Regulatory Affairs Co-ordinator

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

We are looking for a motivated and enthusiastic individual who is looking to develop a career within Regulatory Affairs. You will be responsible for supporting our Quality Management System (QMS), handling product complaints and working with the team and wider business in preparation of technical files in line with regulatory 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

- Understand and maintain QMS related activities by ensuring ongoing compliance with the latest regulatory requirements for all medical devices, ensuring they are maintained as per ISO13485:2016
- Prepare, update and coordinate documentation (SOP's, forms and instructions) and maintain them in order to keep the QMS up to date
- Manage and maintain product complaints in accordance with company procedure as well as the reporting criteria set by MHRA (MEDDEV 2.12-1):
    - Ensure a thorough investigation is carried out and that the root cause, corrective preventative actions and effectiveness is obtained and maintained
    - Ensure final investigation and satisfactory closure feedback is provided to the customers, MHRA and notified body
    - Ensure all relevant reports are generated for trend analysis which support product development
- Review quality records, checking compliance/conformity documents as per the required standards and maintain the relevant records for product release as well as for audit purposes
- Support the Regulatory Affairs Manager with preparation and maintenance of technical files in accordance with the Medical Devices Directive 93/42/EEC and Medical Devices Regulation (MDR)
- Liaise with colleagues and suppliers on regulatory matters in the launch of new product lines
- Support new product development (NPD) activities and ensure that any regulatory requirements are completed
- Assist the Regulatory Affairs Manager with any other duties as required from time to time

Experienced Required

- Science degree
- Basic understanding of Quality Management System as per ISO13485:2016
- Basic understanding of CE marking of medical devices as per MDD 93/42/EEC
- Strong working knowledge of Word and Excel
- Excellent written, communication and organisational skills
- Self-motivated, eager to learn and able to work on own initiative
- Strong attention to detail
- Able to prioritise work and key issues in complex situations and be able to resolve these problems with minimal assistance

Desirable

- Auditing skills
- Regulatory qualification or experience

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.