Associate Director/ Director Corporate Drug Safety

Y-mAbs Therapeutics A/S (Y-mAbs) is now looking for an Associate Director/Director of Corporate Drug safety (CDS). In this newly established position, you will report to the Senior Director, CDS.

Y-mAbs is an international biotech company (listed on Nasdaq) with two late stage development programs and an exciting pipeline. Y-mAbs also initiates several new clinical trials in both Europe and US this year. Furthermore, Y-mAbs aim for regulatory submissions of our two most advanced late stage programs within a short time frame.

As our new Associate Director/Director of CDS you will function as part of our experienced drug safety team. Y-mAbs operates with an outsourcing model using an external CRO for safety surveillance and reporting, however, all oversight over clinical studies is kept within the company. Y-mAbs has activities spanning from early stage development through pivotal clinical trial(s), planned license application submission(s), product approval(s) and beyond.

Y-mAbs works in close collaboration with CROs and within the drug safety function area you will ensure proper documentation, record management as well as sponsor oversight.

Key responsibilities:

- Execute Drug Safety oversight for the clinical projects
- Perform medical assessment of reported SAE´s
- Perform overall safety surveillance /risk management activities for Y-mAbs' products
- Perform signal detection and analysis
- Prepare aggregate reports, safety signal assessment reports and benefit risk assessments
- Review of clinical safety data, DSURs, IBs, ICFs, study protocols and reports
- Contribute to review of regulatory submission documents, Risk management plans and BLA submission documents and labelling discussions
- Contribute and participate in external DMC(s)
- Contribute and participate in Y-mAbs' safety committee
- Interact with CRO on outsourcing of safety deliverables
- Contribute to sponsor oversight for outsourced safety deliverables
- Prepare training material and conduct training activities (e.g. internal, CRO, site personnel)
- Contribute to responses to regulators
- Build and maintain Drug Safety Expertise, understanding international safety regulations and guidelines

Personal and professional qualifications

- 3+ years' experience within corporate drug safety
- Certified MD, nurse, pharmacist or equivalent
- Prior experience repsponding to Health Authorities on safety related issues
- Prior experience working with safety CRO's
- Experience with and in-depth knowledge of safety reporting and requirements from a global perspective, covering both EU and US an advantage

- We expect you to have an entrepreneurial mindset
- Demonstrates initiative and capacity to work under pressure
- As a team player, you can work with ambitious timelines in our slim organization with a cross-functional team
- You are result-oriented and committed to contributing to the overall success of Y-mAbs
- Ability to communicate complex clinical issues and analysis orally and in writing
- Capability to synthesize and critically analyze data from multiple sources
- Our company language is English, so your communication in both written and spoken English is fluent

Y-mAbs offers:

- 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 including pension and health insurance

For more details about the job or our company, please contact Steen Lisby, SVP, Chief Medical Officer, at +45 7026 1414. Please note that all applications must be submitted in English and will be treated confidentially.

Deadline: please apply by email to info@ymabs.com as soon as possible as we start interviews in a rolling manner.

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.