ArcScan, Inc.
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Quality Systems Engineer

How to apply: Go to **https://arcscan.bamboohr.com/jobs/view.php?id=1**

Location: CO – Golden, Full Time In-Office

This critical lead role will require understanding of the ArcScan Insight® 100 and ArcScan Quality Management System. An ideal candidate for this position will be a disciplined and effective performer who can efficiently self-manage in order to maintain high productivity. Demonstratable experience in creating and contributing to standardized processes and procedures is essential.

Education/Experience Requirements

- Knowledge and experience with creating and maintaining Quality Management Systems as defined in ISO 13485 international standards for medical device quality.
- Knowledge and experience in creating and maintaining entire product lifecycle design history files/records (DHF/DHR) and device master records (DMR) from concept to post-market surveillance.
- Knowledge and experience with maintenance and execution of engineering change orders (ECO) within the FDA-regulated medical device industry.
- Knowledge and experience with FDA Regulation 21 CFR 820.
- Knowledge and experience with statistical techniques.
- Knowledge and experience with Design Control and Risk Management (e.g. FMEA, Hazard Analysis).
- Training and experience in Internal Auditing of Quality Systems.
- Training and experience in Document Control and Record Control.
- Experience operating in an eQMS.
- Experience in Quality Engineering (in addition to Quality Systems Management).
- Capable of demonstrating technical writing and analytical reporting skills.
- Capable of demonstrating leadership, time management, and communication skills.

Duties and Responsibilities:

- Lead and support the Quality Management System (QMS) to ensure that it is established, implemented, and maintained for effectiveness in accordance with applicable regulations, standards, and/or regional requirements.
- Identify and implement opportunities for continuous improvement of the QMS.
- Oversee and participate in the monitoring, measurement, and analysis process. Generate analysis reports and present QMS analyses to ArcScan management.
- Oversee and participate in the QMS processes of Internal Auditing, Complaint Handling and Adverse Events, Corrective / Preventive Action, Document and Records Control.
- Create, maintain, provide and track training on Quality System procedures and other required documents to ArcScan employees.
- Provide oversight, support and approvals for contract manufacturing production testing and controls (e.g. equipment controls, process validation, test method validation, DHR review and maintenance).
- Lead and participate in internal and external audits.
- Oversee and participate in the Risk Management process.
- Participate and manage Quality Planning, Design Control, and Design Transfer processes.
- Analyzes quality system data and generates reports for top management.
- Provide service engineering support of field devices as a quality engineer, as needed, with regards to ensuring field complaints/issues are routed in appropriate manner to ensure effective and efficient root cause analysis and mitigation.

Knowledge and Skills Required:

- Intermediate level.
- Candidate has at least five years of experience in medical device or pharmaceutical industries.
- Quality Systems development and management REQUIRED.

Compensation:

- $70,000 per year (somewhat negotiable)
- Annual Bonus of $5,000 based upon meeting certain criteria to be stipulated.