

Bavarian Nordic is a fully integrated biotechnology company focused on the development, manufacturing and commercialization of cancer immunotherapies and vaccines for infectious diseases. The company has a diverse and growing portfolio of vaccines, supported by proprietary development, public-private partnerships and industry collaborations. The company was founded in 1994 and has been listed on the Nasdaq Copenhagen Stock Exchange since 1998. Headquartered in Kvistgaard, Denmark and with operations in Munich, Germany and North Carolina, USA, the company employs more than 500 people. Bavarian Nordic is an Equal Opportunity Employer.

For more information visit www.bavarian-nordic.com or follow us on Twitter @bavariannordic

To strengthen our **Clinical Safety** and **Pharmacovigilance** Department in **Martinsried/Munich** we are searching for a qualified

(Senior) Physician, Clinical Safety and Pharmacovigilance (m/f/d)

Your tasks

- Analysis of comprehensive product information, synthesis, benefit-risk assessment and reporting
- Proactive Monitoring of product safety profile from first in human throughout lifecycle
- Primary ownership and accountability for product signaling review, analysis, delivery and approval – medical safety
- Leadership and ownership of internal medical safety governance bodies
- Active contribution to internal and external forums (e.g., DMC, Advisory Boards)
- Contribute to label development, scientific regulatory responses
- Provide medical and PV oversight and key input to: Protocols, Investigator brochures, Safety summaries, Clinical study reports, Regulatory reports (periodic, ad hoc), Labeling changes
- Train drug safety personal and contribute to mentoring and on-boarding of new colleagues
- Ensure all activities are of the highest medical safety, ethical and compliance standards
- Manages all medical safety aspects of allocated studies and post market products.
- Oversee and maintain PVA/SDEA management, as well as CRO management in respect to medical safety processes, for example signal management
- Ensures that all assigned medical safety activities are set-up in line with the PV standard operating procedures (SOPs) and relevant guidelines.
- Serves as a contact for any product specific medical safety matters internally and externally

- Directly report on overall product medical safety to the QPPV and other local persons for pharmacovigilance
- PV Audit and Inspection preparation and support in respect to product specific medical safety aspects

Skills

- Quality-oriented personality
- In depth knowledge of GVP, FDA guidance documents and in general global PV legislation
- Effective communication and negotiation skills, be able to work with matrix and local teams, and be able to break down problems to find solutions
- Safety database knowledge and data visualization skills

Your profile

- Degree in human or veterinary medicine or a similar field
- Minimum 2 years of work experience in medical safety
- Fluent in German and excellent command of English with strong written and oral skills

Your prospect

- An exciting position in our Clinical Safety and Pharmacovigilance department within an international environment
- Working in a highly motivated team
- Broaden your experience in an internationally operating, biopharmaceutical company

Contact

If you are interested in the position, we look forward to receiving **your application in English with your earliest possible start date and your salary expectations (annually)** via our internal system. Just click [here](#) and you will be redirected to our application site.

We kindly ask recruitment agencies/headhunters to refrain from contacting Bavarian Nordic GmbH. Unsolicited documents will not be considered

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