

JOB DESCRIPTION

Position Title: Process Development Engineer

Department: Operations

Reports To: Equipment Manager

POSITION SUMMARY:

The Process Development Engineer will be responsible for overseeing all production activities within the manufacturing area, ensuring the smooth operation of processes and maintaining overall efficiency. Your expertise, experience and insights will be instrumental in refining our processes and playing a vital role in meeting daily and quality targets. We're looking for a highly motivated individual who is ready to push boundaries and dedicated to achieving production goals through determination and effort.

ESSENTIAL DUTIES:

- Create, maintain and improve “mid-volume” manufacturing assembly lines, specifying and/or refining BOMs, workflow processes, manufacturing plan and detailed work instructions.
- Design, document, procure, qualify, implement, and improve fixtures, tools and equipment.
- Analyze manufacturing line from a risk perspective (PFMEA) to incorporate and implement critical tests used in manufacturing.
- Responsible for the validation and qualification of manufacturing equipment and processes leveraging standard qualification approaches (IQ/OQ/DQ/PQ).
- Provide production line support for day-to-day engineering issues production lines.
- Identify and implement continuous improvement projects with respect to first pass yield, cycle time reduction, product reliability, capacity enhancement and cost reduction.
- Provide product and process DFX (Manufacturing, Assembly) input to enhance manufacturability of core instruments.
- Takes responsibility for maintaining compliance with medical device quality system including corrective action closure, discrepant material dispositions and ECO implementation.
- Provides technical support analyzing and /or performing failure analysis for discrepant production components, assemblies and field returns.
- Prior lean manufacturing experience prefer.

QUALIFICATIONS

SKILL/JOB REQUIREMENTS:

- Minimum BS / MS degree in Engineering discipline a must.
- A minimum of 3 years' experience as a manufacturing engineer supporting products with mechanical / electromechanical content.
- Must possess strong communication skills to interface with technicians, product development, planning, purchasing, inspection, and customer.
- Prior responsibility for process, equipment or product validation/verification is a plus.
- Prior experience designing automated equipment, complex mechanism manufacturing is a plus.
- CAD experience (preferred SolidWorks).
- Experience in an ISO 13485, ISO 9001, or medical device manufacturing environment a plus.