

Aseptic Processing Technician

Full-time

FLSA Status

Non-exempt

Summary

This position requires an individual who can work within a cGMP environment in collaboration with other Aseptic Processing Technicians under the direct supervision of the Manufacturing Manager. The successful candidate must be focused on achieving individual and team productivity goals while maintaining a high level of precision and quality.

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

- Practice current Good Manufacturing Practices (GMP) and Good Documentation Practices (GDocP) at all times
- Participate in all aspects of aseptic production (i.e., component preparation, set-up, aseptic processing, etc.) while maintaining cGMP records (e.g., batch record)
- Ensure daily operations are run efficiently to maintain anticipated production output and maintain product quality for patient safety
- Complete batch documentation in accordance with GDocP
- Assist in the development of Standard Operating Procedures (SOP) and related cGMP processes
- Assist in qualification/validation protocols for processes and equipment
- Maintain room and equipment logbooks for department (i.e., controlled areas, autoclave, etc.)
- Ability to troubleshoot critical manufacturing processes with appropriate communication and documentation (i.e., batch records, logbooks, and other related documentation)
- Report all unusual, non-routine occurrences when performing tasks (NOE report)
- Ensure personal training records are up to date and assist in training other technicians
- Attend training classes, workshops, meetings, etc., as required to improve job skills and product related procedures
- Work in collaboration with other members of the manufacturing team and other departments such as quality and facility maintenance to achieve company goals
- Perform cleaning and maintenance of environmentally controlled areas
- Abide by all company gowning requirements as well as operational requirements
- Properly use all equipment (i.e. pH meters, balances, peristaltic pumps, etc.) involved in compounding and aseptic processing operations
- Calibrate scales, electronic meters, etc., and document the activities in the appropriate logbook
- Coordinate with Supply Chain Technicians to ensure in-stock conditions on all manufacturing materials
- Demonstrates, at all times, safe work habits and maintains a safe work environment
- May participate in other Manufacturing Operations as needed

Required Education and Experience

- Minimum high school diploma or general education degree (GED)
- Experience working in cleanrooms using aseptic technique is preferred
- Experience in manufacturing is preferred
- Must develop knowledge of 21 CFR Part 210 and 211 for cGMP operations
- Must be capable of working with small and large pieces of machinery
- Must be capable of wearing all protective gear (gown, hair bonnet, mask, beard cover, gloves, goggles) and maintain good personal hygiene (makeup, jewelry, and other cosmetics are prohibited from the production areas)
- Must be able to perform aseptic gowning and related procedures
- Must possess strong verbal, written, and oral communication skills
- Must be able to work independently and with a team
- Must possess problem-solving skills
- Ability to recognize priorities and actively make productive use of time to build operational efficiencies
- Must exhibit punctuality and low absenteeism

Competencies

- Communication
- Organizational Skills
- Problem Solving/Analysis
- Results Driven
- Technical Capacity
- Detail Oriented

Supervisory Responsibility

This position has no supervisory responsibilities.

Work Environment

This job operates primarily in 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 need to lift up to 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.