



Quality Associate

PART-TIME OR FULL-TIME, CALGARY, ALBERTA, CANADA

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ABOUT THE TEAM:

THE VIBE ATTRACTS THE TRIBE

The people at Orpyx are flexible thinkers and creative innovators. We come from a variety of backgrounds and carry a wealth of expertise in multiple industries, including medical, technology, software, marketing and finance. What we all have in common is an intense passion for the work we do. We have an extraordinary collection of talent that makes working here fun, unique and inspiring. Our hiring goal moving forward is to continue to build and grow a strong, effective team, while maintaining our friendly and innovative company culture.

Orpyx develops sensor-based wearable solutions that address the growing demand for self-monitoring devices to more effectively quantify real-world human movement. These devices can be used to optimize the management of chronic diseases, enable sport performance assessment, and prevent injuries. Our flagship device, the SurroSense Rx® smart insole system, is a device used to empower people with diabetes to take control of their disease and play a more active role in the prevention of diabetes-related complications such as foot ulcers and amputation. The insert sends feedback to a wristwatch, alerting the wearer in real-time of dangerous plantar pressure or injury, enabling them to adjust behavior immediately to prevent damage.

HOW YOU'LL MAKE AN IMPACT AND WHAT YOU'LL DO:

As a Quality Associate, you will be reporting to the Quality Manager. The successful candidate will provide support to development and maintenance of the company's quality system. This position will be multi-disciplinary, adapting in the early-stage company environment as needs and priorities change.

YOUR RESPONSIBILITIES WILL INCLUDE:

Quality Assurance Analysis:

- Conducting weekly support review meetings, communicating and resolving support issues within the organization. This includes creating detailed meeting agendas and meeting minutes, including action items with deadlines.
- Creating Quality Management System (QMS)-related tickets
- Following up and resolving action items created in the support review meetings.
- Creating, tracking and maintaining QMS-related tickets using the company's software tools
- Assisting the Operations department with product non-conformity investigations
- Working with relevant personnel to prepare and update QMS documents, including work instruction, standard operating procedures, and reference documents.

Quality System Management:

- Being responsible for general maintenance of the company's QMS to ensure compliance with ISO 13485, US FDA Title 21 CFR 820, Health Canada Canadian Medical Device Regulations (CMDR) and other requirements based on new jurisdictions the company may choose to operate in.
- Developing and writing standard operating procedures (SOPs) per the company's QMS requirements

- Assisting the company's Quality Manager with the preparation for, and participation in audits (internal, external, and vendor-initiated)
- Assisting Sales, Marketing and Operations in the event of a regulatory notification and/or product recall
- Assisting management representative and department heads with personnel training related to QMS processes as required
- Assisting Product Management and Operations with the maintenance of Device Master Record and distribution records.

Additionally, due to the ever-changing and sometimes chaotic environment of an early-stage high-tech company, the Quality Associate may assume additional roles and responsibilities as the company requires.

Daily travel may be required between Orpyx Headquarters and patient care facilities. Occasional travel outside of the city may be required.

MINIMUM COMPETENCIES REQUIRED:

Experience

- A minimum 3 years' experience in customer service or related field, with specific experience in:
 - Designing, implementing and managing quality systems
 - ISO 9001:2015 and ISO 13485:2016 quality systems

Skills

- Professional and effective communication skills are essential
- Proven self-motivation and ability to deliver under pressure
- Ability to thrive in a start-up environment
- Excellent written and verbal communication skills
- Ability to work in a small and rapidly growing high-tech company environment

Fluency in foreign language(s) is considered an asset.

Education

- 4 years bachelor's degree, or equivalent
- QMS-related training an asset

Will consider relevant experience a substitute in some cases.

ABOUT ORPYX MEDICAL TECHNOLOGIES INC.

Founded in 2010, Orpyx Medical Technologies empowers people with diabetes to maintain mobility. Orpyx's core product line, SurroSense Rx[®], helps prevent foot ulcers and limb loss through FDA cleared, advanced foot sensor technology and analytics, delivered in an easy-to use ultra-thin insole. Orpyx's technology is used by researchers to access clinical-grade plantar pressure measurement data for health and human performance applications. Orpyx is focused on collaborating with stakeholders around the world to achieve a healthcare future that is prevention focused and sustainable in cost. Learn more at www.orpyx.com.

To apply, please submit your resume and cover letter to: careers@orpyx.com

Orpyx is an equal opportunity employer.