

Associate Director, GMP QA

Y-mAbs Therapeutics A/S is looking for an Associate Director, GMP QA who will report to 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, contribute to the continuous improvement of the company's Quality Management System, ensure GMP compliance of the company's operations, provide QA support to the CMC project teams, and participate in execution of the GMP/GDP audit program.

Key responsibilities

- Function as a Delegate Qualified Person
- Perform review and disposition of IMP and medicinal product batches
- Contribute to preparation of SOPs and Policies for GMP/GDP areas
- Conduct audits of CMOs, contract laboratories, warehouses and other GMP/GDP vendors
- Facilitate preparation of Product Quality Reviews for commercial products
- Maintain Product Specification Files
- Participate in preparation activities for regulatory GMP/GDP inspections and facilitate the inspections
- Handle deviations, CAPA, complaints and recalls
- Provide QA support to CMC project teams
- Provide input to Quality Management Review

Travelling: up to 4 days per month

Education, experience, skills

- Education required by the EU Directive for a Qualified Person
- 5+ years of experience in pharma/biotech industry in Quality Assurance, GMP/GDP
- QP or Delegate QP experience, including with commercial products
- Thorough knowledge of US, EU and global requirements in GMP area
- Training and extensive experience as a lead auditor, GMP/GDP
- Experience in hosting of FDA, EMA and DKMA inspections
- 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
- Understanding of the specifics of working in a small company
- EU citizenship

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

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

Deadline: Please note that all applications must be marked with position ID number: 1005 and submitted via email to hr@ymabs.com no later than April 10, 2020.

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.