MorphoSys' 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 (gn) Quality Assurance GVP

Your Responsibilities:

- Plan, perform and follow-up pharmacovigilance (PV) and Drug Safety (DS) audits of internal PV/DS systems and processes of MorphoSys headquarters and subsidiary as well as at external PV vendors/ PV service providers (e. g. CROs), distributors, partners
- Coordinate and supervise PV audits contracted to external auditors, including the selection of external auditors
- Hosting and follow-up of authority inspections, especially in PV / safety topics
- Write/ review Quality Assurance SOPs, and review of SOPs related to drug safety / PV topics
- Provide expert advice in Good Pharmacovigilance Practice (GVP) to MorphoSys internal procedures within relevant departments (e. g. Drug Safety & Pharmacovigilance, Medical Affairs, Clinical Operations, Clinical Development, Regulatory Affairs)
- Ensure continuous improvement of our internal quality management system, with particular attention to the generation and update of the PV auditing strategy as well as the establishment of PV quality metrics and analyses
- Provide GVP support, advice, education and training to other departments involved in clinical trials and drug safety / PV activities
- Establish and maintain a database of references (regulations, standards, guidelines) applicable to drug safety / PV topics

Your Requirements:

- University Degree with a minimum of six years of professional experience in GVP Quality Assurance within pharmaceutical and /or biotech industry
- Experience in hosting and following-up of authority inspections including pre-approval inspections
- Sound knowledge in international regulations and guidelines (EU / FDA regulations, ICH, etc.)
- Strong communication skills both verbally and written
- Team player with well-developed interpersonal abilities
- Strong problem solving and negotiation abilities
- Flexible, highly motivated, with strong organization skills
- Fluent in English
- Ability to travel
- Willing to relocate in Munich area

We offer:

- Creative working in X-functional teams
- Open and appreciative corporate culture
- Multicultural environment
- Working in an attractive, high-quality equipped building with 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 necessary.

MorphoSys AG, Semmelweisstraße 7, 82152 Planegg