QA – RA Manager

Company description

SkylineDx is a commercial-stage biotech company based in Rotterdam, the Netherlands. Originally a spin-off of the Erasmus Medical Centre in Rotterdam, we specialize in the development and marketing of innovative gene signature based diagnostic tests to assist healthcare professionals in making personalized treatment decisions for individual patients.
These tests are designed to accurately determine the type or status of the disease or to predict a patient's response to a specific treatment. Based on the test results, healthcare professionals can tailor the treatment to the individual patient. The MMprofiler(tm) is the company's lead product.

As an innovative company, SkylineDx is continuously seeking for ambitious colleagues. At this moment we currently looking for a **QA & RA Manager** who will manage the company to work by the rules of our Quality system.

Job description

You will be responsible for the support for a very wide variety of QA/RA related tasks to ensure that all of the company's activities are performed at the appropriate quality level. Amongst others you will improve and maintain the quality system according to the ISO-13485, ISO-15189 and FDA 21CRF820 Quality system regulations. You will be managing during writing and executing Quality related procedures and plans with the QA/RA Officer. Reviewing design and development related documents like procedures, technical file documents, and validation documents. You will be managing, organizing and executing internal and external audits.

Organizing and providing quality related trainings. Reviewing analytical data for diagnostic services, incoming goods QC and batch release purposes. Managing change control, document control, deviation and non-conformance handling.

Profile

We are looking for a candidate with the following profile:

- Bachelor or Master Degree in life science related topic
- Demonstrated experience (> 5 years) as a QA officer in a medical device or in-vitro diagnostic device company.
- Experienced in writing and reviewing quality, and design and development related documents.
- Experience in quality planning, auditing, hosting audits and inspections.
- Experience in deviation, non-conformance, CAPA and change control handling
- Experience with quality evaluation of laboratory test results
- Demonstrated experience with successfully implementing relevant quality system regulatory requirements with respect to at least GMP (good manufacturing practice), 21 CRF 820, medical devices (ISO-13485)
- Familiar with directive 98/79/EC for in vitro diagnostic medical devices
- Familiar with FDA guidance documents in relation to in-vitro diagnostic product development

- Additional experience with implementing quality system regulatory requirements with respect to and - or diagnostic laboratories (ISO-15189) is a pre.
- Experience in writing CE registration files and IVD submission files for FDA 510(k) clearance or pre-market approval is a strong pre.

Skills & Competences

- Requires leadership skills/experience sufficient to assume the responsibilities of this QA/RA position and must be able to delegate.
- Dare to be though
- Efficiency
- Accurately
- Flexibility
- Team player

We offer

At SkylineDx we transform life sciences into the daily practice of clinical diagnostics. SkylineDx has a dedicated team with unique expertise and the technology needed for a highly efficient identification of novel relevant biomarkers, development, registration and commercialization of (companion) diagnostics. Our mission is to improve quality of life of patients through the development of reliable, clinically validated molecular diagnostic tests. For more information, please visit www.skylinedx.com.

SkylineDx offers you to become part of our challenge to translate state-of-the-art scientific achievements into diagnostic products that will contribute to improve patient care. We are a young and dynamic company offering excellent opportunities for personal growth and development. Skyline is well embedded in the infrastructure of the Hematology and Bioinformatics Departments of the Erasmus MC in Rotterdam, the Netherlands. Therefore we believe the company can offer you the best of both worlds; a career in life sciences with emphasis on product development and clinical diagnostics in close collaboration with an academic environment. We offer a full-time position and a market competitive salary.

Contact

For information you can contact Onno Goedhart (Senior Recruitment Strategist, SIRE Lifesciences)
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*Acquisition to this vacancy is not appreciated