Position: Device Quality Manager

Reports to: Associate Director of Quality
Location: Remote – Seattle area

Blaze Bioscience, Inc. is a biotechnology company committed to improving outcomes for cancer patients. We are developing an imaging agent, Tumor Paint: BLZ-100, to help surgeons distinguish tumor from normal tissue during surgery, with our lead indication in pediatric brain cancer. In conjunction with BLZ-100 we are developing an imaging system, Canvas, to enable BLZ-100 visualization during surgery. BLZ-100 and Canvas are being evaluated in a Phase 2/3 clinical study in pediatric brain tumors.

Position Summary

The Company is seeking a Device Manager of Quality Assurance with experience in the medical device industry and with extensive knowledge performing their function within the Food & Drug Administration (FDA) Quality System Regulations (QSRs), International Organization of Standardization (ISO) 13485:2016, Medical Device Regulation (MDR) 2017/745, ISO 14971:2019.

The Device Manager Quality Assurance will report directly to the Associate Director of Quality and will work closely within project teams (and in some cases independently) contributing technical leadership/knowledge in the testing and evaluation of Blaze Bioscience products. This position will contribute to the review of design choices with project management, design architects, design engineers and other quality staff while developing test plans and test cases. This position will interact with project management, design engineers and other technical/support staff on a regular basis.

Detailed Responsibilities

- Implementing and maintaining Quality Management System (QMS), that complies with ISO 13485, ISO 14971 and FDA 21 CFR Part 820
- Develop, administer and maintain quality assurance procedures and activities required to ensure that the company's processes and products are in compliance with applicable quality standards and requirements.
- Design, implement, execute, and manage test plans, test cases and test results for Blaze products.
- Root cause analysis and implementation of corrective action for process related concerns.
- Interface with Engineering, Operations and Product Management to design and implement appropriate verification methodology and documentation supporting release of products (alpha, beta, final)
- Support the quality inspection to ensure projects, products and processes comply with the relevant requirements of the QMS
- Analyze failure, corrective and preventive action to respond to internal/external customer complaints.

- Create and maintain company quality documentation, such as manuals, procedures, etc.
- Continuously improve QA processes and procedures.
- Preparation of QA reports.
- Preparation of documentation for submission to FDA for medical device approval and/or response to FDA inquiries.
- Other duties as required.

Education/Experience:

- Minimum BS/BA in a science or engineering discipline
- 5+ years of experience implementing test strategies, test plans and test cases for product validation and verification in FDA-compliant medical device industry
- Demonstrated success in a start-up or fast pace, entrepreneurial work environment
- Thorough knowledge of FDA Quality System requirements, ISO 13485:2016 (Quality System) requirements, ISO 14971 (Risk Management) requirements, Medical Device Directives (MDD) requirements, Knowledge of Good Manufacturing Practices (GMP) and applicable Quality System Standards
- Working with contract design/development and/or contract device manufacturing, or overseeing manufacturing operations
- Familiar with EN 60601, Safety requirements for medical electrical systems
- Familiar with ISO 62304, Medical Device Software – Software Life Cycle processes
- 4 or more years of experience with QMS implementation that complies with FDA 21 CFR Part 820, ISO 13485 and ISO 14971 standards
- Administrative or technical role in one or more FDA submissions for approval of a medical device
- Lead role (administrative or technical) in one or more FDA audits for review of a medical device

Special skills/knowledge:

- Self-motivated with ability to effectively prioritize
- Project management skills and proficiency and analyzing and interpreting data
- Excellent written and verbal communication skills
- Accuracy and attention to detail
- Excellent cross-functional team leadership skills

To apply for this position, please send your CV with cover letter to:

Blaze Bioscience, Inc.
Attn: Human Resources 530 Fairview Avenue N, Suite 1400
Seattle, WA 98109
Email: careers@blazebioscience.com
Blaze Bioscience, Inc. is an Equal Opportunity Employer.