



InflaRx is a NASDAQ listed biotechnology company with offices in Jena and Munich, Germany. We research and develop new medicines for the treatment of inflammatory diseases within a global development approach. We stand out for an excellent team of highly motivated and skilled individuals who put strong emphasis on a team effort.

To support our expanding Drug Safety Team we are looking for a

Drug Safety Manager (m/f/d) *

(Reference number: 2020117)

The global Drug Safety Manager is responsible for providing expertise throughout the lifecycle clinical safety and manages the operational activities both internally and through a third-party pharmacovigilance vendor related to the processing of safety data from clinical trials. The holder of this position ensures that performed tasks comply with InflaRx SOPs and procedures, best industry standards and applicable regulations.

The position is located in Munich or Jena.

Primary responsibilities:

- Independently manage the third-party Pharmacovigilance vendor outsourced for Clinical Trial activities within an ongoing phase II to phase III clinical program
- Represent the Drug Safety Department in program and study teams and in external study team meetings
- Contribute to /Manage the set-up of new safety projects, including development of study-specific Safety Management Plans and contractual agreements with third-party vendor
- Provide sponsor oversight of SAE processing by an outsourced vendor including the monitoring of reporting compliance (by KPIs) and ensuring a high standard of case narrative writing by quality review
- Collaborate with Medical Affairs personnel to monitor and maintain high quality of SAE reporting
- Ensure vendor surveillance with regards to cost control, on time completion of outsourced activities and on-budget delivery of pharmacovigilance services
- Contribute to evaluation, analysis and presentation of safety data in respective documents (DSUR, IB, CSR) and in collaboration with independent expert boards (DSMB)
- Proactively drive cross-functional activities and work with external partners to maintain high quality safety processing
- Ensure compliance with SOPs, GCP, and relevant regulatory environment of activities and documentation
- Maintain knowledge of adverse event reporting processes and safety systems and contribute to the development, implementation, improvement, and standardization of new processes and methods
- Participate in and support internal/external inspections and audits

Education/Experience/Skills:

- Bachelor's or Masters' degree in Life Science/Pharmacy/Medical Sciences, or other equivalent experience/education
- 2 - 5 years of relevant experience in a pharmaceutical/ biopharmaceutical organization with safety reporting (expedited/periodic) in clinical development
- Good understanding and working knowledge of safety reporting and general regulatory environment in a clinical development environment

- Knowledge of clinical operations and biopharmaceutical drug development activities and processes would be advantageous
- Experience with immunologically active pharmaceutical products would be advantageous
- Ability to work harmoniously within international cross-functional teams, engage in open, constructive and continuous dialogue with internal staff and external partners
- Target orientation and flexibility to adapt to changing situations in a fast-paced environment
- Ability to plan, organize and manage multiple projects and priorities simultaneously
- Highly motivated, self-driven, dependable, and solution oriented
- Effective communication and presentation skills
- Fluent in written and verbal business English. Fluency in German desirable
- Must be familiar with MS Word, Excel and PowerPoint

We offer:

- An open-ended employment contract with 30 days leave per year
- Attractive remuneration and above-average employer participation in the company pension scheme
- You design your workplace by bringing in your own ideas and visions
- You work in an ambitious company with a highly motivated team

We offer you a challenging and varied opportunity with an innovative, dynamic and expanding company. InflaRx strives to be a company that is recognized by its employees as best place to work for in the industry. We want to accomplish this by working with passion and professionalism on thru medical innovation. We pride ourselves in maintaining a friendly, honest and trusting relationship with each other.

If you are interested in this position, please contact:

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* This job description applies equally to candidates of all genders, regardless of the wording used in the text.