Regulatory Affairs Manager - Maternity Cover

Come join our dedicated regulatory team! Y-mAbs Therapeutics A/S (Y-mAbs) is now looking for a Regulatory Affairs Manager for a 9-month maternity cover with the possibility of extension to support the Life Cycle Management & Development activities within Global Regulatory Affairs.

Y-mAbs is a fast-paced, late-stage clinical biopharmaceutical company focused on the development and commercialization of novel, antibody-based therapeutic products for the treatment of cancer. It is expanding rapidly, following approval of its first product in November 2020 and second product anticipated approval later this year. The company has a broad and interesting pipeline with several compounds in clinical development

As a Regulatory Affairs Manager you will support the LCM team in building up the necessary structure, procedures, and systems required for Y-mAbs to handle new markets and LCM activities. You will support planning and execute LCM activities and geographic expansion together with the LCM RA team, key internal stakeholders and external partners. You will report to the Life Cycle Management Lead of Global Regulatory Affairs. Furthermore, you will in collaboration with the Regulatory Project Leads support our development projects (CTAs / INDs) and be an important contributor in preparing responses to Biologic License Application Requests.

Key responsibilities

- Support Life Cycle Management activities of marketed products globally incl. annual reports, safety update submissions (PSURs/DSURs/PADERs) in close collaboration with our CROs or external partners
- Involved in review of change controls to support post-approval changes globally
- Preparation of country specific documents supporting new Marketing Authorization Applications (MAAs) and post-approval submissions
- Tracking and documenting Health Authority correspondence, submissions and commitments in our regulatory information management (RIM) database
- Contribute to the continuous improvement of Y-mAbs' procedures and secure best practices

Personal and professional qualifications

- MSc within natural science e.g. biology, pharmaceutical science or equivalent
- You are structured, organized, and have good coordinating skills
- You are flexible and enjoy handling multiple tasks at the same time
- You take responsibility and work independently, but at the same time you are a strong team player
- You have experience in document management
- You can work with ambitious timelines in our slim organization with a cross-functional team

- You preferably have 1-2 years' regulatory experience, maybe through student work in Regulatory Affairs, and some knowledge of regulatory requirements
- 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

For more details about the job or our company, please contact VP of Regulatory Affairs, Rikke Valentin Oxholm at +45 53 88 02 88 or Daniel Dam Doktor, RA LCM Lead at +45 53 88 01 65.

Your application must be submitted in English and will be treated confidentially.
You can apply for the position by sending an email to HR@ymabs.com. Please mark your application with **Job ID no. 1074.**

Deadline for applications: 18 July 2022. We will initiate interviews in a rolling manner as applications are received.

Y-mAbs Therapeutics A/S is located in Hørsholm, Denmark - a Danish affiliate of Y-mAbs Therapeutics Inc.. Our mission is to discover, develop and deliver novel antibody therapeutics for the treatment of both pediatric and adult cancer patients.

Please access the company website www.ymabs.com for more information regarding the company and our development projects.