



## JOB DESCRIPTION

Position Title: Quality Engineer, Production Support (11:00 a.m. to 6:00 p.m.)  
Reports to: Director of Quality  
Department: Quality  
FLSA Status: Exempt

---

**PURPOSE OF JOB:** Responsible for supporting the quality needs of commercial and clinical operations. Responsible for the establishment and maintenance of quality assurance standards that adhere to QSR and ISO regulations. This position will be a bridge shift, supporting both the first and second manufacturing shifts. The core working hours for this position will be from 11am to 6pm, in which this position must be onsite.

**MAJOR DUTIES AND RESPONSIBILITIES:**

- Support the commercial and clinical manufacturing activities on the production floor.
- Review and approve Lot History Records (LHRs)
- Perform in-process inspections and pre-sterile packaging inspections
- Identify and assist with implementation of preventive and corrective actions via CAPAs, audits, NCMRs, and complaint handling systems.
- Support new equipment implementation for the manufacturing floor.
- Work with engineers to resolve line issues, suggest improvements and implement corrective actions.
- Maintain cleanroom integrity via company adherence to proper gowning techniques cleanroom environment practices and procedures.
- Interact cross functionally between Quality, Manufacturing and R&D.
- Ensure that all company employees follow written SOPs and process specifications.
- Work with Manufacturing Engineering and R&D on special projects, tests, or tasks as required.
- Provide training on Quality System elements to production staff as required.
- Participate in inspections for FDA, FDB, ISO, MDD, and other regulatory agencies
- Support company goals and objectives, policies and procedures, QSR, and FDA regulations.
- Maintain accurate records/documentation related to quality, test results, and special projects.
- Adhere to general safety rules, manufacturing procedures, company policies and procedures, QSR, Good Manufacturing Practices, and FDA regulations.

**EDUCATION /EXPERIENCE REQUIREMENTS:**

Bachelor's degree in Engineering/Life Sciences and 5-10 years of medical device experience. Experience with quality system elements pertaining to combination products (drug/device) and cGMP familiarity is strongly preferred.

**OTHER QUALIFICATIONS:** Strong written and verbal communication skills and attention to detail. Must work independently and have the ability to mentor junior quality associates. Must be flexible, as work may require occasional support of production's 2<sup>nd</sup> shift (1:30pm to 10pm) .

*This job description is not all inclusive. Incumbents may be required to complete other miscellaneous responsibilities as required.*