



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® to treat Friedreich's Ataxia, is marketed in Canada. We currently prepare to file the drug for marketing approval for the treatment of Leber's Hereditary Optic Neuropathy. Catena® is also being investigated in a pivotal study in Duchenne Muscular Dystrophy. Our second compound, fipamezole, to treat levodopa-induced Dyskinesia in Parkinson's Disease is currently prepared for Phase III development by Biovail, our partner in the US and Canada. Santhera's shares are traded on the SIX SwissExchange (symbol: SANN).

Currently we are looking for a

## **JUNIOR REGULATORY AFFAIRS SPECIALIST**

initially for a 6 month contract to assist with regulatory activities such as:

### Clinical Trial Applications

- the preparation and submission for regulatory approval of clinical trial authorization applications as required.
- the maintenance of existing clinical trial authorizations, i.e. for the preparation and submission of amendments and the notification of start of trial and end of trial to Competent Authorities, and liaising with Clinical Operations and CRO to ensure appropriate notifications and submissions to Ethics Committees as required.

### Regulatory Intelligence

- prepare and maintain a central source of Regulatory Intelligence information, including but not limited to therapeutic area and general EU and US regulatory guidance information
- the preparation of Orphan Drug annual reports for EU and US, US IND Annual Reports and briefing packages for meetings with regulatory authorities

### Document management

- filing and archiving the regulatory documents according to SOPs
- maintenance of electronic filing systems

### **As an ideal candidate for this role you should;**

- Have a University degree or equivalent in life science field
- Be wishing to develop pre-existing regulatory experience or seeking an internship within a specialty pharmaceutical company
- Have excellent organizational and communication skills
- Be highly motivated and self driven
- Be fluent in English (other languages would be an asset)

If you are interested in applying for or hearing more about this position, please send your CV and a cover letter by email to: [hr@santhera.com](mailto:hr@santhera.com) or by letter post to:

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