



Job Description – Equipment Engineer

Reports To – VP, Quality

Job Responsibilities

The Equipment Engineer will be responsible for the capital equipment preventive maintenance, calibration, and maintenance of inspection, measuring, and test equipment in accordance with the company's Quality System and customer requirements. This position will facilitate meeting Operations requests, serving at times as the interface between Manufacturing, vendors and/or suppliers. This position complies with the Quality system by engaging in appropriate levels GMP/ISO test methodologies, adherence to Quality System Design Controls, and applies proper documentation skills.

General Description and Duties:

To perform this job successfully, an individual must be able to perform each essential job task satisfactorily. The tasks listed below are representative of the knowledge, skill, and/or ability required to perform this job effectively.

- Works as part of the Quality Department, troubleshoots and analyzes manufacturing equipment problems to identify, evaluate, propose, and implement corrective actions while documenting the process and verifying the results. Ensures that documentation is in accordance with Quality System requirements. Executes training programs by determining methodology, preparing training materials, developing course content, and communicating effectively with key stakeholders, management, and trainees.
- Contributes to the development and implementation of inspection fixtures, measurement systems, and facilitates/performs calibration and preventive maintenance (PM) of such, as applicable. Works with all internal customers and external service vendors to schedule service dates and consolidate equipment into staging areas and then distribute back out to points of use. Acquires vendor quotes for items being serviced. Collaborates with Engineering to resolve equipment related non-conformances (e.g., out of tolerance conditions, missing, lost, or damaged equipment).
- Reviews assigned controlled documents (e.g., work instruction, quality specifications, engineering specifications, calibration records / reports) and might suggest edits to improve compliance and/or efficiency of processes.
- Performs job functions in a safe and effective manner. Helps promote employee adherence to safe procedures and practices throughout the company.
- Logs & Recordkeeping: Maintains compliance of quality related logs and records, including but not limited to, TE Items List, CAL/PM, Training, and others as assigned.

Projects and Other Duties:

- As assigned by the manager

Position Qualifications

- Knowledge and exposure to manufacturing equipment qualification, testing, calibration, and maintenance.
- Experience in a fast paced, multitasking environment with the ability to organize and prioritize multiple tasks and meet deadlines.

Minimum Education:

- Bachelor's Degree in Engineering, preferably Mechanical Engineering

Minimum Experience:

- 2 years of experience in medical device manufacturing, including calibration and Preventive Maintenance of complex electromechanical equipment and fixtures.
- Experience working under regulated quality systems such as cGMP's, ISO, and the MDD / AIMDD / MDR is a plus.
- Familiarity with Design Control procedures and requirements is a plus.
- Experience with Class II or III devices is a plus.