



JOB DESCRIPTION

Position Title:	Quality Associate I (2 nd Shift)
Reports to:	QA Supervisor
Department:	Quality
FLSA Status:	Non Exempt

PURPOSE OF JOB: Support quality assurance and production activities and adhere to QSR and ISO regulations. This is a 2nd shift position supporting a 1:30 p.m. to 10 p.m. production shift.

MAJOR DUTIES AND RESPONSIBILITIES:

- Review lot history records for product release
- Periodically audit production lines for conformance to QSR/GMP and documented procedures.
- Initiate nonconforming material reports and coordinate reports/dispositions with MRB and responsible engineers
- Perform device testing to support regulatory filings
- Perform in-process inspections and pre-sterile packaging inspections
- Create and maintain supplier files
- Provide backup support for Receiving Inspection
- Periodically inspect production facility to ensure QSR/GMP compliance.
- Cross train with technicians on all areas of inspection: incoming, in-process, final test, etc.
- Perform special inspections per engineering's request
- Cross-train and provide back-up support for the document/change control system (QCBD)
- Coordinate calibration schedules with outside source and maintain calibration files
- Provide support on validation studies for Engineering and Research and Development departments
- Thoroughly document all issues related to quality assurance, QSR, GMP and ISO compliance.
- Support company goals and objectives, policies and procedures, QSR, and FDA regulations.

EDUCATION /EXPERIENCE REQUIREMENTS:

High school diploma. 3 + years' related experience in the medical device industry.

OTHER QUALIFICATIONS:

Proficiency with MS Office Applications (Word, Excel, Outlook, etc.) and Adobe Acrobat, is a must. Knowledge of PowerPoint and Access, MS Project and Visio, preferred. Must have excellent communications and time management skills required. Must be organized and have strong attention to detail. Will perform many responsibilities independently once trained.

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