ZENTIVA

Regulatory Affairs Specialist/Coordinator - Life Cycle Management

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.

OTHER RESPONSIBILITIES

QUALITY

- Adheres to the principles of GMP in the extent related to the performed activity. Is obliged to regularly train in this policy.

HSE / BOZP

- Adheres to the principles communicated within the ESMS Policy of Zentiva detailed in the internal rules of the Company for the purpose of observing the rules of the

PHARMACOVIGILANCE

• All employees are obliged to report any suspicion to adverse events of medicinal products, any adverse events concerning use of a medical device and any other safety information about medicinal products or medical devices in line with relevant internal regulations.

COMPLIANCE

• The employee will comply with all internal rules of the Company, mainly with the Working Order of the Company and all other internal rules specifying the provisions of the Working Order. The employee will make her/himself acquainted with the Code of Ethics (Zentiva "Code of Common Senses") and will comply with the principles stated therein and in all related policies and other internal documents.

MANAGERIAL POSITIONS REQUIRE:

• Creates, manages and evaluates the risk register and environmental aspects. Informs and trains employees and verifies their knowledge of the above.

COMMUNICATIONS & WORKING RELATIONSHIPS

Internal

• Central RA organization in Czech Republic, Romania, Bulgaria, India
• Business units (RA, Scientific Affairs) in the markets
• All other functions within the Zentiva organization

External

• External partners
• National/Regional competent authorities

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 with leading small team of people
• Experience in leading projects

REQUIRED COMPETENCIES & SKILLS

• Acts in line with Zentiva Superpowers principles and values
• Very good communication skills, both verbal and written, with a passion for accuracy and attention to detail
• Very 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
• Very good project management skills - ability to manage and measure work by reflecting resources, goals and by keeping high performance
• Skilled at managing small team of people
• 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 to **alina.duna@zentiva.com** until 15th of January included.