https://www.biolink360.com/job/manufacturing-quality-engineer/

Manufacturing Quality Engineer

Hiring organization
BioLink 360

Employment Type
Full-time, Contractor

Industry
Medical Device

Job Location
Puerto Rico

Base Salary
$ 45 - $ 55

Date posted
January 8, 2025

Description

Job Title: Quality Engineer
Reports to: Senior Manager of QMS
Location: Puerto Rico-Hybrid
Type of Role: Contract Position
Start Date: Feb 2025

Company Overview: Our client is a global healthcare leader dedicated to improving lives through innovative medical technologies. With a global presence, they provide solutions ranging from diagnostics to medical devices, offering transformative products that aid in patient care decision-making across various health conditions.

This person in this role will provide engineering expertise to the development, installation, validation and qualification of equipment to ensure proper operation of the equipment.

Responsibilities

- Collaborate with Manufacturing, Information Management, Research Development & Engineering, Quality Assurance Operations, and Product Performance Analysis teams to ensure compliance with LifeScan software development procedures and industry regulations.
- Provide expertise in troubleshooting and resolving technical issues with equipment.
- Conduct all verification and validation activities for a new site.
- Handle IQ, OQ, PQ protocol generation and execution, deviations and reports generation.
- Assist teams in developing tailored Standard Operating Procedures and Work Instructions.
- Develop and execute process validations, conduct studies, and perform evaluations as needed to ensure process capability
- Perform daily check-ins on assigned production lines and areas
- Coordinate new product or process start-ups with all operational departments
- Develop machine specifications and manage outside vendors to ensure compliance with developed machine specifications and schedules
- Comply with statutory responsibility under the national/federal regulations – take reasonable care of your own health, safety and welfare along with teammates that may be affected by your acts at work
- Participate in EH&S activities such as: root cause analysis, finding solutions, implementing improvements, inspections, and meetings, training
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Qualifications

- Bachelor’s degree in Engineering required,
- 3-5 years of experience in Engineering, preferably within the medical device

manufacturing industry.

- Strong attention to detail and ability to manage regulatory compliance and reporting requirements.
- Strong background in V&V activities
- Knowledge of FDA Quality System Regulation, ISO13485, and other international standards.
- Excellent communication and interpersonal skills, with the ability to collaborate effectively across teams.
- Proven ability to lead and drive quality improvement initiatives in a dynamic environment.