Associate Director / Director of Global Drug Safety

Would you like to contribute to the continuous improvement of our company's Safety Management System?

Y-mAbs is looking for a (Senior) Associate Director/Director to perform surveillance activities and ensure that safety signals are handled appropriately in collaboration with the rest of the team for a proper benefit-risk assessment, this in addition to other safety-related deliverables for dedicated projects/products. Joining us, you will be part of a growing team of five highly qualified and motivated colleagues to ensure that Y-mAbs clinical studies are handled in compliance with regulatory requirements.

You will also be able to put your fingerprint on the future structure, procedures, and systems for product safety management as we transition from the development stage to a commercial company.

Welcome to Y-mAbs Therapeutics A/S
We are a rapidly growing late-stage clinical biopharmaceutical company focused on the development and commercialization of novel, antibody-based cancer products that address unmet needs in pediatric oncology.

You will join us at an exciting time as we have already established a broad and advanced product pipeline, including two pivotal-stage product candidates, for which the company's first BLAs have been submitted.

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 e.g. DSUR and Risk Management Plans
- Contributed to review of regulatory submission documents such as IB, protocols and BLA/MAA submission documents and labelling discussions
- Contribute and participate in external DMC(s)
- Contribute and participate in Y-mAbs' safety committee
- Contribute to responses to regulators
- Build and maintain drug safety expertise, understanding international safety regulations and guidelines

A position with an outstanding support base
You will join us at our great office location in the DTU Science Park in Hørsholm, where all pre-clinical and clinical activities are coordinated from. From here you will report directly to the Sr. Director of Global Drug Safety and collaborate with a team of leading safety specialists who are ready to support you in your endeavors.

Experienced in Clinical Drug Safety and knowledge of natural sciences
It is vital that you are ready to take on the responsibility for the development of an safety infrastructure and work with a wide array of processes in collaboration with colleagues and partners alike. You must also be highly organized, and have a strategic, pro-active approach, being able to coordinate and prioritize between tasks with a pragmatic mindset, even with ambitious timelines.

Furthermore, you:

- Hold a relevant academic background (MSC/PhD) in natural sciences, e.g. biology, pharmaceutical sciences, medicine, or veterinary science
- Have 5+ years of experience with Clinical Drug Safety
- Are knowledgeable about regulatory requirements in the USA and EU
- Speak and write fluently in English

Interested?
If you want to know more about the position, you are welcome to contact Eva Widebæk Rasmussen, Sr. Director and Global Lead of Clinical Drug Safety, at +45 23 22 19 68.

You can apply for the position sending an email to **hr@ymabs.com no later than August 14, 2020**. We will initiate interviews in a rolling manner as applications are received.

Please note that applications must be submitted in English and will be treated confidentially. Mark your applications with position ID number: 1021.