

Position Title: Manufacturing Engineer
Functional Group: Production, ME, Materials
Reports To: Director of Operations

PURPOSE OF POSITION: The Manufacturing Engineer completes assigned projects as required for Production. Responsibilities include but are not limited to inspection, production, equipment introduction, preventative maintenance, and process validation.

MAJOR DUTIES AND RESPONSIBILITIES:

- Support company goals and objectives, policies and procedures that comply with worldwide regulations.
- Develop manufacturing process instruction and device master records.
- Develop and perform process validations protocols and reports (IQ, OQ, PPQ).
- Review non-conforming product, assess condition and viable rework, and prepare rework instructions.
- Correct quality issues which may include meeting with management to develop quality or process improvement plans for the long term.
- Manage equipment files including facilitating calibrations, preventative maintenance, and back up parts purchase.
- Proactively report project activities, issues, and schedule to management.
- Collect, analyze and interpret manufacturing data to make sound decisions which impact production, personnel and processes.
- Support incoming inspection, finish good inspections and final product release for distribution.
- Validate cleaning of product and components per established procedures.

EDUCATION / EXPERIENCE REQUIREMENTS:

- Minimum Engineering degree is required
- Minimum 5 years' experience in medical device manufacturing

EDUCATION / EXPERIENCE REQUIREMENTS:

- Prefer 1 - 5 years of Manufacturing Engineering Experience in the medical device industry.
- Working knowledge of Quality Systems pertaining to medical device development and manufacturing.

OTHER SKILLS AND QUALIFICATIONS:

- Solid understanding of manufacturing processing
- Good data recording skills.
- Working knowledge of GMP, Gage R&R, and process controls
- Detail-oriented and strong organization skills
- Effective management of multiple tasks simultaneously

Associate Signature

Date Reviewed

Management Signature

Date Reviewed