Toll Free: 800-826-2926
Phone: 410-715-1700
Fax: 410-715-4511
Website: www.acell.com

Job Description

Title: Quality Systems Engineer
Department: Quality
Location: Columbia, MD
Type: Full-time

Job Summary
In collaboration with Quality team members and other departments cross-functionally, the Quality Systems Engineer will ensure that products are safe and effective, and that the Quality Management System (QMS) complies with ISO 13485 and 21 CFR Parts 11, 803, 806, and 820.

Principal Responsibilities

- Perform Test Method Validations for all in-process monitoring, analytical laboratory tests, and final release inspection and testing
- Participate in internal and external quality audits
- Practical application of Corrective Actions and Preventive Actions (CAPA) system
- Develop, execute, and analyze quality-reporting measures
- Report to management on quality issues, trends, and losses
- Monitor storage and distribution of components and finished goods
- Serve as a resource to internal departments for problem identification and resolution
- Support concurrent engineering efforts by representing Quality in design development projects
- Design and implement methods for process control, process improvement, testing, and inspection
- Conduct trend analysis of non-conformances and other quality indicators as needed
- Participate in supplier selection, assessment, and monitoring program
- Participate in quality control activities such as batch records, receiving records, environmental monitoring, and product release

Required Education and Experience

- B.S. degree in a scientific discipline (Chemistry, Biology, Physics, Biomedical Engineering, Chemical Engineering, etc.)
- Minimum of 3 – 5 years of Quality engineering experience in the biomedical industry, preferably in medical devices
- Thorough understanding and application of validation principles with an emphasis on Test Method validation
- CQE, CQA, Six Sigma Black/Green belt preferred

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- Well-versed in CFR Part 820, Part 11, ISO 13485, and ISO 14971 Standards
- Quality engineering experience with analytical tools
- Experience in applying statistical methods for quality improvements
- Experience in design control and process validation, root cause analysis, and corrective and preventive action (CAPA)

Required Knowledge, Skills, and Abilities

- Computer literacy—experience with Microsoft Outlook, Excel, PowerPoint, Word, Access, and project databases
- Management and/or interaction with multilevel staff
- Excellent organizational skills; organized file management
- Strong communication skills, both written and verbal
- Professional, assertive demeanor
- Knowledge in supplier quality engineering and management