Regulatory Affairs Associate

Reporting to: Regulatory Affairs Manager	**Direct Reports:** None
Department: Clinical and Regulatory	**Location:** Office – Harrow/Watford
Contract Type: Permanent	

Company Information

Established in 2000, Clinisupplies is a UK based medical devices company specialising in the manufacturing and marketing of products for the primary and secondary healthcare sectors.

Vision: Access to precision medtech for every patient, globally

Values

- Agile
- Inquisitive
- Collaboration

What do we stand for?

Same on outcomes. Better on price
At Clinisupplies, we want to make a difference in healthcare. That means understanding our customers' needs and delivering on their biggest priorities. We recognise that the NHS needs to offer quality of care and save money – that's why Clinisupplies offers products that are designed to deliver value to customers. With a strong focus on Urology, Wound & Skin care, and Wound Closure, our products and services are developed to assist clinicians and patients, with practical solutions that provide high quality outcomes at an exceptional price.

Role summary

This role will be supporting the Regulatory team across a wide range of activities some of which include managing our Quality Management System (QMS) including creating and reviewing Standing Operating Procedures. You will manage and handle product complaints including incident and vigilance reporting as per MHRA criteria. You will be responsible for conducting internal audits across departments as well as supporting during external audits. You will also work with the wider business in preparation of technical files and be responsible for the registration process with MHRA in line with guidelines.

Key Responsibilities

The following provides an indication of the key responsibilities involved in this role but is not intended to be an exhaustive list of all the duties that you may be required to do

- Assist line manager for all regulatory aspects of the CE marking process for the assigned medical devices with emphasis on regulatory compliance and life cycle maintenance.
- Provide final approval for incoming medical devices by checking compliance documents and Accepted Quality Level (AQL) parameters to ensure that products released for sale comply with the regulatory requirements.
- Manage and maintain product related complaints in accordance with the company procedure and vigilance reporting criteria set by MHRA (MEDDEV 2.12-1).
    - Ensure root cause, corrective and preventative action can be taken with suppliers to improve the quality of products
    - Ensure final investigation and satisfactory closure feedback is provided to the customers, MHRA and notified body and any follow up actions are followed as per the MEDDEV 2.12 guidelines
    - Trend analysis and subsequent improvement and development of products which can provide real benefits to the business
- Ensure products are registered and maintained with the competent authorities.
- Assist during external audits.
- Conduct internal audits and manage Corrective Actions and Preventative Actions (CAPA) arising from internal audits.
- Update and maintain the QMS related activities by ensuring an ongoing compliance with the latest regulatory requirements for all medical devices are maintained as per ISO13485:2016.
- Write new Standard Operating Procedures or update existing ones as per the document control process and maintaining them on the support platform within the organisation.
- Assist line manager in negotiating regulatory bodies for marketing authorisation.
- Liaise with the suppliers on a regular basis to obtain thorough investigation report for complaints or any quality matters.
- Review quality records, checking compliance /conformity documents as per the required regulatory standards for ETO and Gamma sterilisation and maintain the relevant records for product release and audit purposes.
- Prepare and maintain Technical Files in accordance with the Medical Devices Directive 93/42/EEC and Medical Devices Regulation (MDR)
- Register new product lines on MHRA database and update the existing line registration where required.
- Support new product development (NPD) activities and ensures that any regulatory requirements are completed.
- Assist line manager with any other duties as appropriate within their competence, as required from time to time such as conducting inductions or training new members.

Skills and knowledge required

- Science degree
- Excellent communication skills both verbal and written
- Strong collaborative skills
- Knowledge of regulatory requirements for medical devices including Medical Device Directive (MDD) 93/94/EEC, ISO 13485
- Experience in managing internal audits and supporting external audits
- Self-motivated with excellent organisational

- Strong knowledge of Word and Excel to prepare month end reports
- Able to prioritise work and key issues in complex situations and be able to resolve these problems with minimal assistance
- Strong attention to detail

Desirable

- Awareness of New Medical Device regulations (MDR)
- Knowledge of ISO 14971

Clinisupplies is dedicated to the continuous development of our employees and offer excellent career prospects for the strong candidate. We offer an attractive benefits package including a competitive salary, 27 days holiday pro-rata (increasing with service) plus bank holidays, pension, profit related pay.

Clinisupplies Limited is an equal opportunities employer and positively encourages applications from suitably qualified and eligible candidates regardless of sex, race, disability, age, sexual orientation, gender reassignment, religion or belief, marital status, or pregnancy and maternity.

How to apply

If you are interested in this position, please forward your CV to recruitment@clinisupplies.co.uk

Please note that in addition to the interviews there will be assessments as part of our recruitment and selection process.