

Safety Specialist, Corporate Drug Safety

Y-mAbs Therapeutics A/S (YmAbs) is now looking for a Safety Specialist who will be part of a growing team within Corporate Drug Safety (CDS). In this newly established position you will report to the Director, CDS.

YmAbs is a growing, clinical stage biotech company with offices in USA (New York) and Denmark (Hørsholm). YmAbs has opened two IND's for our two lead products with development in pivotal phase II and phase II/III, respectively. YmAbs also plans to initiate new clinical trials in both Europe and US this year. Furthermore, our innovative pipeline is expected to result in more clinical activity in near future.

YmAbs operates with an outsourcing model using an external CRO as safety vendor, however, all oversight over clinical studies (sponsor oversight), case handling (with focus on follow-up) and signal detection is kept within the company. YmAbs has activities spanning from early stage development through pivotal clinical trial(s), planned license application submission(s), product approval(s) and beyond.

As our Safety Specialist 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 our clinical projects
- Medical assessment of reported SAE's
- Conduct sound risk assessment
- Initial signal detection activities and analysis together with Director of CDS
- Knowledge of regulatory guidelines and provide drug safety expertise to our project teams
- Prepare and/or review PV sections of protocol submissions and amendments in collaboration with our CROs
- Review safety sections of regulatory documents
- Interaction with our safety CRO

Personal and professional qualifications

- 4+ years' experience within corporate drug safety
- Certified nurse, pharmacologist or equivalent
- Prior experience working with safety CRO's an advantage

- We expect you to have an entrepreneurial mindset
- Ability to demonstrate initiative and capacity to work under pressure
- You are result-oriented and committed to contributing to the overall success of YmAbs
- Our company language is English, so your communication in both written and spoken English is fluent

YmAbs 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 Eva Widebæk Rasmussen, Director CDS at +45 23221968. Please note that all applications must be submitted in English and will be treated confidentially.

Deadline: please apply by email to info@ymabs.com by September 10, 2018.

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.