

## Associate Director, GMP QA, Commercial Operations

Y-mAbs is a rapidly growing late-stage clinical biopharmaceutical company focused on the development and commercialization of novel, antibody-based therapeutic products for the treatment of cancer. The company has a broad and advanced product pipeline and got the first product approved by FDA in November 2020, which is expected to be launched early this year.

Y-mAbs Therapeutics A/S is looking for an Associate Director, GMP QA Commercial Operations who will report to Sr. Director, Quality Assurance and be 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 for commercial products, contribute to the continuous improvement of the company's Quality Management System, ensure GMP compliance of the commercial manufacturing and distribution operations, and maintain efficient collaboration with contract acceptors and license partners.

### Key responsibilities

- Function as a Delegate Qualified Person
- Function as GDP Responsible Person
- Perform review and disposition of medicinal product and product intermediates
- Conduct audits of CMOs, contract laboratories, warehouses and other GMP/GDP vendors
- Perform product importation into EU
- Facilitate preparation of Product Quality Reviews for commercial products
- Handle Quality Agreements with contract acceptors and license partners
- Manage change control, deviations, CAPA, complaints and recalls
- Communicate on quality related issues with contract acceptors, distributors and license partners
- Participate in preparation activities for regulatory GMP/GDP inspections and facilitate the inspections
- Contribute to preparation of SOPs and Policies for GMP/GDP areas
- Train, support and mentor the company staff in GMP and GDP
- Maintain oversight of relevant CMC and regulatory activities

**Travelling:** 3 days per month (under regular circumstances)

### 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/GDP
- Previous involvement in (contract) manufacturing activities with biologics; experience with radiopharmaceuticals will be beneficial
- Extensive QP or Delegate QP experience with commercial products
- Thorough knowledge of US, EU and global GMP/GDP requirements
- Training and extensive experience as a lead auditor, GMP/GDP
- Record of successful collaboration with license partners, affiliates, etc.
- Experience in hosting of regulatory inspections
- Experience with preparation of Product Quality Reviews or Annual Product Reviews
- Proficiency in English and Danish, written and orally
- 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

- Strong mentoring skills
- 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 or the company, please contact Natallia Misuna, Sr. Director Quality Assurance, [nmi@ymabs.com](mailto:nmi@ymabs.com), phone +45 5388 0788.

You can apply for the position by sending an email to [hr@ymabs.com](mailto:hr@ymabs.com) **no later than February 28<sup>th</sup>, 2021** and please mark your applications with position ID number: 1031. We will initiate interviews in a rolling manner as applications are received.

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

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