(Senior) Clinical Safety Specialist
with Experience in Clinical Trial Safety

Orphazyme is looking for a (Senior) Clinical Safety Specialist to join our team and lead benefit-risk assessments, surveillance activities, and safety-related deliverables for dedicated projects/products.

The candidate will be responsible for ensuring that Orphazyme's clinical studies are handled in compliance with regulatory requirements, and in ensuring that safety signals are handled appropriately in collaboration with the rest of the team. He/she will also help ensuring that the business has appropriate processes and systems in compliance regulatory requirements and product safety management.

The person will be part of clinical trial teams and cross-functional Safety Committees and work collaboratively with other departments (such as Clinical Science, Medical Affairs, Clinical Operations, Regulatory Affairs, Quality Management, and Nonclinical Safety) within the business to address and resolve issues relating to development projects and processes.

The person will provide guidance to key stakeholders in addressing issues related to clinical safety in the clinical trial programs.

She/he will contribute to the evolvement of the clinical development strategy for dedicated projects/products.

The job will include the following main responsibilities:

- Responsible for benefit-risk assessments, surveillance activities, and safety-related deliverables, including, but not limited to, Risk Management Plans, aggregate safety reports, safety sections of labelling documents, investigator brochures, relevant aspects of clinical study reports and submission dossiers for dedicated projects/products
- Act as ambassador for safety governance within and outside the company
- Contribute to improvement of the PV system and its performance
- Contribute to our maintenance of the overview of safety profiles and emerging safety concerns
- Engage with the relevant functions in the development and review of key regulatory documents related to safety for products/projects
- Collaborate with service providers

The position will report to the Head of Clinical Safety.

Profile:

- At least 5 years of experience with pharmacovigilance (pharma, biotech, or CRO) including strong knowledge of global pharmacovigilance legislation and regulations
- Experience with filing for marketing authorization is an advantage
- Experience with clinical trial safety
- Relevant scientific background with good medical understanding (e.g medicine or human biology)
- Good ability to use initiative, prioritize, multi-task, and work well under pressure to meet deadlines
- Ability to drive projects and deliver results
- Work independently
- Ability to contribute to documents with consistency and attention to detail
- Clear and systematic thinking that demonstrates good judgment and problem-solving competencies
- Good written and oral communication skills
- Willing to be part of interdisciplinary teams with a spirit of initiative and proactivity

We can offer you:
Orphazyme is a listed biotech company based in Copenhagen that develops new treatment options for orphan protein-misfolding diseases (lysosomal storage and protein-aggregation diseases). This position is a chance to be part of a small company and a Clinical Safety department that is developing each day. Orphazyme has an exciting pipeline and a collaborative working environment.

Application
Please apply by sending an email marked "Clinical Safety Specialist" with your application and CV to career@orphazyme.com. If you have questions about the position, you are welcome to contact Head of Clinical Safety, Marie Aavang Geist at +45 3144 3136.

We encourage anyone interested in the job to apply, irrespective of gender, age, race, religion, or ethnicity.

Deadline
Feb 29, 2020. Interviews will be held on an on-going basis.

About Orphazyme A/S
Orphazyme is a biopharmaceutical company focused on bringing novel treatments to patients living with life-threatening or debilitating rare diseases. Our research focuses on developing therapies for diseases caused by misfolding of proteins and lysosomal dysfunction. Arimoclomol, the company's lead candidate, is in clinical development for four orphan diseases: Niemann-Pick disease Type C, Gaucher disease, sporadic Inclusion Body Myositis, and Amyotrophic Lateral Sclerosis. The Denmark-based company is listed on Nasdaq Copenhagen (ORPHA.CO). For more information, please visit www.orphazyme.com.