



Regulatory Affairs Submission Coordinator / Senior Associate

Y-mAbs Therapeutics A/S (Y-mAbs) is expanding and is now looking for an experienced Regulatory Submission Coordinator in a newly established position.

Y-mAbs is facing an exciting time planning for BLA and MAA submissions, as well as initiating clinical development for new projects.

As Regulatory Submission Coordinator you will have a key role in all our ongoing and future projects and activities in support of BLA and MAA submissions, CTA submissions and Question/Answer rounds between the health authorities and Y-mAbs. You will thus actively be supporting Y-mAbs' 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 support regulatory submissions such as clinical trial applications and amendments, IND submissions and amendments, BLA submissions, and MAA submissions in collaboration with our CROs
- Tracking health authority correspondence together with our CROs
- Keeping the Regulatory Overviews up to date
- Coordinate and ensure shared information with and between the CROs
- Contribute to the continuous improvement of Y-mAbs' procedures and secure best practices
- Ensuring that Y-mAbs regulatory documents are uploaded in the document management system according to compliance and quality standards

Personal and professional qualifications

- Relevant educational background, as minimum a bachelor's degree in for example science, business administration or English.
- You have +5 years administrative experience previous positions in regulatory affairs or related fields in the pharmaceutical industry.
- 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
- Our company language is English, so your communication in both written and spoken English is fluent



Y-mAbs offer:

- An exciting work environment where challenging assignments will come your way
- Great office location at DTU Science Park including canteen and easy 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 apply by email to info@ymabs.com no later than 20 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.