

Senior Manager, Regulatory Affairs CMC, New Markets & Life Cycle Management

Come join our dedicated regulatory team at Y-mAbs Therapeutics A/S!

Y-mAbs is now looking for a Regulatory Affairs CMC senior manager in a newly established position in Global Regulatory Affairs. You will become an important part of managing regulatory submissions and approvals in new markets and establishing LCM. You will report to the LCM Lead of Global Regulatory Affairs.

Y-mAbs is a rapidly growing late-stage clinical biopharmaceutical company focused on the development and commercialization of novel, antibody-based therapeutic products for the treatment of challenging pediatric cancers, and ultimately adult patients. The company has a broad and advanced product pipeline and had the first product approved by FDA in November 2020, which has been launched early this year.

In this newly established position, you will play a crucial role in new markets and LCM activities globally. As Y-mAbs is transitioning from being a development stage company to a commercial company, you will take part in building up the necessary structure, procedures, and systems required to handle regulatory CMC activities for new markets and in LCM. You will be a key player in ensuring planning and execution of CMC LCM activities and geographical expansion together with internal stakeholders and external partners.

Y-mAbs works in close collaboration with regulatory CROs and external partners and you will be responsible for maintaining a proper oversight and communication with the CROs regarding CMC activities, e.g. variations, annual updates, tracking and documenting health authority correspondence worldwide.

If you find the above interesting, join Y-mAbs and become part of our team in a fast-moving environment that offers a unique combination of scientific insight, entrepreneurship, and exciting challenges!

Key responsibilities:

- Handle new markets and LCM CMC activities
- Cover regulatory CMC across products from MAA/BLA stage and into LCM and new markets, including providing input to and reviewing regulatory CMC documents
- Responsible for regulatory maintenance of marketed products globally (major / minor changes, annual reporting etc.)
- Build up and structure collaboration and interactions with QA, CMC, and product supply
- Evaluate Change Request cases
- Plan and execute regulatory submissions with CROs or external partners in new markets
- Ensure timely follow-up on CMC commitments / requirements from health authorities
- Responsible for regulatory oversight of CROs and external partners involved in the regulatory CMC LCM activities, as well as coordination and alignment of changes world wide
- Ensure tracking and documenting of health authority interactions in our newly established regulatory information management (RIM) database
- Contribute to the continuous improvement of Y-mAbs' procedures and secure best practices

Personal and professional qualifications

- MSc within natural sciences, e.g. biology, pharmaceutical science or equivalent
- You have regulatory CMC experience with LCM and submissions in new markets
- You have a good understanding of global regulatory CMC requirements within LCM
- You are flexible and enjoy handling multiple tasks at the same time
- You take responsibility and work independently, and at the same time you are a strong team player
- You have the drive to build up the LCM infrastructure at Y-mAbs in collaboration with internal stakeholders
- You have experience in document management
- You are structured, organized, and have excellent coordinating skills, while still being pragmatic and thriving in an entrepreneurial environment
- You can work with ambitious timelines in our slim organization with a cross-functional team
- +8 years experience in regulatory affairs, mainly CMC
- You are result-oriented and committed to contributing to the overall success of Y-mAbs
- Our company language is English, so your communication in both written and spoken English is fluent

Some travel activity may be expected.

For more details about the job or our company, please contact Rikke V. Oxholm Lillesø, VP of Regulatory Affairs, at +45 53 88 02 88 or Daniel Dam Doktor, RA LCM Lead at +45 53 88 01 65. Please note that all applications must be submitted in English and will be treated confidentially.

You can apply for the position by sending an email to HR@ymabs.com no later than **09 May 2021**. Please mark your application with **Job ID no. 1045**.

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. Please access the company web site www.ymabs.com for more information regarding the company and our development projects.