

QA Specialist, GMP QA

Y-mAbs Therapeutics A/S is looking for a QA Specialist, GMP QA 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; maintain the product specification files; 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 disposition decision
- Handling of deviations, changes, complaints and CAPAs
- Review of various validation protocols and reports
- Review of product stability reports
- Review and approval of printed packaging materials
- Maintenance of Product Specification Files
- Participation in hosting of regulatory GMP inspections
- Contribution to preparation of SOPs for GMP area

Travelling: occasionally

Education, experience, skills

- Education as a pharmacist or similar
- Minimum 2-3 years of experience in pharma/biotech industry or at a hospital pharmacy in Quality Assurance (GMP) or Quality Control
- Previous involvement in manufacturing activities with biologics and/or with radiopharmaceuticals will be beneficial
- Comprehensive GMP training
- Proficiency in English and Danish, written and orally
- Ability to work efficiently and to complete the tasks within defined deadlines
- Good planning and multitasking abilities
- 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, nmi@ymabs.com, phone +45 53880788.

You can apply for the position by sending an email to HR@ymabs.com **no later than 15th of April, 2021** and please mark your applications with position ID number: 1041. 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.