

Tech Transfer & Products Lead

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 Technology Transfer & Products Lead will be to create an environment that transforms great ideas into global products that will establish our company, our technologies and our people as a credible new force in diagnostics. The role includes supplier identification/outsourcing as well as significant contributions to obtain accreditation under the appropriate quality and regulatory standards; the position reports to the VP of Operations.

Principal Duties and Responsibilities

Product Development – work closely with internal and external stakeholders to develop a competitive portfolio of products and services to maximise PredicTImmune’s value proposition.

Management – Set up and lead the transfer of research products from the laboratory to launch of products with full regulatory compliance largely through outsourcing and supplier management.

Compliance – contribute to the strategy and implementation of a company Quality Management System and ensure compliance with all Quality and Regulatory standards in our target markets and organization.

Suppliers – identify and manage suppliers to support laboratory based operations and the introduction of new products and services.

Candidate Profile

The ideal candidate will be PhD level educated (or equivalent) with a successful track record in diagnostic product development and thrives in a start-up environment.

The candidate will possess:

- Strong experience in molecular biology, ideally combined with bioinformatics skill set
- Extensive experience and a proven track record supervising R&D and manufacturing teams in a regulated environment
- Previous experience in product development and provision of services, experienced in all aspects of validation
- Understands quality requirements and the diagnostics regulatory landscape with a strong desire to be involved hands-on in submissions

- Solid understanding of the biomarker diagnostics landscape desirable
- Excitement to work in a start-up environment

Main Skills

- 5-10 years post PhD (or equivalent) with understanding of molecular biology and bioinformatics
- Experience in leading teams, ideally in R&D and/or manufacturing environment and will have brought product to market
- Understanding of diagnostics regulatory environment
- Previous experience in outsourcing and supplier management
- Methodical and detailed approach to product development, contracts and adherence to Quality and Regulatory standards
- Strong project management skills involving complex projects as well as customer interactions