September 23, 2020

Company
Amalgam Rx, Inc.

Department
Regulatory & Quality

Company Overview
Amalgam is a digital health technology company that develops mobile solutions to drive behavioral and clinical change in chronic disease. Amalgam's goal is to improve patient self-management and help healthcare providers improve decision making to improve clinical outcomes and decrease cost. Amalgam is developing multiple digital health solutions across the chronic disease spectrum. Digital health solutions have the potential to support the gap between patients and providers during the time that individuals are living their lives outside the healthcare system. Amalgam has a proven executive team and has partnerships with leading life sciences companies to accelerate R&D and commercialization.

Job Purpose

The Quality Engineer will ensure that Amalgam's portfolio of products meet all necessary requirements before they reach the consumer and maintain compliance while in the market. The role will involve supporting the continuous improvement of the quality system, guiding members of other teams within Amalgam on the quality system requirements throughout the product lifecycle, support supplier management and risk management activities, support internal auditing, inspect the final product and documentation to make sure it has been built with compliance to legal and regulatory standards and meets customer expectations (e.g. patients, providers, and payers).

Position Type
Full time position requires 40 hours.

Job Responsibilities

- Support the development and maintenance of the quality management system in accordance with 21 CFR Part 820, MDD 93/42/EEC, ISO 134815:2016, and other regulatory requirements and applicable international standards.
- Support the development and submission of global market authorization applications.
- Develop comprehensive approach to achieve external standards for quality, safety, and reliability including data management and outcomes reporting.

- Aggregate data, provide reports to management, and participate in audits of departments/processes for compliance with regulatory requirements.
- Lead communication, networking, and knowledge transfer of regulatory information and data outcomes to appropriate internal and external stakeholders.

Required Skills & Experience

Desired Attributes:

- A minimum of 2 years of experience in medical device development; strong knowledge of software development is preferred
- Results-oriented, with an ability and flexibility to manage multiple projects simultaneously
- Ability to distill and communicate complex information
- Ability to execute in a fast-paced environment
- Uncompromising with respect to quality in all regards
- Team player, good listener and capable of building strong relationships
- Enthusiasm, high energy, and mind-blowing determination to succeed
- Proven problem solver and ability to build and lead a successful team
- Self-starter, able to work independently or in a team environment
- Strong written communication skills
- Unquestionable integrity and ethics

Knowledge & Experience:

- Experience with startup/early stage companies
- Proven experience with software design and development
- Proven experience with regulatory, quality and compliance requirements

Required Education

A strong academic background with a Bachelor's degree in Computer Science, Engineering or similar major is required.

Compensation & Benefits

Amalgam offers competitive compensation, outstanding benefits, plus equity ownership for all employees.