Associate Director, GMP QA, Commercial Operations

Exciting QA opportunity within commercial operations

Y-mAbs Therapeutics is a rapidly growing late-stage clinical biopharmaceutical company with a broad and advanced product pipeline. They got the first product recently approved by FDA and launched on the US market.

In the newly established role as Associate Director, GMP QA, Commercial Operations, you will report to Sr. Director, Quality Assurance and be part of a rapidly growing team of highly qualified and motivated colleagues. You 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.

Your main tasks are:

- 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

Your qualifications are several years of experience from the pharmaceutical or biotech industry within Quality Assurance, GMP/GDP. Moreover, you have previously been involved in (contract) manufacturing activities with biologics (experience with radiopharmaceuticals will be beneficial).

You have extensive QP or Delegate QP experience with commercial products and a thorough knowledge of US, EU and global GMP/GDP requirements. You have training and extensive experience as a lead auditor, GMP/GDP. Furthermore, you have a record of successful collaboration with license partners, affiliates, etc. Experience in hosting of regulatory inspections is preferred together with experience with preparation of Product Quality Reviews or Annual Product Reviews.

You have a Master's Degree together with the education required by the EU Directive for a Qualified Person.

You are a person with proficiency in English, written and orally. You are able to work independently, with multiple tasks, and under ambitious timelines. You possess good planning and problem handling abilities. Moreover, you have good collaboration skills, both internally and with external parties together with strong mentoring skills. Finally, you have good IT skills and experience with EDMS (knowledge of Veeva is an advantage).

Y-mAbs offers an exciting opportunity in a successful biotech company in which you will have a high degree of influence on your own job and gain experience with a diverse range of molecular biological

modalities and disease targets. The position will allow you to create a sustainable footprint while developing professionally.

Travelling: Approx. 3 days per month (under regular circumstances).

Domicile: Hørsholm, Denmark.

Unique Human Capital is handling the recruitment. For more details about the job or the company, please contact Senior Research Consultant Elisabeth Haun, Unique Human Capital on M: + 45 28 90 33 88. All applications must be submitted in English and are treated confidentially.

You can apply directly via this link: https://uhc.dk/en/available-jobs/associate-director-gmp-qa-commercial-operations/

Y-mAbs is a 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, including 2 pivotal-stage product candidates - naxitamab and omburtamab - which target tumors that express GD2 and B7-H3, respectively. Their mission is to become the world leader in developing antibody-based cancer products that address clear unmet needs in pediatric oncology. With the right partnerships and collaboration, they envision expanding their capabilities to treat adults - changing the course of cancer care and its outcomes. Currently, there are 100+ permanent employees in Y-mAbs.

Read more at www.ymabs.com.