like UPLC, HPLC, GC, AAS, UV spectrophotometer, Dissolution apparatus, Laser Diffraction Particle Size analyzer, etc.
- Evaluate existing, develop and validate new analytical methods of drug products and drug substance as per FDA, USP and ICH guidelines by different analytical techniques.
- Document all performed analysis as per cGMP, USFDA and 21CFR211.194 guidelines.
- Follow cGMP (current Good Manufacturing Practices), GLP (Good Laboratory Practices), 21CFR211.22, 21CFR211.28 and 21CFR211.170.
- Follow the OSHA (Occupational Safety and Health Administration) and EPA (Environmental Protection Agency) safety regulations.
- Follow all DEA (Drug Enforcement Agency) guidelines
- Research and gather information in a timely manner
- Prepare, label, organize and maintain files
- Follow all SOPs accurately
- Work with Analytical Instrumentation
- Work with Microsoft Excel, Word, and possibly PowerPoint
- Handle and complete special projects as required
- Work with Analytical Instrumentation and perform Wet Chemistry test
- Operate and perform routine trouble shooting of analytical instruments like UPLC, HPLC, GC, AAS, UV spectrophotometer, Dissolution apparatus, Laser Diffraction Particle Size analyzer, etc.
- Other duties as required or delegated

ESSENTIAL JOB REQUIREMENTS AND QUALIFICATIONS:

- Leadership skills which reflect directives for compliance of all pharmaceutical products
- Innovative
- Bachelor of Science Degree, Masters Degree is highly beneficial
- 1-4+ years of relevant work experience
- Naturally positive, upbeat attitude
- Demonstrates a high level of confidence, integrity and motivation
- Knowledge in all aspects of 21 CFR 210 and 211
- Strengths with root cause analysis and technical writing
- Handles confidential and non-routine information with poise, tact, and diplomacy

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- Flexible and responsive
- Outstanding organization skills; is detail-oriented self-starter; is able to independently prioritize and multitask; follows through consistently; demonstrates ownership through responsibility and accountability for end product; is proactive and persistent in job efforts; does not get frustrated with time limitations or high pressure situations; works productively when under pressure
- Anticipates and meets the needs of executives, teams and administrative colleagues
- Ability to work effectively in a fast paced, timeline-driven, extremely high-expectation environment; is flexible to occasionally work overtime on short notice
- Takes initiative and exhibits resourcefulness in problem solving; experienced in working in a collaborative team environment
- Maintains confidentiality at all times and exercises solid, dependable judgment and discretion
- Displays effective communication skills, both oral and written (timely, clear, succinct); constructively delivers and receives feedback
- Experience with FMEA and Risk analysis approaches.
- Must understand chemical component and safety practices required for handling chemicals used in batch processing equipment and room cleaning.

PHYSICAL DEMANDS: While performing the duties of this job, the employee is required to walk, sit, and use hands to finger, handle or feel tools or controls, reach with hands and arms, balance, stoop, crouch, bend, talk and hear. The employee must lift and/or move up to 20 pounds. Specific vision abilities required by the job include close vision, distance vision, color vision, peripheral vision, and depth perception.

The job demands here are representative of those that must be met by an employee to successfully perform the functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions. This job description is not intended and should not be an exhaustive list of all principal job elements essential for recruitment and selection, for making fair job evaluations and for establishing performance standards. The percentage of time spent performing the various job duties is not absolute. The incumbent, who has the right to amend, modify, or terminate this job in part or in whole. This document is not a contract for employment.