Safety Advisor / Safety Specialist of Global Clinical Drug Safety

Do you want to lead safety surveillance activities for innovative cancer products?

Y-mAbs is seeking a Safety Advisor/Safety Specialist to develop and successfully execute the safety surveillance strategy for assigned products.

You will apply your strong safety knowledge and skills in all aspects of surveillance, including signal detection and evaluation, authoring safety-related documents, and providing expert input into the safety monitoring and risk management strategies for clinical studies and programs. You will achieve this through close collaboration with your colleagues in the safety department as well as counterparts in other functions.

You will also be able to influence the development and implementation of departmental processes, systems and working practices as we transition from the development stage to a commercial company.

This a great chance to make a real difference for patients with serious disease and there will be many opportunities to lead key activities and develop your career. You will join an enthusiastic and motivated team and enjoy a friendly and informal work environment.

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 SAEs
- Perform overall safety surveillance /risk management activities for Y-mAbs products
- Perform signal detection and analysis
- Prepare aggregate reports e.g. DSUR, PBRER and Risk Management Plans
- Contribute to the development and 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(s)
- 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. This is the central hub for pre-clinical and clinical activities, and you will be very much at the heart of things.

You will report directly to the Sr. Director of Global Clinical Drug Safety and collaborate with a team of leading safety specialists who are ready to support you in your endeavors.

Your continued personal and professional growth will be also encouraged through training and the sharing of best practice.

Experienced in Clinical Drug Safety

It is vital that you ready to take on responsibility for leading safety surveillance activities in a cross functional setting. Your range of knowledge will also enable you to contribute more widely across the safety department including the development of Y-mAbs's safety processes

You are collaborative by nature and adept at building strong working relationships with company colleagues and external partners alike. You must be highly organized with a strategic, pro-active approach, and bring a pragmatic mindset to your work. A wide array of tasks will come your way and the ability to manage competing priorities, even with ambitious timelines, is important.

Furthermore, you:

- Hold a relevant academic background such as a Masters/PhD in biology, veterinary medicine, pharmaceutical sciences or similar within natural sciences
- Have 5+ years of experience with Drug Safety
- Are knowledgeable about regulations applicable to drug safety
- Have prior experience leading product safety monitoring and risk management activities
- Speak and write fluently in English

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

You can apply for the position by clicking the "Søg jobbet online" link below **no later than March 1, 2021**. 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: 1034.