Associate Director, GCP QA

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

Y-mAbs is currently experiencing exciting times; the company is well funded, following a successful public offering last year and a secondary offering last month; we are expanding significantly, preparing for the submissions of our first BLAs for our lead products omburtamab and naxitamab. Moreover, we have an interesting pipeline with several compound modalities entering clinical development. Next in line is our vaccine compound for neuroblastoma patients in remission. At the same time, we also want to initiate two clinical studies with naxitamab for line-extensions. We are therefore looking for two dedicated CPMs that can be our lead for these new activities.

It is our expectation you will contribute to the continuous improvement of the company's Quality Management System, ensure compliance of the company's operations within GCP, provide QA support to the clinical and safety project teams, and execute the clinical part of the audit program. You may expect to travel up to 6 days per month.

Key responsibilities

- Provide guidance in local and global GCP requirements
- Contribute to preparation of SOPs and Policies for Clinical and Safety areas
- Conduct audits of CROs, central laboratories, clinical sites, TMF, CSR
- Lead preparation activities for regulatory inspections and facilitate the inspections
- Train employees in GCP
- Handle deviations, quality investigations and CAPA
- Provide QA support to project

Education, experience, skills

- MSc/BSc in pharmaceutical sciences, biological sciences or similar
- 5+ years of experience in pharma/biotech industry in Quality Assurance, GCP
- Thorough knowledge of US, EU and global requirements in the area of clinical trials
- Training and extensive experience as a lead auditor, GCP
- Experience in hosting of FDA, EMA and DKMA inspections
- Previous experience with oncology product development is beneficial
- Proficiency in English, 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

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 apply by email to info@ymabs.com no later than December 5th, 2019

www.ymabs.com

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.