Regulatory Affairs Specialist

MISSION STATEMENT

Prepares, compiles and submits under supervision high quality post-approval regulatory applications in compliance with EU and other countries national requirements. Participates in definition of regulatory strategies for preparation of the post-approval regulatory applications. Provides regulatory support to project teams and key internal/external customers.

MAIN ACCOUNTABILITIES AND DUTIES

- Preparation, compilation, review and submission of high quality regulatory applications in accordance with EU and national requirements and legislation with limited oversight.
- Track and monitor queries/deficiency letters/commitments from/to Regulatory Competent Authorities to ensure these are implemented and conformed to in a timely manner.
- Communicate critical regulatory information for assigned projects before, during and after approval until the point of handover to regulatory maintenance teams.
- Develop and maintain a thorough and up-to-date understanding of the regulatory environment and supporting data requirements.
- Align resources and discusses regulatory issues in cross-functional teams to ensure completion of project tasks.
- Communicate with peers and supervisors and ensure alignment on issues, questions and goals.
- Employ effective technical and regulatory writing skills to author standard regulatory documents and reports.
- Preparation for and participation in meetings with internal and external stakeholders.
- Provide regulatory support to project teams, stakeholders and customers, as required.
- Evaluate the regulatory environment and contribute to providing internal advice and regulatory information throughout the product lifecycle (e.g., concept, development, manufacturing, marketing) to ensure product compliance.
- Review written correspondence from peers and entry-level employees.
- Provide regulatory input and appropriate follow-up for inspections and audits.
- Identify the need for new regulatory procedures and SOPs, and participates in development and implementation.
- The employee will perform other tasks under the direction of the Manager within the agreed type of work.

REQUIRED QUALIFICATIONS & EXPERIENCE

- Degree in biomedical sciences (Medicine/Pharmacy/Veterinary/Pharmaceutical Sciences/ Science) or Chemistry
- Two or more years of regulatory experience in relevant discipline
- Very good knowledge of regulatory requirements, process, procedures & pathways
- Experience in registration of pharmaceutical in the EU and other countries.
- Knowledge of clinical development, pharmacovigilance and products life cycle management
- Experience in working in project teams or leading projects

REQUIRED COMPETENCIES & SKILLS

- Acts in line with Zentiva Superpowers principles and values
- Good communication skills, both verbal and written, with a passion for accuracy and attention to detail
- Good interpersonal skills – ability to effectively interact with a diverse group of people from different functions, of different nationalities and at different levels within the company
- Good project management skills
- Good communication skills to transfer knowledge to entry-level employees
- Good communication skills to negotiate with regulatory authorities throughout the product lifecycle
- Willingly accepts challenging assignments and new career opportunities that stretch and build capabilities.
- Good written and oral knowledge of English

Please send your application or recommendations to **carieromania@zentiva.com**
until **1st of July 2021 included**.