Senior Manager of Quality and Regulatory Affairs

909 Davis Street Suite 500
Evanston, IL 60201
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Contact:
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Job Description

Rhaeos, Inc. is a clinical stage, venture backed medical device company developing wireless wearable and non-invasive sensors for a number of healthcare applications. The company's first product has been designated as a breakthrough device by the FDA. Rhaeos is located in Chicago and Evanston, IL and is led by an experienced medical device team. The Director of Quality and Regulatory Affairs reports to the company's Chief Executive Officer. He or she is responsible for the overall quality and regulatory activities of the company. Specific responsibilities include, but are not limited to the following:

- Quality Responsibilities
  - Responsible for planning, directing and maintaining an effective Quality program in compliance with ISO 13485:2016, FDA, CMDR, MDR, and will assist all areas of the company including design, manufacturing, purchasing, shipping and receiving, training, and other areas to implement a comprehensive, effective quality system consistent with Rhaeos' Quality Policy and Quality Objectives.
  - Review and analyze quality trends with the manufacturing team.
  - Implement quality system improvements.
  - Evaluate the implemented corrective and preventive actions against trends and quality issues to assess effectiveness of it.
  - Appointed as the Quality Management Representative and is responsible for ISO13485 quality system including oversight of the quality policy manual, procedures, work instructions, Device Master Record, Design History file, Corrective and Preventative Actions, handling of complaints, and all other related quality areas. The management representative will also support all customer driven quality requirements and ensure vendors and supplier meet Rhaeos' quality requirements.
- Regulatory Responsibilities
  - Under the direction of the Chief Innovation Officer, oversee regulatory affairs for Rhaeos including strategy, FDA registrations, submissions, inspections, and interactions with FDA. Responsibility of regulatory matters also extends to outside of the United States.
  - Research, prepare, construct, and submit documentation for product registration and clearance/approval applications.
  - All activities must be performed in compliance with the company's Quality System.

Required Qualifications

- Bachelor's degree in the life sciences or technical (health, science, or engineering) field.
- ISO13485:2016 quality systems experience.

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- Participation in FDA submissions and related interactions.
- Minimum 4 years in a senior quality or regulatory position.
- Excellent written and oral communication skills and ability to work with multi-disciplinary collaborators.
- Ability to handle multiple activities simultaneously and to effectively prioritize tasks and responsibilities.
- Strong organizational and problem solving skills.
- Strong interpersonal skills.

Desired Qualifications

- Upper management experience in a start-up.
- CE marking and notified body interaction experience.
- CMDR and MDR experience.
- Working knowledge or experience in business development, technology analysis, intellectual property protection and licensing, and commercialization of technology.

Other

- Work Location: Evanston, IL; remote work also an option.
- Full-time with benefits: health, dental, 401(k)