HEAD OF REGULATORY AFFAIRS (GLOBAL)

Posted on 6 december, 2019

Company Name CareDX

Location Stockholm

Job Description

Responsibilities:

- Primarily act as the main point of contact with Regulatory Authorities and internal/ external stakeholders such as regulatory partners, translators, Quality, Supply Chain, Commercial and work cross-functionally.
- Responsibility for product registrations. Ensure correctness regarding submission or any other local requirements.
- Monitoring of new regulatory and legal requirements to ensure compliance for commercially available products and products under development.
- Ensure IVDD, IVDR and EN ISO 13485:2016 regulatory compliance.
- Regulatory functional budget responsibility
- As part of the wider Global CareDx Regulatory Affairs team, having overall responsibility for post-approval/life-cycle Regulatory activities
- Member of the Site Lead Team

Qualifications:

- At least 5 years' of demonstrated experience and an excellent track record in management level Regulatory Affairs position(s) within the Medical Devices/IVD industry.
- The position puts high demands on being able to act independently but also effectively collaborating internally, as well as externally. Effective interpersonal skills are a requirement.
- The role requires an organized, structured, accurate, independent and pro-active way of working. You must have strong analytical and project management skills combined with a communicative ability and being detail oriented.
- Excellent communication skills in both oral and written English
- Support in Quality Assurance activities as applicable

Your Application:

We would like your application to include a CV and a cover letter in English. Please send your documents to daniel.kremer@moveup.se asap, or contact Daniel for questions under 0733-87 27 24!

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