Regulatory Affairs & Safety Manager for NBCD A/S

Are you known for being well-organized and structured with a keen eye for details? Do you thrive on working independently and taking accountability for your responsibilities? Are you passionate about making a difference in a global research organization dedicated to providing first-class clinical research? If you find yourself nodding to these questions, then you might be the one we are looking for.

Join us in an environment fueled by dedication and inspired by our core values: "Team up, Take on, and Try out." Here, you'll have the chance to make a significant difference while expanding your skillset.

Who are we?

NBCD, a key part of the Sanos Group with around 245 employees, is a world-leading CRO specializing in osteoarthritis and musculoskeletal diseases. We provide top-tier scientific and clinical trial services to the biotech and pharmaceutical industries. At NBCD, innovation is at our core, enabling us to develop life-changing medications efficiently through pioneering study designs and flawless execution. We focus on a few therapeutic areas, letting science drive our business, particularly in connective tissue diseases like osteoarthritis and rheumatoid arthritis. Our comprehensive support covers everything from study design to regulatory affairs, ensuring expert handling at every step. Renowned worldwide for our scientific and operational excellence, NBCD leads in international medication development.

Your key role and responsibilities

In your role as RA & Safety Manager, you will lead the planning and execution of the Regulatory Affairs & Safety activities and collaborate closely with the Clinical Trial Management team and the Medical Affairs team, in addition to other frequent cross-functional collaborations in regular study activities.

Your job as Regulatory Affairs and Safety Manager will be highly varied and will amongst other responsibilities include the following:

- Ensure that the regulatory process for clinical trial submission is planned and executed including management of the Clinical Trial Application documentation for international Phase I-III clinical trials. You will handle document writing and collection, and coordinate submissions with multiple global stakeholders.
- You will be the main responsible for global trials submissions covering phase 1-3. With focus on ph2 and ph3 submission, the number of allocated trials may change over time. We expect that you would be responsible for at least one ongoing submission while supporting fellow team members in the maintenance and RFI work for other submissions. Coordination of interactions with national and international Regulatory Agencies and Independent Ethics Committees regarding new and existing clinical trials.
- Prepare Safety Management Plans in collaboration with internal and external stakeholders, and process Serious Adverse Events from Investigator sites, including handling, review and querying.
- Responsible for complete and accurate safety data collection and registration of adverse events.
- Completion and submission of expedited safety reports from our clinical trials to Competent Authorities and Independent Ethics Committees in accordance with local and global regulations.
- Together with the rest of the team, you will as a RA & Safety Manager be responsible to keep up with updated regulatory requirements and continuously adapt our procedures to be fit for purpose.
- Maintaining regulatory and safety parts of our Clinical Trial Master Files
- Engaging in correspondence with Sponsors, Contract Research Organizations and other Vendors, such as participation in recurrent sponsor and trial team meetings, as well as participation in internal and external audits.

Desired skills and experience

You hold an educational degree in health sciences and have experience interacting with competent authorities concerning clinical trials or marketed products. Familiarity with GCP, clinical trials, eTMF, and/or safety databases is a plus. Excellent communication skills are essential, and since

most of our communication is in English, you must be fluent in business English (both oral and written) and possess basic medical writing skills. We expect that you can manage both your own and others time to a high degree and therefore solid project management skills are seen as essential to be successful in this role.

Personal profile

You are a responsible professional who can work independently and take accountability for your delegated responsibilities. You prefer to have things well-organized and structured, with a keen eye for detail. This is essential for accurate planning, reporting, documentation, and filing in Regulatory Affairs and Pharmacovigilance. You are enthusiastic about innovative research and eager to learn new approaches to expand your core skill set. With excellent collaboration skills, you can effectively cooperate and communicate with different professions and at various business levels. You are committed to fostering a positive working environment and ensuring a supportive atmosphere among your colleagues, even in busy periods.

Are we the right cultural fit for you?

Our commitment to you is encapsulated in our promise to every one of our employees saying '*Trust in you - in your development and impact´.*

This pledge extends uniformly across all entities within the Sanos Group organization, including NBCD, ensuring that you feel its effects from the very offset of your interaction.

If you are curious about whether you would thrive within the Sanos Group culture and the Sanos Way of Leading, reflect on whether you see yourself working within our principles:

- **Take on -** Responsibility is given, and we inspire you to take it.
- **Try out -** Explore diverse tasks and grow professionally.
- **Team up -** We don't just work together; we thrive together.

Apply and make a real impact

We look forward to hearing from you, so please send your application through the "apply" link.

We will be performing interviews ongoing in the process and look to fill the position as soon as possible. We close the position when we find the right candidate.

For further information about the role please contact COO, Sara Daugaard Popik mail: sdp@sanos.com

Work location: Telefonvej 8D, 2860 Søborg, Danmark.

You will have the opportunity to work remotely two days a week.

If you proceed in the recruitment process, you will go through a few additional steps where both you and we will assess whether this position is the right match for both parties. As part of the recruitment process, we use assessments to ensure the optimal match and the best foundation for future collaboration.

NBCD is dedicated to fostering a diverse and inclusive workplace. We believe that a variety of perspectives leads to better decision-making and innovation. We welcome applicants from all backgrounds and are committed to creating an environment where everyone can thrive.

We value your data and take care to protect it. Please see more information regarding privacy for job applicants here: https://nbcd.career.emply.com/privacy-policy