Job Title
Site Mechanic

FLSA Status
Non-exempt

Summary
This position requires an individual who can work within a cGMP environment and is hard-working, dedicated, and reliable. The successful candidate must be focused on achieving both individual and site goals by showing an innate ability to manage equipment, remediate both planned and unplanned issues, be flexible and respond effectively to changing priorities at a moment's notice.

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

- Practice current Good Manufacturing Practices (cGMP) and Good Documentation Practices (GDocP) at all times
- Must have the knowledge, experience and capability to perform the following functions with precision and a sense of urgency while achieving desired results
    - Effectively assess, troubleshoot, repair and replace parts for pharmaceutical manufacturing and facility equipment
    - Must keep site management informed by communicating issues in a timely manner, provide approximate duration to remediation and have the courage to escalate unresolved issues
    - Liaison with vendors and contractors as it pertains to equipment servicing and repairs when necessary
    - Become an SME for future equipment selection process
    - Participate in the drafting and execution of equipment IQ/OQ/PQ
    - Manages equipment storage and keeps asset inventory list up to date
    - Maintains equipment functionality and performs routine, periodic preventive maintenance (PMs) and servicing on equipment as needed
- Must ensure safe working conditions and practices are always maintained. Must comply with Good Housekeeping Practices by keeping work areas clean, neat and orderly
- Must keep accurate records for all equipment to include but not limited to inventory asset records, execution of PMs, record of repairs or replacement parts as well as logbook and batch record entries
- All documented entries must be clear, accurate and in accordance with cGMP, GDP and EHS requirements
- Must be willing and able to collaborate on the initiation, review and closure of QMS items (included, but not limited to event, deviation, and CAPA reports, change controls and investigations) as it pertains to manufacturing and facility equipment
- May originate, revise, approve and/or review GMP documentation including but not limited to Batch Records, SOP's, Change Controls, Planned Deviations, Work Orders, Training Programs and Documentation as it pertains to manufacturing and facility equipment
- May be asked to train and on occasion perform setup of manufacturing equipment
- Lead and/or participate in equipment related projects
- Identify method improvement throughout the workplace. Assess and propose equipment layout for optimization
- Ensure all equipment complies with cGMP's, customer specifications and safety standards
- May assist in the training of personnel to ensure equipment is operated safely, efficiently and as intended

Required Education and Experience

- Minimum education requirements include a degree in mechanical, industrial, or process engineering or equivalent work experience
- The candidate has experience with successfully troubleshooting and maintaining manufacturing and facility equipment
- The ideal candidate is a mechanical or facilities engineer in the pharmaceutical industry
- Prior experience with Aseptic Filling and/or Solid Dose Packaging equipment is required
- Must be a certified boiler operator or willing to become certified within the 1st year of employment
- Experience with water systems a plus
- 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 troubleshooting and problem-solving skills
- Ability to recognize priorities and actively make productive use of time to build operational efficiencies
- Must exhibit punctuality and low absenteeism
- Able to sit and/or stand 8-10 hours or more per day as needed
- May need to lift up to fifty (50) pounds as needed

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 however duties can extend to the internal and external infrastructure of the site. This position requires the use of standard office equipment and responding to equipment-related tasks at the site.

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, stand, bend, or kneel for 8-10 hours or more in combination per day as needed
- May need to occasionally work in tight or confined areas
- May need to lift up to 50 pounds as needed

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
Travel may be required 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.