

## **Senior Medical Writer**

Y-mAbs is a listed biotech company based in Hoersholm and New York. We develop new treatment options for pediatric cancers. Y-mAbs Therapeutics A/S (Y-mAbs) is expanding and is now looking for an experienced Senior Medical Writer in a newly established position.

Are you our new Senior Medical Writer in a busy and ambitious working environment? This is your opportunity to join a dedicated team of professionals and become an important part of the Clinical Development staff of an innovative biopharmaceutical company.

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

As Senior Medical Writer you will have a key role in all our ongoing and future projects and activities in support of BLA and MAA submissions. 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 to and from these related to medical writing activities. Moreover, you will be responsible for proper documentation and record management.

### **Key responsibilities:**

- Build-up medical writing as a functional area
- Preparation and gate-keeping of regulatory clinical documents (e.g. Clinical Trial Protocols/Reports, Investigator's Brochures, responses to authorities, Clinical Summaries and Overviews, DSUR)
- Planning and coordination of activities in a cross-functional setting
- Medical writing support to various regulatory and scientific documents
- Review of clinical trial documents e.g. Clinical Development Plans, Statistical Analysis Plans (SAPs), protocols, and protocol amendments
- Support to other functional areas on communication best practices
- Contribute to the continuous improvement of Y-mAbs' procedures and secure best practices

### **Personal and professional qualifications**

- You have at least 5 years of experience as Medical Writer, preferably at least 2 years at a senior level

- You have experience as medical writer on market authorization submissions to both FDA and/or EMA
- You have a university degree within Natural Sciences incl. skills within scientific research methods.
- You have the ability to drive, manage and write concise and targeted regulatory, scientific documents in collaboration with many stakeholders
- You have analytical skills and the ability to work with large amounts of information
- You are structured with an eye for detail
  
- You are self-driven and can work independently
- You have excellent communication skills and fluent in English written as well as spoken
- 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 René dePont Christensen (Director of Biometrics) at +45 5379 1088. Please note that all applications must be submitted in English and will be treated confidentially.

Deadline: 20 November 2018. We will initiate interviews in a rolling manner as applications for the job are received.

Please send your application to [info@ymabs.com](mailto:info@ymabs.com)

[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.*