Regulatory and Quality Assurance Support

To oversee product development and deployment for MyWay Digital Health.

Salary: £25-30K, plus share options and wider employee benefits. Salary will be negotiable commensurate with experience

Duration: Part-Time contract, with options for flexible working (upon successful completion of the probationary period)

Role

1. **Documentation and Submission:**
   - Assist in preparing, reviewing, and organising regulatory documents required for product registration for a medical software device.
   - Ensure accuracy, completeness, and compliance of regulatory documentation.
   - Support with the submission of applications, amendments, and variations as per ISO 13485 standards.

2. **Compliance Support:**
   - Review various documents to ensure compliance with regulatory guidelines.
   - Monitor changes in regulations and update internal processes accordingly.
   - Assist in maintaining regulatory compliance standards within the organisation.

3. **Recordkeeping and Tracking:**
   - Maintain and organise regulatory files and databases.
   - Manage product registration information, licenses, and correspondence with regulatory authorities and consultancies.
   - Track and monitor the status of regulatory submissions and approvals.

4. **Incident Reporting:**
   - Support the collection, documentation, and reporting of incidents or product complaints.
   - Ensure timely and accurate reporting of incidents as per MWDH SOPs (Standard Operating Procedures).

5. **Training and Awareness:**
   - Assist in organising training sessions or workshops to enhance regulatory knowledge and awareness among MWDH employees.
   - Support initiatives to promote a culture of regulatory compliance and quality assurance within the organisation.

6. **Audits and Inspections:**
   - Assist in preparing for regulatory audits and inspections, such as ISO 27001 and ISO 13485.

- Ensure all required documents and information are readily available for audits and inspections.
- Support the regulatory team during inspections, responding to requests and addressing findings.

Essential Requirements

- Strong understanding of regulatory compliance requirements, preferably in the relevant industry (e.g., medical software devices).
- Familiarity with ISO 13485 and other applicable regulatory standards.
- Excellent organisational skills and attention to detail.
- Strong written and verbal communication skills.
- Proficiency in document management systems and databases.
- Ability to work collaboratively with cross-functional teams, specifically the technical development team.
- Knowledge of incident reporting procedures and quality management systems.

Desirable requirements

- Prior experience in regulatory affairs or quality assurance role.
- Experience in preparing for and participating in regulatory audits and inspections.
- Knowledge of international regulatory requirements

Person Specification

- Positive outlook
- Motivated
- Proactive
- Flexible
- Pride in your work
- Keen to make a difference
- Ownership of tasks
- Able to work independently or as part of a team
- Excellent inter-personal skills
- Honest
- Reliable
- Great communication and presentation skills

About Us

MyWay Digital Health Ltd is a purpose-driven SME that was spun-out of Dundee University in Jan 2017, with the aim of supporting chronic disease management globally through affordable data-driven approaches starting with diabetes. Our flagship self-management platform, MyWay Diabetes (previously known as MyDiabetesMyWay- the national diabetes platform in Scotland) has a very strong evidence base and value story. Current commercial coverage is around 1/4 of NHS England and over 80,000 data registrants/ 2.6 million people have used our platform to access advice. We aim to grow our UK market coverage further through additional products and services including clinician facing platforms and cutting-edge AI-driven predictive analytics tools. Internationally, we

have set up an office in Dubai and currently transferring from pilot projects in the Middle East to commercial deployment. This is an incredibly exciting time to be joining the company and the possibilities are almost limitless for the right candidate.

The existing team are friendly, positive and keen to make a difference.

Our Vision: Transforming Care of Diabetes and other Long-Term Conditions

Our Mission: Improving the lives of people living with chronic conditions through data driven technology solutions