

Job Description



Manager Product & Process Support

May 2022

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The company

Company: Immunovia AB
Role: Manager Product & Process Support
Reporting to: Vice President R&D
Place of position: Lund, Sweden

The company's missions:

- *To develop and commercialise non-invasive blood tests, so that more patients can receive a timely diagnosis, that can lead to improved treatment outcomes.*
- *Immunovia's long-term goal is a 30% share of the US pancreatic cancer testing market for IMMray™ PanCan-d after reimbursement and widespread insurance coverage has been achieved.*

Immunovia's strategy is to decipher the wealth of information available in blood – and translate it into clinically useful tools to diagnose complex diseases such as cancer, earlier and more accurately than previously possible. Immunovia's unique technology platform – IMMray™ – is an antibody-based multiplex test that is designed to provide a snapshot of the immune system response – based on the information available in a single drop of blood. But IMMray™ is more than a technology, it is a systematic approach, based on cutting-edge bioinformatics, to finding the most clinically relevant changes that appear in the blood, and combining this knowledge into a “disease fingerprint” – also called a biomarker signature – that is highly specific to the particular disease.

In 2017, Immunovia, Inc. was established in Marlborough, Massachusetts. The IMMray™ PanCan-d test, the first blood-based test dedicated to the early detection of pancreatic cancer, is offered as a laboratory developed test (LDT) exclusively through Immunovia, Inc. For more information see www.immunoviainc.com. In addition to the USA, Immunovia aims to launch the test in suitable markets in Europe and Asia with the aim of providing global access to the test.

In collaboration with Create HEALTH Translation Cancer Center at Lund University and others, Immunovia also has [ongoing projects in the discovery phase](#) targeting other cancers.

Immunovia has developed since 2016 a [clinical prospective study program](#) in the three main risk groups for pancreatic cancer as follows: PanFAM- 1 is the clinical study for individuals with familial/hereditary pancreatic cancer, PanSYM-1 for patients with early non-specific symptoms suggestive of pancreatic cancer and PanDIA-1 designed for individuals at risk due to the diagnosis of new onset diabetes after the age of 50. These three large clinical studies cover today more than 10 000 subjects recruited at 30 sites in the US and Europe.

Immunovia AB was founded in 2007 by investigators from the Department of Immunotechnology at Lund University and CREATE Health, the Center for Translational Cancer Research in Lund, Sweden. Immunovia has been a [listed company](#) since 2015, with shares traded (as IMMNOV) on Nasdaq First North in Stockholm and since April 2018 traded on Nasdaq Stockholm.

The headquarter is based at Medicon Village in Lund, Sweden and has today 60+ employees, 44 in Lund and 24 in US.

For more information, please visit www.immunovia.com.

The role as Manager Product & Process Support

General description and main responsibility

As a Manager Product and Process Support, you will have responsibility for Immunovia's Product and Process Support function for our pancreatic cancer test IMMray PanCan-d. Accountabilities include leading the product and process support team and developing staff covering required competences, as well as line/functionality management as described below.

You will be managing a dedicated and highly experienced group of three people within the Product and Process Support function. You will motivate and supervise the team to adhere to their responsibilities and to meet project goals and milestones. We believe you have strong leadership skills with a positive and solution minded personality.

We are looking for a dedicated and driven person, with excellent communication skills, as the position involves many interactions cross functionally.

You are goal- and results-oriented, have a structured approach with ability to prioritize tasks within and between projects to achieve the strategic objectives.

You will report directly to the Vice President R&D.

Tasks and responsibilities include, but are not limited to

- Develop and lead the Product and Process Support team at R&D. Recruit new employees if needed.
- Accountability for the R&D part of complaints handling, corrective and preventive actions (CAPA) handling, non-conformance handling, process validation and change management
- Accountability for support processes for Production support to Operations department, and Tech support for Immunovia Inc.
- Ensure communication and implementation of any Design changes and corrective and preventive actions (CAPA)
- Product life cycle management for IMMray PanCan-d, including risk management
- Participate during regulatory quality and qualification audits and inspections
- Develop, administer and maintain quality assurance for R&D owned procedures required to ensure that the documentation and results are in compliance with applicable quality standards and requirements

Requested qualifications

- MSc in natural sciences like molecular biology, chemistry, biotechnology or equivalent
- Substantial experience with IVD product/medical device development processes, design control and product care
- Deep understanding of ISO 13485 quality requirements and standards, and how to apply these within product care processes
- Proven people management skills and experience
- Excellent proficiency in English both written and oral
- IT skills, proficient with Microsoft Office products

Personal characteristics

- Takes responsibility for actions, projects and people; makes prompt, clear decisions
- Provides others with a clear direction; motivates and empowers others
- Build relations and interact efficiently with different functions within the organization
- Sets clearly defined objectives, plans activities and projects well in advance and takes account of possible changing circumstances
- Adapts to changing circumstances and accepts new ideas and change initiatives

Opportunities with the role

You will be part of a dedicated team working towards *Immunovia's vision* to revolutionize blood-based diagnostics and increase survival rates for patients with cancer. You will join a growing organization that puts people in focus, with an engaged management team in a company with short decision-making processes. There is an informal and personal atmosphere where each employee's contribution is important for the company's development and results. Be part of a company characterized by a fantastic team feeling and where they have mandatory "fika med knäckebröd" every day.

Immunovia is taking the next important step in bringing a solution to the unmet need of early detection of pancreas cancer to the market, by development of a world leading test from Lund university to a clinical laboratory testing for early diagnosis of pancreatic cancer.

Contact

For inquiries and more information about the position, please contact:

Catharina Herbertsson or Eva Runnerström, Sr Recruitment Consultants at PeakSearch.

catharina.herbertsson@peaksearch.se, +46 (0)706 152 772

eva.runnerstrom@peaksearch.se, +46 (0)701 725 379

www.peaksearch.se

Application

Apply for the position at www.peaksearch.se

PeakSearch is a recruitment consultant company specialized in recruiting Executives, Managers and Specialists in the Nordics. We have developed a top-quality recruitment model to attract, select and deliver the optimal match to our candidates and clients. Our talent network is huge and all our consultants have a long experience from the industry. PeakSearch headquarters is situated in central Stockholm, with affiliates in Lund, Uppsala, and selected partners in the Nordic countries.