MorphoSys's mission is to make exceptional, innovative biopharmaceuticals to improve the lives of patients suffering from serious diseases. Innovative technologies and smart development strategies are central to our approach. Success is created by our people, who focus on excellence in all they do, collaborate closely across disciplines. We all are driven by a desire to make the medicines of tomorrow a reality. Guided by mutual respect and trust, each member of the MorphoSys team is given the opportunity to develop and flourish within this exciting and inspiring environment. Join us in Planegg near Munich!

We would like to fill the following vacancy as soon as possible:

Associate Director Drug Safety & Pharmacovigilance (gn)

Your Responsibilities:

- Supports the development of a PSMF prior to MAA of MOR00208 in Europe
- Regularly maintains the PSMF
- Supports the implementation and maintenance of a post-marketing pharmacovigilance system in Europe
- Supports drug development concerning all aspects of clinical safety
- Medical evaluation and assessment of safety data
- Supports the generation of periodic reports such as DSUR / PSUR, periodic line listing reports
- Contributes to the generation of safety parts of clinical trial related documents such as Investigator's Brochure, protocols, patient information and consent forms, clinical study report and clinical and product development plans
- Supports the Drug Safety Officer / GPO in assessing the medical risk of product complaints and to initiate the necessary actions if needed

Your Requirements:

- A Medical educational background is mandatory
- At least 10 years of experience in drug safety (both pre- and post-marketing) in a pharmaceutical or biotechnology company
- Thorough understanding of ICH-GCP, cGMP, EMA Guidelines and European Regulations and Directives, and other national regulatory requirements pertaining to adverse event assessment and reporting
- Experience in drug approval process for biologic products
- Able to interpret and apply medical information, instructions, policies, procedures and guidelines pertaining to drug safety
- Able to interpret safety data and to write safety texts for MAA dossiers
- Detailed knowledge of the use of drug safety databases, individual case processing experience and practical expertise with MedDRA
- Experience with preparation and maintenance of a PSMF

We offer:

- Creative working in X-functional teams
- Open and respectful corporate culture
- Multicultural environment
- Working in an attractive, state-of-the-art building with in-house restaurant
- Free sports and language courses

Thank you for your interest! We are looking forward to receiving your pertinent application documents. For your application please use exclusively our career portal www.morphosys.com/careers/job-opportunities. We offer not only excellent career prospects, but also support you from the very beginning – even helping you move if neccessary.

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