



Senior Quality Assurance Engineer

The Senior Quality Assurance Engineer is responsible for implementing, maintaining, and improving Precision Biopsy's (PB) internal Quality Management System (QMS). The Senior Quality Assurance Engineer is also responsible for collaborating with design partners, OEM vendors, and suppliers in defining, managing, and integrating their quality system documents and records into the PB QMS. The PB QMS is a critical asset for advancing the company's novel optical biopsy and tissue classification system toward commercialization in the cancer market. More information can be found at www.precisionbiopsy.com

Responsibilities:

- Create, implement, maintain, improve, and verify PB's QMS.
- Generate and review applicable quality system documentation including SOPs, Work Instructions, Test Protocols and Reports, Risk Management and Design & Development documents, labeling, and other quality system documentation.
- Participate in developing and reviewing product and subsystem requirements to ensure they are unitary, complete, consistent, traceable, feasible, unambiguous, testable, and verifiable. Support the traceability of risks and requirements to execution of verification.
- Support design control activities including development and maintenance of appropriate documentation such as risk management reports and design history files, and other documentation related to change control.
- Contribute to verification activities including developing the Verification & Validation Plan that defines all V&V activities, work closely with the engineering team to develop black box functional test protocols that verify the system level requirements and provide visibility into the tests that the design will need to meet.
- Participate in risk analysis and requirements reviews to ensure that identified risks are mitigated to an acceptable level and that all requirements have test coverage.
- Ensure that all appropriate Software Verification & Validation activities are followed including that low-level unit testing is adequate to the level of concern

and that all configuration management, build, release and version control methods are followed.

- Conduct testing per test protocols and develop test reports. Complete traceability of requirements to tests.
- Participate in internal audits and assessments of the Quality System with suggested changes for continuous improvement.
- Implement and maintain procedures and processes related to external suppliers, their quality systems, and integration of their quality records into PB's QMS.
- Perform and/or coordinate supplier audits and assessments of the supplier's Quality System and expected QMS deliverables.
- Develop inspection documentation and support incoming inspection of materials.
- Coordinate and/or assist in the preparation of approval applications and technical documentation for Regulatory Agencies and Compliance Agencies.
- Assist with Regulatory Agency and Compliance Agency audits.
- Support compliance with the company quality standards, FDA regulations and guidance, applicable EU Medical Device Directives, applicable ISO standards, and other pertinent country specific medical regulatory requirements.
- Other duties as assigned by PB Senior management.

Qualifications:

- Working knowledge of FDA QSR, ISO 13485, ISO14971 and MDD regulations.
- Excellent attention to detail and documentation practices.
- Proven product development track record in medical device industry.
- Willing to do what it takes to get the job done, efficient multi-tasking abilities.
- Energetic self-starter with strong initiative and sense of ownership.
- Demonstrated problem solving abilities and excellent communication skills.
- Team player and strong work ethic.
- Willingness to travel as required: 10%-15%.

Education and Experience Requirements:

Senior Quality Assurance Engineer must have a BS or MS in science, engineering, quality, or equivalent experience as determined by PB Senior Management. Must have a minimum of 7 years of related experience. Medical device industry experience is a must.

To apply for this position, please send resume to:

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