Sr Manager, Quality and Regulatory

PredictImmune Limited, Cambridge, UK

The Company

PredictImmune was created in early 2017 as a spin-out from the Department of Medicine, University of Cambridge UK.

It is a new generation molecular diagnostics company offering a unique approach for the prognosis of immune-mediated diseases such as Inflammatory Bowel Disease, Lupus, Multiple Sclerosis etc.

PredictImmune is developing prognostic assays that are simple, robust and based on RT-PCR using whole blood samples and test methodology that is routine in clinical laboratories. We aim to be the first company to offer predictive tests in immune-mediated diseases which will facilitate personalised treatment and thereby improve patient outcomes and health economics.

PredicTImmune will provide its proprietary technology as both a laboratory service and as a kit depending on the needs of global markets.

The Role

The primary focus of the Sr Manager, Quality and Regulatory, will be to direct, lead and manage all aspects of the Quality Assurance strategy and regulatory compliance function, for our key products and services. The position reports to the VP of Research Operations.

Principal Duties and Responsibilities

- Direct all aspects of the Quality Assurance and Regulatory Affairs functions, including Europe, US and Asia for key products as medical devices and associated clinical lab activities
- Responsible for the generation of regulatory submission documents and preparation of technical file documentation
- Serve as the company points person to interact with the appointed Notified Body
- Serve as the company representative during quality and regulatory audits
- Develop and maintain internal awareness and knowledge of regulatory standards, ensure compliance of the internal quality system, and provide suitable interpretation to the company
- Manage customer tracking as related to quality of products, complaints and post-market surveillance
- Develop and implement programs for audits (internal, vendors) as well as the CAPA system
- Promote a culture of compliance to regulations, standards and procedures and risk management throughout the organization
- Maintain an awareness of new and proposed legislation that impacts the business and communicate/implement as required.

Candidate Profile, Experience and Knowledge

- Significant experience (at least 5 years) in QA ISO quality systems for IVDD and managing a quality assurance function; working experience of ISO-13485 quality systems, CE marking and 510 (k) submission a must
- Experience with regulatory submissions and compliance

- Degree or equivalent in physics/chemistry/biology/engineering or closely related field; solid understanding of molecular diagnostics preferred
- Experience of direct interaction with national regulatory authorities eg MHRA, desirable
- Good interpersonal and leadership skills; experience working with various levels of personnel
- Excellent communication skills both written and oral.

Please send to Karin Schmitt
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