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

Specialist (f/m/d) Pharmacovigilance

Your tasks

- Management of all Serious Adverse Events (SAEs), Adverse Events of Special Interest (AESIs) and pregnancy reports submitted to the company, including all necessary inter-departmental and CRO related tasks
- Processing of safety cases in BN's Pharmacovigilance database, including preparation of case files, listings and data outputs per requests
- Entry, coding and QC check of all SAE/AESI/pregnancy cases, according to BN SOPs
- Preparation and compliant submission of reports in appropriate format (e.g. MedWatch, CIOMS forms, EUDRACT, cover letters, etc.) for SAEs requiring expedited (15-day) reporting to US and European Regulatory Authorities
- Generation and revision of SAE /pregnancy report forms for various clinical trials
- Contact study investigators, CROs, monitors, etc. to obtain follow-up information of SAE reports
- Continuous, effective communication with external contractors
- Reconciliation of SAEs between BN Pharmacovigilance database and parallel databases (e.g. CRO clinical database, etc.)
- Preparation of line listings for DSURs/PSURs
- Monitoring of compliance, e.g. for reporting to regulatory authorities
- Contributes to writing and review of the Pharmacovigilance Master File
- Support in preparation of clinical documents for submission to Ethic Review Committees and other authorities
- Review and formatting of large documents (e.g. Investigator Brochures, Clinical Trial Protocols, etc.)
- Support in preparing publications and presentations for the Clinical Department

Your profile

- Life science background, e.g. nursing degree, medical technician, doctor's assistant, B.S. in biology or similar
- Minimum 5 years of work experience in the pharmaceutical or biotech industry, preferably in the area of pharmacovigilance and/or clinical research
- In-depth knowledge of Office standard applications (Word, Excel, Powerpoint)
- In-depth knowledge of database systems and document management solutions, preferably in the pharmacovigilance area
- Excellent command of English with strong written and oral skills
- Basic knowledge of international drug legislation

Your prospect

- An exciting position 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 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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