

CMC Project Manager

- join the Development team in a leading and fast-growing biotech company on its way to becoming a fully integrated pharmaceutical company!

Welcome to Y-mAbs Therapeutics A/S

We are a rapidly growing late-stage clinical biopharmaceutical company focused on the development and commercialization of novel, antibody-based cancer products that address unmet needs in pediatric oncology.

You will join us at an exciting time as we have already established a broad and advanced product pipeline, including two pivotal-stage product candidates, for which the company's first BLAs have been submitted.

Y-mAbs Therapeutics A/S (Y-mAbs) is starting up CMC development work on new exciting technology platforms and we are therefore seeking a new Project Manager in our CMC development team.

As our new CMC Project Manager you will:

- contribute to our efforts in bringing our pipeline of new product candidates through early and clinical development phase and into commercial supply. You will work on all CMC activities associated with our development programs, and work in close collaboration with other functional groups within Y-mAbs.
- have a good understanding of the outsourcing process, from quotations and contract negotiations to follow-up, and troubleshooting with our CMC partners is a key competence as all manufacturing is outsourced.
- the ideal candidate has an entrepreneurial mindset and must be able to work with ambitious timelines in a slim organization with a cross-functional team and close relations to both regulatory and clinical activities.

It is key that you have in depth expertise within the following areas:

- Drug development of biologics in clinical development programs
- Experience in working with CMO/CRO's and international regulatory agencies like FDA and EMEA
- Project management cross functionally and in teams with different cultures.

Your main responsibilities will be:

- Manage, coordinate and drive the Chemistry, Manufacturing and Control (CMC) part of projects in early and late stage development and towards commercial launch
- Coordinate activities within drug development and quality control using external vendors
- Support other projects with the selected candidate's expert knowledge
- Be responsible for writing and reviewing the technical content of the regulatory documents for IND's, IMPD's and other regulatory submissions
- Work with CMC senior management to create project schedules that are integrated across all functions and aligned with Y-mAbs' project prioritization and strategy
- Identify and monitor critical path, utilizing Project Management tools and develop contingency plans if the project deviates from the planned path
- Project management of international project teams

The successful applicant will:

- Have an enterprising mindset that seeks solution supporting the overall goal
- Keep the overall direction and momentum despite many unsolved details
- Have a PhD or MSc in pharmaceutical sciences, engineering or biological sciences
- Have 5+ years of experience in biopharmaceutical/biotech industry
- Be fluent in English with excellent communication skills, written and orally

Y-mAbs offers:

- An exciting work environment where challenging assignments will come your way
- Great office location in Hørsholm including canteen and easy parking
- Competitive salary, pension and benefit package

Interested?

If you want to know more about the position, you are welcome to contact Director of CMC Development Tore Söderblom at +45 5388 0988.

You can apply for the position by sending an email to HR@ymabs.com. We will initiate interviews in a rolling manner starting in week 38 as applications are received.

Please note that applications must be submitted in English and will be treated confidentially.

Mark your applications with position ID number: 1025.

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.