

## **Associate Director, Pharmacovigilance QA to Y-mAbs Therapeutics A/S**

### **Would you like to contribute to the continuous improvement of our company's Quality Management System?**

Joining us, you will be part of a rapidly growing team of highly qualified and motivated colleagues to ensure compliance of the company's PV operations, and provide QA support and expert advice to operational PV.

### **Welcome to Y-mAbs Therapeutics A/S**

We are a rapidly growing late-stage clinical biopharmaceutical company focused on the development and commercialization of novel, antibody-based cancer products that address unmet needs in pediatric oncology.

You will join us at an exciting time as we have already established a broad and advanced product pipeline, including two pivotal-stage product candidates, for which the company's first BLAs have been submitted.

### **As Associate Director Pharmacovigilance QA you will**

- Provide guidance in local and global PV requirements
- Contribute to preparation of SOPs and Policies for PV area
- Support maintenance of Pharmacovigilance System Master File
- Ensure the quality oversight of the company PV operations, including case processing, medical safety, risk management, health authority reporting, PV IT systems
- Conduct audits of vendors relevant to PV area as well as internal audits in PV area
- Lead preparation activities for regulatory inspections and support the inspection facilitation
- Train employees and business partners in Good Pharmacovigilance Practice
- Handle deviations, quality investigations and CAPA relevant to PV area

**Travelling:** 2 days per month on average

### **A position with an outstanding support base**

You will join us at our great office location in the DTU Science Park in Hørsholm, where all pre-clinical and clinical activities are coordinated from. From here you will report to the Director of Quality Assurance.

## **Experienced in pharma/biotech industry in Quality Assurance, PV**

It is vital that you have thorough knowledge of US, EU and global requirements in the area and that you have training and experience as an auditor, and in hosting FDA, EMA and DKMA inspections. You are able to work independently, with multiple tasks, and under ambitious timelines, and you have good planning and problem handling abilities. Good collaboration skills, both internally and with external parties are highly appreciated and you are fluent in written and spoken English.

Furthermore, you:

- Hold an MSc/BSc in pharmaceutical sciences, biological sciences or similar
- Have 5+ years of experience in pharma/biotech industry in Quality Assurance, PV
- Have knowledge of requirements and experience with validation of computerized systems

## **Y-mAbs 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, Director of Quality Assurance, at +45 53 88 07 88.

Please submit your application letter and CV in English by email to [hr@ymabs.com](mailto:hr@ymabs.com) **no later than 31 July 2020**. Applications will be treated confidentially. **Mark your applications with position ID number: 1014.**

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](http://www.ymabs.com) for more information regarding the company and our development projects.