ITalent SA are search and recruitment experts for Executives, Managers and Technical Specialists positions.

We are recruiting on behalf of our client, a pharmaceutical company, an experienced and qualified:

SENIOR DIRECTOR, REGULATORY AFFAIRS EUROPE (M/F)

The Regulatory Affairs Senior Director is responsible for all activities related to regulatory requirements of product development including developing the EU regulatory strategy and document preparations for registration and submissions (paper and electronic) in the EU region. He/she will be responsible for providing scientific and technical support according to the regulations to the development and commercial teams for all the projects. He/she will be responsible for supporting commercial team to engage with various countries to optimize the product launch strategy across the EU.

He/she will be project managing the document preparations/dossier compilations and submissions by interacting with country specific regulatory experts. He/she will provide regional regulatory guidance to all functional experts internal/external.

He / she will report to the Regulatory Affairs VP to support all the submission activities.

RESPONSIBILITIES

- Provide strategic, scientific and technical support according to the EU regulations (also global regulations, desired) to the development and commercial teams for all the projects. Support commercial team to engage with various countries to optimize the product launch strategy across the EU.
- Projects manage MAA compilation by providing a comprehensive plan and regulatory input to the project teams. Participate in preparing the clinical data for the New Drug Applications. Provide EU regulatory affairs support to the global regulatory affairs group to generate comprehensive global regulatory strategies.
- Coordinate and participate preparing all regulatory submissions (MAA, CTA applications, reports, or correspondences, investigator updates, safety reports, and annual reports, as well as assistance in the preparation of CTA amendments) and ensure compliance with domestic and international regulations and standards under supervision.
- Review all regulatory agency submission materials to ensure timeliness, accuracy, comprehensiveness, or compliance with regulatory standards.
- Participate in setting a document control system, maintain and organize the existing files for easy access.
- Develop and maintain standard operation procedures or local working practices.
- Maintain current knowledge of relevant regulations, including proposed and final rules.

PROFILE

- Scientific background (M.S. or Ph.D. (preferred));
- A minimum 10 –15 years experience in EU Regulatory Affairs is preferred;
- Comprehensive knowledge in drug development (branded products);
- Good, practical knowledge of European pharmaceutical legislation, guidelines and procedures relevant to the activities described above;
- Extensive experience GXP activities and supervision of inspection or audit programs or of clinical research;
- Extensive experience in clinical trials, pharmacovigilance, manufacture, quality assurance, pharmaceutical engineering or regulatory affairs in the pharmaceutical sector either within a regulatory authority or industry environment;
- International experience relevant to the activities described;
- Experience in project management;
- Experience in the use of information and communication technologies;
- Ability to communicate and present the Company's position externally and to staff internally;
- Ability to network and interact effectively with colleagues and work as part of a team and take the lead as needed;
- Experience in working in a multicultural environment;
- Strong understanding of the European and global GXP environment;
- Strong sense of responsibility;
- Strong communication skills, and in particular, the ability to explain complex issues;
- Ability to establish and promote open communication;
- A can-do and proactive approach, brining urgency to his/her work environment;
- Team-player and confident;
- Ability to work under pressure;
- Tact, discretion and diplomacy;
- Experience in multi-cultural organizations;
- A good command of English and a thorough knowledge of another official language of the European Union to the extent necessary for the performance of duties.

Please apply on our website: recrutement@i-talent.com and attach a copy of your resume and a motivation letter. We thank you in advance for your interest in this opportunity.

Please note that only applications via this e-mail address will be considered for this position. If you don’t receive a reply to your application within 2 weeks, please consider that your file has not been shortlisted.