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 400 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 **Pharmacovigilance** Department in either **Martinsried/Munich** or **Morrisville, North Carolina** we are searching for a qualified

Director (f/m/d) Pharmacovigilance

Your responsibilities

- Overall accountability for Pharmacovigilance (PV) at Bavarian Nordic (BN)
- Responsibility for BN's PV system, including oversight and maintenance of PV standards within BN Clinical Development Department and medical monitoring in clinical trials
- Close interaction with other groups and departments within BN (Clinical Operations, Data Management, Regulatory, QA, Research, Commercial)

Your specific tasks

- If located in the EU, serving as the EU-QPPV and German Commissioner of the Graduated Plan ("Stufenplanbeauftragter") of BN which includes acting as single contact point for Competent Authorities on a 24/7 basis and in case of inspections, as well as acting as medical representative for BN, e. g. in meetings with regulatory agencies
- Line management of the Pharmacovigilance group (currently four direct reports)
- Establish/maintain the PV department infrastructure (such as in-house PV database, expedited adverse event reporting to US and European regulatory authorities including medical assessment of individual ADR cases, SOPs)
- Maintenance and management of BN's PV system, including set up of the Pharmacovigilance Master File as mandated by current guidance and legislation
- Oversight and responsibility of safety profiles and any emerging safety concerns in relation to medicinal products for which BN holds marketing authorisations or has filed applications for marketing authorisations
- Ensuring provision of any information necessary for the evaluation of the benefits and risks of BN's medicinal products to Competent Authorities

- Responsibility for PV (incl. SAE workflow, processing and reporting) in BN's clinical trials and for expedited adverse event reporting to US and European regulatory authorities including medical assessment of individual ADR cases
- Monitoring of compliance, e. g. for reporting to regulators as for time and quality
- Responsibility for safety relevant sections in clinical development programs and clinical study protocols
- Creation of PV related documents, including risk benefit assessments and risk management plans, core safety information documents
- Responsibility for creation and distribution of periodic reports and reports of post-authorisation safety studies
- Contribute to preparation of Investigator Brochures, Statistical Analysis Plans, Clinical Study Reports
- Responsibility for policy documents and processes relevant to PV and Clinical Safety Data Management
- Collaborating with QA to establish and maintain an adequate quality management system for pharmacovigilance
- Contribute to publication of clinical study results
- Serve as primary BN contact to independent Data Safety Monitoring Boards

Your profile

- Medical Doctor, Pharmacist or Human Biologist with minimum of five years experience working in Pharmacovigilance in the biotechnology/pharmaceutical industry
- Experience interacting with regulatory agencies, particularly US and EU (FDA, EMA)
- Knowledge of international laws, regulations and policies governing Pharmacovigilance
- Experience with vaccines and/or infectious diseases and/or oncology would be beneficial
- Excellent command of English with strong written and oral skills, including experience in medical and regulatory terminology (MedDRA)
- Highly self-motivated, conscientious, meticulous individual able to work with a minimum of supervision
- Team player who enjoys establishing and maintaining good working relationships
- In-depth knowledge and skills in use of database applications, MS Office and other relevant software

Your prospect

- A leading position within an international environment
- Working in a highly motivated team
- The chance of professional development through our dynamic company structure

Contact

If you are interested in the position, we look forward to receiving your application in English via our internal system. Just click here APPLY and you will be redirected to our application site.

Further information

For additional information on the position please contact
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