

Compliance Officer

Fixed Term Contract



The Role:

The Compliance Officer will have responsibility to lead and drive the management and maintenance of The Quality Management System and regulatory systems in place in PEI. You will provide compliance and quality assistance to the highest international standard, across a broad range of areas including ISO and Health Care Compliance. Reporting to the Human Resources Manager, you will work closely with members of the Business Teams. You have strong people management skills and are tenacious in overcoming objections or resistance to achieve your goals and drive the company-wide compliance program.

The Person:

You are someone with an ability to get things done who is looking to join a leading Medical Company and a Great Place to Work. You demonstrate accountability and strong commercial awareness allowing you to adapt quickly in line with business changes. You have excellent communication, organisational and problem-solving skills. You are self-motivated and constantly seeking smarter ways of working. With excellent influencing skills, you have an ability to foster relationships at all levels. You are pragmatic in your approach to how you challenge whilst ensuring compliance and best practice at all times.

The Company:

Certified a "Great Place to Work" for 2022, PEI is a leading medical and surgical sales, marketing and distribution company. PEI's product portfolio includes major brands from world class manufacturers such as DePuy Synthes, Boston Scientific, Ansell and ResMed. This is an exciting opportunity to work for a company whose focus is in developing its people and ensuring they are equipped to provide service solutions to its customers.

Basic Requirements:

- Relevant Life Science / Business 3rd level qualification essential
- Minimum of 4 years quality assurance experience within a regulated (pharmaceutical/medical device) industry with strong knowledge of ISO standards and industry regulations
- Experience in the development and maintenance of ISO based quality systems
- Experience in the training and assessment of staff in compliance, regulatory and quality standards
- Knowledge of review and appraisal of regulatory and/or legal documentation an advantage
- Ability to work independently and with self-direction
- Excellent interpersonal skills with a focus on the development of strong relationships internally as well as externally between partners, affiliates and suppliers
- Process driven with strong organisation skills a must
- Proven attention to detail and follow through
- Demonstrates initiative/Solutions oriented
- Flexible with a positive attitude towards change
- Proven ability to multi task in a pressurised environment in order to meet strict deadlines
- Computer literate in Word and Excel
- Excellent communication and people skills
- Experience of working on cross-functional teams

Roles & Responsibilities:

Reporting to the HR Manager, your role and responsibilities include:

- Healthcare Compliance - Leads and drives the Health Care Compliance (HCC) program to ensure business practices are compliant with internal guidelines and regulatory requirements
- Deviation management
- Maintain the HCC database
- Review and approve incoming HCP/Sponsorship requests in line with HCC guidelines
- ISO – General upkeep of the quality system in terms of ISO 9001 and 13485 standards and the online documentation system
- Proposing and implementing improvements to the quality system in line with industry best practices and standards
- Develop and roll-out QMS as required
- Upkeep of the quality system and business practices in terms of Medical Devices Regulation (EU) 2017/745
- Facilitate on-going compliance for the company by assisting in the adherence to the quality manual and internal quality policies
- Co-ordinating and submitting information to customers as requested and supporting the complaints and product recall system from a quality perspective
- Review/lead process investigations and ensure any such investigations are documented appropriately with relevant corrective actions, if necessary

- Preparation of Key Performance Indicators for the Quality Department and also assisting in the maintenance of records for the company KPIs as per Quality Management review requirements
- Delivery of quality systems and HCC training as required
- Develop and write SOP's & controlled documents and provide QA approval of procedures and protocols
- Completion of internal audits and supporting the hosting of customer audits (point of audit set up and Quality Department representative during audits)
- Liaise with HPRA as required
- Perform additional assignments as directed by the manager

PEI Compensation Package:

An attractive package is available to the right candidate.

How to apply

To apply for this position, please send your C.V. and cover letter to hr@pei.ie, and include the job title and your name in the subject line of your email.