RESPONSIBLE PERSON (RP)

Posted on 29 december, 2020

Company Name Recordati

Location Stockholm

Job Description

The Responsible Person (RP) leads the implementation of the registration strategy for the company, in order to obtain registration and market authorization in due time: Preparation, submission and tracing of MA dossiers. You plan and control dossier filling process (e.g. Marketing Authorization, Renewals, Amendments of existing Mas). The RP also maintain and improve the local quality assurance system in accordance with legislation and good distribution practice (GDP) and for the operation of other legally required systems (e.g. Health Care Compliance, Pharmacovigilance, Medical Information, Distributor Management) to ensure that the company operates within legal requirements.

Your responsibilities include:

- Ensuring that a quality management system is implemented and maintained.
- Securing that initial and continuous training programs are implemented and maintained.
- Coordinating and promptly performing any recall operations for medicinal products and ensuring that relevant customer complaints are dealt with effectively.
- Ensuring that suppliers and customers are approved from a QA point of view.
- Approving any subcontracted activities which may impact on GDP.
- Monitoring the evolution of laws and regulations related to registration, quality requirements commercialization, manufacturing and market access of drugs.
- Providing medical advice to the creation of marketing material and ensures control of the compliance of promotional material / activities within the code of practice.
- Supporting Market Access activities required for the preparation of the pricing and reimbursement dossiers.
- Overviewing our PV/PQC/MI processes currently managed by an external vendor.

Key Requirements / Knowledge

- Master's degree in medical, pharmaceutical or science discipline

- A solid and successful track record of experience in pharmaceutical industry (PV, RA, QA, Medical and Compliance)
- Demonstrated high level of understanding of regulatory and compliance guidelines (GxP)
- Proven ability to successfully /work in a cross functional team setting
- Native speaker Swedish, business fluent in English, good understanding of other Scandinavian languages in writing.

Personal Competencies

- Patient driven mindset.
- Able to handle client and project management issues and complex tasks without guidance and direction.
- Excellent communication/editing skills, research and teamwork skills, and attention to detail.
- Deadline driven, strong sense of urgency and commitment.
- Excellent analytical, communication (oral and written) and organizational/planning skills
- Strong written, verbal and presentation skills; ability to gain confidence from clients during presentations.
- Solid conflict resolution skills.
- Strongly developed problem-solving skills.

Apply today!

This recruitment is handled by our recruitment partner, Moveup Consulting AB. To apply, please send your CV and a cover letter to daniel.kremer@moveup.se

If you have questions regarding Recordati or this open position, please contact Daniel Kremer at +46 733-87 27 24.

By submitting your application, you also consent to us storing your personal data, including CV & cover letter and that we have the right to share this information with third parties (our client). You can revoke the consent whenever you want.

Om företag

***Recordati**, established in 1926, is an international pharmaceutical group, with a total staff of more than 4,300, dedicated to the research, development, manufacturing and marketing of pharmaceuticals. An efficient field force of medical representatives promotes a wide range of innovative pharmaceuticals, both proprietary and under license, in a number of therapeutic areas including a specialized business dedicated to treatments for rare diseases. Recordati is a partner of choice for new product licenses for*

its territories. Recordati is committed to the research and development of new specialties with a focus on treatments for rare diseases.

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