

Associate Director, GMP QA, Biologics/Radiopharmaceuticals

Y-mAbs Therapeutics A/S is looking for an Associate Director, GMP QA who will report to Sr. Director, Quality Assurance and be a part of a rapidly growing team of highly qualified and motivated colleagues.

It is our expectation that this person will function as a Delegate Qualified Person, contribute to the continuous improvement of the company's Quality Management System, provide support to CMC Development and Product Supply teams, and maintain efficient collaboration with quality units of contract manufacturing organizations. The products in scope are primarily Investigational Medicinal Products in various phases of development, Biologics and Radiopharmaceuticals.

Key responsibilities

- Function as a Delegate Qualified Person
- Perform review and disposition of IMP and product intermediates
- Maintain Product Specification Files
- Manage change control, deviations, CAPA, complaints and recalls
- Conduct audits of CMOs
- Handle Quality Agreements with CMOs
- Communicate on quality related issues with contract acceptors
- Participate in preparation activities for regulatory GMP/GDP inspections and facilitate the inspections
- Contribute to preparation of SOPs and Policies for GMP areas
- Support and mentor the company staff in GMP

Travelling: overage 2 days per month

Education, experience, skills

- Education required by the EU Directive for a Qualified Person
- 7+ years of experience in pharma/biotech industry in Quality Assurance, GMP
- Previous involvement in (contract) manufacturing activities with biologics or/and with radiopharmaceuticals
- Extensive QP or Delegate QP experience
- Thorough knowledge of US, EU and global GMP requirements
- Training and extensive experience as a lead auditor, GMP
- Experience in hosting of regulatory inspections
- Proficiency in English
- Ability to work independently, with multiple tasks, and under ambitious timelines
- Good planning and problem handling abilities
- Good collaboration skills, both internally and with external parties
- Good computer skills, experience with EDMS (knowledge of Veeva is an advantage)
- EU citizenship

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

For more details about the job, please contact Natallia Misuna, Sr. Director Quality Assurance, Cell +45 53880788. Please note that all applications must be submitted in English and will be treated confidentially.

Deadline: please apply by sending an email to hr@ymabs.com as soon as possible and no later than 31 Jan 2022. Applications will be processed immediately.

Y-mAbs Therapeutics A/S is a Danish affiliate of Y-mAbs Therapeutics Inc., which is located in New York. 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.