

VP Drug Safety and Pharmacovigilance (m/f)*

Reference Number: 1001322

Company Information

Our client is an international Biotech Company with locations in Europe and the US. The company is focused on the research and development of novel biological products for the treatment and control of cancer, and inflammatory and autoimmune diseases.

Position

- Responsible for all aspects of Drug Safety
- Create and deliver the company's Drug Safety and Pharmacovigilance strategy and related plans in alignment with their business priorities
- Ensure sufficient capacity exists to accomplish key Drug Safety accountabilities and strategies. Build organizational depth and competence
- Reinforce compliance with relevant regulation, policies and procedures and align key Drug Safety processes therewith
- Drive resolution of complex, cross functional issues
- Partner with senior leaders to define and implement solutions to any issues and to plan integrated strategies to address emerging challenges and opportunities
- Supervision of and responsibility for compliance with reporting obligations and GCP regulation for Germany and applicable international regulatory guidelines
- Supervision of the Senior Director Drug Safety
- Monitoring of implementation and enhancement of SOPs covering the pharmacovigilance system
- Evaluation of all serious adverse events as to seriousness, expectedness and causality
- Supervision of the generation of periodic safety update reports (PSURs) and annual safety reports (ASR)
- Analysis of safety data, Benefit-Risk assessment and Signal detection for the company products
- Evaluation of risk management plans for the company products
- Chairing the Company Safety Committee
- Initiation and supervision of recalls related to drug risks
- Generation of the safety parts in dossiers for Marketing Authorization, renewal applications, answers to deficiency letters of authorities of the company products
- Monitoring of collaboration in the generation of protocols, Investigators Brochures and CRFs
- Collaboration in national and international teams and project groups
- Act as QPPV and Graduated Plan Officer (GPO)
- Decision making in processes related to the collection, evaluation and reporting of serious adverse events in the company sponsored studies

Candidate Profile

- Medical doctor, with a focus on hematology
- 7-10 years as QPPV and GPO in an international environment
- Strong interest and up-to-date knowledge in all applicable regulations and guidelines
- Excellent communication skills, integrative thinking, assertive, results oriented
- Ability to work in a team-oriented environment and to interface effectively with peers in other departments, in particular Clinical Development, Clinical Operations, Regulatory Affairs and Quality Assurance
- Excellent command in English, fluency in German is a plus

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If you are interested in this position please email your CV to

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* This job description applies equally to male and female candidates, regardless of the wording used in the text.