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 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. Furthermore, Y-mAbs aim for regulatory BLA 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. Additionally, CDS operates with a semi-outsourcing model where case management and reporting has been outsourced to a safety vendor, whereas safety surveillance is kept within the company.

As our new Associate Director/Director your main task will be (in collaboration with the Director, CDS) to hold the responsibility for all drug safety related activities for early as well as late stage development projects.

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 with case management
- Prior experience with safety surveillance
- Prior experience responding 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 is 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

For more details about the job or our company, please contact Eva Widebæk Rasmussen, Sr. Director, Corporate Drug Safety, 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 process applications and arrange interviews continually.

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.