



CMC Project Manager

A new position is now open! Y-mAbs Therapeutics A/S (YmAbs) is looking for a CMC Project Manager. You will primarily focus on CMC activities associated with our late stage development programs, and you work with CMC interfaces to other functional groups within YmAbs. 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 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 the following areas:

- Analyses and validation of release and stability analyses according to ICH guidelines
- Specific knowledge about biological assays like cell based assays
- Formulation development of proteins
- Experience in working with CRO's and international regulatory bodies 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 with specific focus on analytical and stability issues
- Coordinate development activities within drug product formulation, assay development, control strategies, and quality control using external vendors (CRO's)
- 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 YmAbs' project prioritization and strategy
- Identify and monitor critical path, utilizing Project Management tools and develop contingency plans should the project deviate from the path

Personal qualifications

- PhD or MSc in pharmaceutical sciences, engineering or biological sciences
- 3+ years of experience in biopharmaceutical/biotech industry working with CRO's
- You are fluent in English with excellent communication skills, written and orally
- Excellent computer skills (e.g., MS Excel, MS Project)

YmAbs offer:

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

For more details about the job or our company, please contact Torben Lund-Hansen, SVP, Head of Technical Operations, at +45 25403010. Please note that all applications must be submitted in English and will be treated confidentially.



Deadline: apply as soon as possible as we shall start interviews in week 4.

Please send your application to info@ymabs.com.

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.