Senior Regulatory Affairs Manager

Come join our dedicated regulatory team! Y-mAbs Therapeutics A/S (Y-mAbs) is now looking for an experienced Senior Regulatory Affairs Manager in a newly established position.

Y-mAbs is a fast-paced biopharmaceutical company entering an exciting time preparing for BLA and MAA submissions, as well expanding our clinical development program with new projects. In this new position you will be responsible primarily for one of our late stage projects preparing for BLA and MAA submission in close collaboration with key stakeholders in the Y-mAbs organization and external partners.

As a Senior Regulatory Affairs Manager, you will be a key contributor in developing and executing global regulatory strategies. You will be responsible for preparing BLA/MAA submissions, CTA submissions, and handling Q&A with the health authorities. Furthermore, you will play an essential role in ensuring a successful regulatory transition from development to commercialization. Y-mAbs' regulatory department is expanding and close sparring across projects will be important.

We work in close collaboration with CROs and you will be responsible for maintaining a proper oversight within your project.

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:

- Regulatory submissions such as CTAs, INDs, BLA and MAA in collaboration with our CROs
- Ensure timely follow-up on commitments / requirements from health authorities
- Planning and preparation of meetings with health authorities
- Regulatory oversight of CROs involved in the regulatory activities
- Regulatory input to our regulatory development and submission strategies
- Input to DSURs, IBs and other relevant documents intended for regulatory submission
- Initiate regulatory activities and systems for marketed products
- Contribute to the continuous improvement of Y-mAbs' procedures and secure best

Personal and professional qualifications

- MSc within the medical, biological or pharmaceutical science or equivalent
- You have a broad experience in submissions to health authorities (CTAs, INDs, BLA and MAA)
- You are structured, organized, and have excellent coordinating skills, while still thriving in an entrepreneurial environment
- You take responsibility and work independently
- You have experience in document management

- You can work with ambitious timelines in our slim organization with a cross-functional team
- +5 years' experience and knowledge of regulatory requirements from EMA and FDA
- 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

Y-mAbs offer:

- An exciting work environment where challenging assignments will come your way
- Great office location at DTU Science Park including canteen and parking
- Competitive salary package

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

Deadline: Please send your application to info@ymabs.com no later than 30 November 2018. We will initiate interviews in a rolling manner as applications for the job are received.

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.