

QA Specialist, GMP QA

Y-mAbs Therapeutics A/S is looking for a QA Specialist, GMP, 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 actively contribute to the quality oversight of contract manufacturing activities with commercial products and IMPs; support the Qualified Person(s) by reviewing the product batch documentation and other GMP records; handle deviations, changes and complaints; ensure GMP compliant documentation management.

The position can give great opportunities for further professional development.

Key responsibilities

- Review of batch production and testing records, with input to the disposition decision
- Handling of deviations, changes, complaints and CAPAs
- Review of validation protocols and reports
- Review of product stability data
- Review and approval of printed packaging materials
- Contribution to preparation of SOPs for GMP area
- Generation of Quality reports and metrics

Travelling: occasionally

Education, experience, skills

- Education as a pharmacist or similar
- Minimum 1 year of experience in pharma/biotech industry or at a hospital pharmacy, preferably in Quality Assurance (GMP) or Quality Control
- Knowledge and experience in manufacturing activities with biologics and/or with radiopharmaceuticals will be beneficial
- Basic GMP training
- Proficiency in English
- Ability to work efficiently and to complete the tasks within defined deadlines
- Good computer skills, experience with EDMS (knowledge of Veeva is an advantage)
- Good documentation review skills

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, phone +45 53880788.

You can apply for the position by sending an email to hr@ymabs.com **no later than 31th of January, 2022 and mark the application Job ID 1071**. 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 for more information regarding the company and our development projects.