Our client is a NASDAQ listed biotechnology company with the global Headquarter in Germany. The companies focus is the research and development of new medicines for the treatment of inflammatory diseases within a global development approach. Our client stands out for an excellent team of highly motivated and skilled individuals who put strong emphasis on a team effort

To support their expanding Drug Safety Team we are looking for a:

Pharmacovigilance Manager (m/f/d)

Drug Safety

Standort: Munich
Kennziffer: 26512

Your tasks

- 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.

Your qualifications

- Bachelor's or Masters' degree in Life Science/Pharmacy/Medical Sciences, or other equivalent experience/education.
- More than 3 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.

OPTARES MEDICAL

Seit 2003 vermittelt Optares Medical erfolgreich Fach- und Führungskräfte an Unternehmen der pharmazeutischen, biotechnologischen und medizintechnischen Industrie. Dabei profitieren Sie als Kandidat (m/w/d) durch unsere langjährige Branchenexpertise und unser weit reichendes Netzwerk zu den jeweiligen Entscheidungsträgern. Wir ermöglichen Ihnen somit den Zugang zu passgenauen Positionen inklusive echten Herausforderungen und entsprechenden Weiterentwicklungsmöglichkeiten.

Die professionelle, diskrete und transparente Betreuung unserer Kandidaten (m/w/d) während des gesamten Bewerbungsprozesses steht dabei für uns im Mittelpunkt.

Ihr Ansprechpartner
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