Associate Director, PV/GCP Quality Assurance

Y-mAbs Therapeutics A/S is looking for an Associate Director, Quality Assurance in the area of Pharmacovigilance (PV) and Drug Safety, who will be part of a team of highly qualified and motivated colleagues.

It is our expectation that this person will establish QA processes to contribute to Good Pharmacovigilance Practice (GVP) and Good Clinical Practice (GCP) compliance of the company operations.

Key responsibilities

- Contribute to development of the company Quality Management System and provide guidance in local and global requirements, as applicable to Pharmacovigilance and Clinical Drug Safety
- Maintain Quality oversight of Pharmacovigilance System Master File, pharmacovigilance SOPs, Safety Management Plans, Pharmacovigilance Agreements, and other relevant documents
- Sustain Quality oversight of the company PV and Drug Safety operations, including case processing, risk management, health authority reporting, and relevant IT system validation and maintenance
- Conduct audits of vendors relevant to PV and Clinical Drug Safety areas as well as internal audits in these areas
- Lead preparation activities for and facilitate PV and GCP regulatory inspections
- Train employees and business partners in Good Pharmacovigilance Practice
- Handle deviations, quality investigations and CAPA relevant to PV and Drug Safety area

Travelling: up to 30 days per year

Education, experience, skills

- Hold an MSc/BSc in pharmaceutical sciences, biological sciences or similar
- 7+ years of relevant experience in pharma/biotech industry (QA and/or PV)
- Thorough knowledge of US, EU and global requirements in the area of PV and Clinical Drug Safety
- Training and extensive experience as an auditor
- Knowledge of part 11 compliance requirements to computerized systems, specifically to PV/Safety data bases
- Record of successful collaboration with license partners, affiliates, etc.
- Experience in hosting of regulatory inspections
- Proficiency in English, written and orally
- Ability to work independently, with multiple tasks, and under ambitious timelines
- Good collaboration skills, both internally and with external parties
- Good computer skills, experience with EDMS (knowledge of Veeva is an advantage)

Y-mAbs Therapeutics offers:

- An exciting work environment with opportunities for professional development
- Great office location at DTU Science Park including canteen and easy parking
- Competitive salary package and health insurance

Interested?

If you want to know more about the position, you are welcome to contact Natallia Misuna, Sr. Director Quality Assurance, at +45 53880788.

Please note that all applications must be submitted in English and will be treated confidentially.

Please submit your application letter and CV in English by email to hr@ymabs.com **no later than 31 July 2021** and please mark your applications with position ID number: 1054. Applications will be treated confidentially.

Y-mAbs Therapeutics A/S is a Danish affiliate of Y-mAbs Therapeutics Inc., which is located in New York, N.Y. Our mission is to discover, develop and deliver novel antibody therapeutics for the treatment of both pediatric and adult cancer patients. Please access the company web site www.ymabs.com for more information regarding the company and our development projects.