

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:

Associate (m/f/d) Pharmacovigilance

Drug Safety

Standort: Greater Munich Area

Kennziffer: 26513

Your tasks

- Support the management of third-party Pharmacovigilance vendor processes and internal processes for safety activities within an ongoing phase II to phase III clinical program.
- Receiving, tracking, and filing of SAEs and expedited event reports and surveillance of timely processing by third-party vendor
- Provide sponsor oversight of SAE processing by an outsourced vendor including the monitoring of reporting compliance.
- Coordinate case review with InflaRx Medical Affairs personnel and ensure implementation of recommendations.
- Coordinate on time data preparation with third-party vendor for periodic safety assessment (DSUR, IB, DSMB)
- Contribute to vendor surveillance with regards to invoice verification and cost control.
- 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.

Your qualifications

- Bachelor's degree in Life Science/Pharmacy/Medical Sciences, or other equivalent experience/education.
- A minimum of 6 months of relevant experience in a pharmaceutical/ biopharmaceutical organization with safety reporting (expedited/periodic) in clinical development.
- First experience with safety reporting and general regulatory environment in a clinical development environment.
- 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
- Highly motivated, self-driven, dependable, and solution oriented.
- Effective communication skills.
- Fluent in written and verbal business English. Fluency in German desirable.
- Should be familiar with MS Word, Excel and PowerPoint.

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

Herr Tilman Grumbd

Geschäftsführer

Tel. +49 441 21879-34

tilman.grumbd@optares.de

Optares Medical GmbH & Co. KG

Personalberatung und -vermittlung

Heiligengeist Höfe 8

26121 Oldenburg

www.optares.de

Folgen Sie uns auf

