



## Regulatory Submission Manager

Come join our experienced and dedicated team! Y-mAbs Therapeutics A/S (YmAbs) is now looking for a Regulatory Submission Manager.

YmAbs is facing an exciting time, where we have recently opened our own INDs for our two lead products omburtamab and naxitamab and will start several new clinical trials in both Europe and US. We have further initiated planning for BLA and MAA submissions.

As Regulatory Submission Manager your function will be to prepare for BLAs/MAAs submissions, CTA submissions and oversight, and to coordinate Question/Answer rounds between the health authorities and YmAbs. You will also provide regulatory intelligence and input to regulatory strategies for our projects with the overall goal of developing new and innovative treatment for both pediatric and adult cancer patients.

We work in close collaboration with CROs and you will be responsible for coordinating and securing the information flow between the CROs in a proactive fashion, through clear communication and great teamwork. Moreover, you will be responsible for proper documentation and record management.

### Key responsibilities:

- Coordinate and prepare regulatory submissions such as clinical trial applications, IND submissions and amendments, CMC variations, BLA submissions, MAA submissions in collaboration with our CROs
- Tracking health authority correspondence together with our CROs
- Ensure timely follow-up on health authority commitments / requirements
- Regulatory oversight of CROs involved in the regulatory activities
- Coordinate and ensure shared information with and between the CROs
- Collect and provide regulatory input to our regulatory development and submission strategies
- Contribute to the continuous improvement of YmAbs' procedures and secure best practices

### Personal and professional qualifications

- MSc within the medical, biological or pharmaceutical science or equivalent
- You have experience in coordination of submissions to health authorities (BLA/NDA/MAA and CTA)
- 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 YmAbs
- Our company language is English, so your communication in both written and spoken English is fluent
- Some travel activity may be expected



**YmAbs offer:**

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

For more details about the job or our company, please contact Rikke V. Oxholm Lillesø, Director of Regulatory Affairs, at +45 5388 0288. Please note that all applications must be submitted in English and will be treated confidentially.

Please send you application to [info@ymabs.com](mailto:info@ymabs.com) no later than 22 January 2018. We will initiate interviews in a rolling manner from week 3.

[www.ymabs.com](http://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.*