



Santhera Pharmaceuticals is a Swiss-based specialty pharmaceutical company focusing on the development and commercialization of innovative pharmaceutical products for the treatment of severe neuromuscular diseases in orphan indications. Our first product, Catena®, (idebenone) is marketed in Canada for the treatment of Friedreich's Ataxia. Catena® is also investigated in clinical development for the use in Duchenne Muscular Dystrophy and other indications. Our shares are traded on the SIX Swiss Exchange (symbol: SANN).

We are currently looking for a

Technical Regulatory Specialist

based in our headquarters in Liestal, near Basel, Switzerland.

Reporting to Director Technical Development & Operations, this role will work on development projects and commercial products and will oversee all Technical Regulatory activities for those projects. Strong interest in Drug Development and goal oriented working is supporting the achievement of the company's targets in our high profile, early to late-phase development programmes and commercial products.

In this role you will be expected to:

- timely compile CMC/Quality parts of registration documentation for regulatory submissions (IND/IMPD, NDA/MAA etc.)
- ensure that Regulatory Affairs policies, procedures, and records with respect to CMC / quality parts are in compliance with applicable regulations and standards
- proactively develop effective regulatory strategies for CMC/Quality matters
- interact with Health Authorities on Technical Regulatory aspects of the company
- ensure that Regulatory submissions are accurate and verifiable against source documents to confirm compliance and traceability together with Head of Quality Assurance.
- approve Regulatory specifications
- support Technical Development function in Regulatory aspects
- close collaboration with external contractors, partners and consultants on development and particularly on Technical Regulatory aspects
- contribute to cross-functional activities with Clinical Development, Regulatory, Quality Assurance and other functions
- support Technical Development function in Chemical Development aspects

As an ideal candidate for this role you should have / be:

- M.Sc. or PhD preferably in Chemistry
- 5+ years experience in the Pharmaceutical Industry
- 3+ years experience in Technical Regulatory
- 3+ years of experience in Chemical Development (preferred)
- knowledge of Health Authorities and Technical Regulatory guidelines
- good understanding of scientific, technical, quality, regulatory in the pharmaceutical industry
- fluent oral and written English
- intercultural communication and behavioural skills
- excellent organization skills

If you are interested please send your CV and a cover letter by email to: hr@santhera.com by letter post to:

Santhera Pharmaceuticals (Switzerland) Ltd
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