

CMC Project Manager

Y-mAbs Therapeutics A/S (Y-mAbs) have a growing number of projects in the pipeline and we are therefore seeking new Project Manager in our CMC development team.

Our new CMC Project Manager will contribute to our effort 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.

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.

For this position we are preferably looking for a candidate with analytical work experience within a QC environment.

The ideal candidate has an entrepreneurial mindset and must be able to work with ambitious time lines 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 one or more of the following areas:

- Analytical method for control of biotech drug substance and drug product
- Drug development of biologics in clinical development programs
- Experience in working with CMO/CRO's and international regulatory agencies like FDA and EMA

Main responsibilities:

- You will 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 leadership 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 deviate from the planned path
- Project management of international project teams

Personal qualifications

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



YmAbs offer:

- 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

For more details about the job or our company, please contact Director of CMC Development Tore Søderblom at +45 5388-0988.

Please note that all applications must be submitted in English and marked with ID no. 1002.

All application will be treated confidentially.

Deadline: Please apply by email to hr@ymabs.com as soon as possible as we will start interviews in week 8.

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.