Surgical Innovations

JOB DESCRIPTION

Job Title:	**Regulatory Affairs Assistant**
Department:	**Compliance**
Reports To:	**Regulatory Affairs Manager**
Location:	**Leeds**

JOB SUMMARY

The main focus of the role is to assist with maintaining compliance with the regulatory requirements of the business in line with timelines set by relevant regulations. In addition, assist with the day-to-day regulatory activities which will involve work to departmental priorities to meet the demands of the business. The role may require participation in areas of quality to ensure efficiency of business activities, continuous improvement, and compliance.

KEY DUTIES & RESPONSIBILITIES

- Assisting with global product registrations in accordance with country-specific requirements and internal systems.
- Assisting in the writing and preparation of technical documentation to meet regulatory submission requirements e.g. CE submissions and US FDA 510k submissions.
- Assisting with updating relevant global, regional and local databases in the product registration process, as appropriate.
- Organising and maintaining reporting schedules for regulatory actions i.e. licence renewals.
- Participating in medical device regulatory compliance gap analyses and implementation.
- Assisting with medical device labelling compliance.
- Regulatory point of contact for international distributors, providing support for enquiries and requests.
- Coordinating distributor evaluation and approval.
- General administration such as filing and maintaining electronic and physical regulatory records.
- Any other duties as required by management

FUNCTIONAL & TECHNICAL COMPETENCIES

Essential	Desirable
• Strong administration skills. • Computer competency in Microsoft Office software, data collection and general analysis tools. • Excellent planning and organisational skills. • Effective communicator with good interpersonal skills • Ability to plan and complete tasks to meet deadlines • Cross culturally aware. • Able to work in a cross-functional team. • Team player. • Enthusiastic and committed.	• Project management skills (Work breakdown structure, basic Gantt charting, communication plan) to manage regulatory projects.

QUALIFICATIONS & EXPERIENCE	
Essential	**Desirable**
• Experience of working in an administrative role. • Able to demonstrate work undertaken previously that has been satisfactorily completed within agreed timescales.	• Regulatory experience covering medical devices. • Knowledge and awareness of the requirements of ISO 13485:2016 • Knowledge/understanding of EU Medical Device Regulations (MDR) and MDSAP regulations. • Bachelor's Degree, preferably in a Science or Engineering field • Relevant experience in the Medical Devices industry