Clinical Operations Associate – Job Description

Ascelia Pharma is an oncology-dedicated orphan drug development company located in Malmö, Sweden. The company's strategy is to develop drugs, which target unmet medical needs, have an established mode of action and a relatively low development risk. Ascelia Pharma currently has two drug candidates – Mangoral® (phase III ready) and Oncoral (phase II ready) – in clinical development. Ascelia Pharma's management has a very broad and extensive experience in R&D from leading Swedish/Danish and international biotech and pharma companies. Ascelia Pharma's shares are listed on Nasdaq Stockholm (ticker: ACE).

We are looking for an ambitious and positive colleague who likes to work with many tasks simultaneously, and with a few years' experience in clinical operations. As Ascelia Pharma is a rapidly growing company, it is important that you are flexible, open and willing to contribute with your experience in order to successfully move us forward. Ascelia Pharma will in return offer you energetic and motivated colleagues in a stimulating environment with attractive career development opportunities. If you see yourself or anyone you know in this profile, please don't hesitate to contact us so we can tell you more.

As a **Clinical Operations Associate (COA)** you are a key player to secure that our clinical studies are conducted timely according to study protocol, ICH- GCP (incl high ethical and quality standards) and other relevant regulatory regulations and contracts.

Your main responsibilities as COA will be:

- Perform oversight of international studies (ph I-III), eg vendor / site / quality oversight
- Facilitate confidentiality / study /site agreements with external vendors and sites
- Contribute to identifying and selecting CROs and vendors (CRO management strategy)
- Provide input to the development of relevant SOPs and equivalent quality steering documents
- Ensure that TMF-related filing is up to date, ie contribute to "inspection readiness"
- Represent Ascelia Pharma externally, e.g. through site visits

You need experience to conduct assignments which is part of a Clinical Operations Associate role and we are looking for someone who:

- Have university degree, or corresponding qualification, within life sciences
- Have at least 2-3 years relevant clinical trial coordination/management experience in a pharmaceutical/biotech company or CRO
- Have good communication skills in English and Swedish; speaking / writing / reading
- Have solid knowledge of relevant SOPs, ICH, and GCP guidelines
- Demonstrate sense of proper prioritisation management, including excellent planning and organisational skills
- Excellent interpersonal skills and ability to work within a small biotech environment
- Can work from our Malmö office (Medeon Science Park) and have all necessary work permits

If you have any questions regarding the COA role, and/or for your application please contact:

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For more information, please visit http://www.ascelia.com