SYSTEMS ENGINEER III

Employment Type: **Full-Time / Exempt**
Department: **Device Manufacturing / 210**
Effective: **December, 2021**

Position Summary:

The Systems Engineer is responsible for leading the Nexus IB10 instrument manufacturing, field monitoring, troubleshooting, software/hardware sourcing, and improvement program. Acts as the Lead Engineer supporting the manufacturing of IVD consumables in an ISO-13485 and cGMP medical device manufacturing environment. The Manufacturing Engineer will have a thorough understanding through years of hands-on experience with continuous improvement techniques and with a proven track record of achieving cost savings and measurable operational improvements.

Education and Experience:

Bachelor's degree in Mechanical Engineering, Computer Science, Software Engineering or at least 4-5 years of engineering experience in an ISO and/or FDA regulated medical device manufacturing facility preferred. Experience with injection molding, dispensing, automation, IVD instrument manufacturing and instrument/equipment software. Expertise with IVD chemistry lab and assembly equipment, manufacturing processes, validation processes, fixture design, and terminology required. Three or more years' experience working in Quality System Regulations and ISO-13485 in equipment and process documentation required.

Essential Functions/Major Responsibilities:

- Establish Instrument Manufacturing at Nexus. Involves management of the Nexus IB10 instrument specifications, software, drawings and contract manufacturers. Works with Quality Assurance in creation of the necessary Technical Files, Manufacturing and Quality procedures and other documents in compliance with FDA QSRs, cGMPs, ISO, and MDD standards.
- Primary technical contact for Nexus IB10 instrument contract manufacturers, software developers and technical/development consultants. Drafts technical requirements and develops timelines for supply and service contracts. Works directly with contract manufacturers for the Nexus Instrument.
- Prepare product and component specifications and drawings, Manufacturing and Quality procedures per standards, and other documents in compliance with FDA QSRs, cGMPs, ISO, and MDD standards.
- Prepare, perform and report experimental, IQ/OQ/PQ, and validation protocols for Nexus IB10, equipment, components, devices, and processes.
- Transfer new methods and equipment to Manufacturing.
- Support manufacturing output at all times.

- Responsible for compliance with the company's quality system requirements through training and adherence to policies, procedures and processes.
- Editing of CAD models as required. Creation of artwork files on Adobe as needed.
- Manage Equipment maintenance, calibration, repairs and improvements directly or through subordinates.
- Proficient with standard Microsoft Office tools, Adobe, Statistical Software, mainstream CAD software.

Scope:

Receives assignments in the form of objectives and establishes goals to meet objectives. Works on problems of a diverse scope in which situations or data requires an evaluation of identifiable factors. Exercises judgment within generally defined practices and policies in selecting methods and techniques for obtaining solutions. May assist in developing and modifying functional area policies. Works within functional area budgets; develops schedules and performance requirements and ensures they are met.

NOTE: The above Job Description is intended to communicate the general function of the mentioned position and by no means shall be considered an exhaustive or complete outline of the specific tasks and functions that will be required. Additionally, specific tasks and duties of the position are subject to change as the Company, the department and circumstances change. All employees are expected to perform their duties within their ability as required by the job and/or as requested by management.