Senior Manager / Director of Regulatory Affairs – make your mark on LCM and CMC

Are you ready to take on global regulatory affairs management of products that will have a deep impact on the life of pediatric cancer patients worldwide?

Joining us, you will put your fingerprint on the future structure, procedures and systems of regulatory affairs as we transition from the development stage to a commercial company.

"We offer a flexible environment with a unique combination of scientific insight, entrepreneurship, exciting challenges and with room to be inventive and to find creative solutions to achieve success."
– Rikke V. Oxholm Lillesø, VP of Regulatory Affairs.

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.

Taking the lead on Regulatory Affairs, LCM, you will:

- Drive the establishment of necessary regulatory processes, systems, and structures for Y-mAbs to comply with requirements for marketed products
- Develop and execute LCM strategies for label updates, PIP/PSP fulfilment, manufacturing changes, etc. together with Commercial and other key internal stakeholders
- Carry out regulatory submissions such as variations, annual updates, safety commitments/PSURs/DSURs and PASS, in collaboration with our CROs
- Perform regulatory maintenance of marketed products globally
- Handle regulatory management of CMC change requests for marketed products and development projects
- Ensure proper regulatory review of promotional material in collaboration with our CROs
- Maintain proper oversight and communication with our CROs regarding our marketed products' activities

A position with an outstanding support base
You will join us at our great office location in the DTU Science Park in Hørsholm, where all pre-clinical and clinical activities are coordinated from. From here you will report directly to the VP of Regulatory Affairs and collaborate with carefully selected CROs and a team of leading Regulatory specialists who are ready to support you in your endeavors.

Experienced in Regulatory Affairs and knowledge of natural sciences
It is vital that you are ready to take on the responsibility for the development of an LCM infrastructure and work with a wide array of processes in collaboration with colleagues and partners alike. You must also be highly organized, and have a strategic, pro-active approach, being able to coordinate and prioritize between tasks with a pragmatic mindset, even with ambitious timelines.

Furthermore, you:

- Hold an MSc in medicine, biology, pharmaceutical sciences or similar within natural sciences
- Have 7+ years of experience with Regulatory Affairs, including LCM and CMC and document management
- Are knowledgeable about regulatory requirements for LCM in US and EU
- Speak and write fluently in English

Interested?
If you want to know more about the position, you are welcome to contact Rikke V. Oxholm Lillesø, VP of Regulatory Affairs, at +45 53 88 02 88.

You can apply for the position by sending an email to hr@ymabs.com **no later than August 14, 2020**. We will initiate interviews in a rolling manner 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: 1012.