

Job Description



Quality Assurance Manager

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The company

Company: Immunovia AB
Role: Quality Assurance Manager
Reporting to: QA/RA Director
Place of position: Lund, Sweden

Mission

The company's mission is to establish its blood-based test for early diagnosis of pancreatic cancer as a standard amongst pancreatologists and diabetes physicians worldwide for detecting pancreatic cancer in high-risk groups much earlier than is possible today.

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's strategy is to decipher the wealth of information 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 core technology platform, IMMray®, is based on antibody biomarker microarray analysis. The company is now performing clinical validation studies for the commercialization of IMMray® PanCan-d that could be the first blood based test for early diagnosis of pancreatic cancer. In the beginning of 2016, the company started a program focused on autoimmune diseases diagnosis, prognosis and therapy monitoring. The first test from this program, IMMray® SLE-d, is a biomarker signature derived for differential diagnosis of lupus, now undergoing evaluation and validation.

The headquarter is based at Medicon Village in Lund, Sweden. Today, there are 37 employees in total, of which 7 in Boston, USA. Immunovia's shares (IMMNOV) are listed on Nasdaq First North in Stockholm and Wildeco is the company's Certified Adviser.

For more information about the core technology platform, please see Appendix 1. Also, for more information about the company, please visit www.immunovia.com.

The role as Quality Assurance Manager

The QA Manager will have responsibility for Immunovia's Quality Management System (QMS), interaction with relevant authorities globally and reporting to the management team on QA questions. High emphasis will be put on QMS maintenance, advise and reporting to management on QA issues and interaction with relevant authorities globally.

The position is based at Medicon Village in Lund, Sweden and you will report to the QA/RA Director.

Key responsibilities

- Develop and lead implementation and monitoring of companywide quality system based on EU IVDD regulations, US FDA regulations and international standards such as ISO 13485 and ISO 17025
- Develop, administer and maintain quality assurance procedures and activities required to ensure that the company's processes and products are in compliance with applicable quality standards and requirements
- Participate actively in all stages of design development, Verification&Validation testing and design control activities, ensuring quality assurance considerations and requirements are met
- Lead and implement an effective Corrective and Preventive Action (CAPA) program as a part of continuous improvement to capture and process customer complaints, non-conforming products, and other quality input sources
- Implement and monitor effective and efficient quality document management process for timely processing of document changes and distribution of quality information
- Implement and monitor internal and supplier audit programs to ensure compliance with quality system requirements
- Act as a company liaison during customer and regulatory quality and qualification audits and inspections. Ensure any corrective and preventive actions during external audits are communicated and implemented in a timely manner
- Arrange and coordinate management review meetings by presenting quality data with actionable information for continuous improvement and achievement of quality objectives
- Provide support for release of products and Clinical laboratory results
- Provide comprehensive Quality System Training to all employees

Profile

We are looking for a dedicated and driven person, with very good communication skills, as the position involves many interactions, both internally and externally. You need to be good at analyzing data and translating the outcome to action. The QA Manager has a very important function in the company, to ensure that the company's processes and products are in compliance with applicable quality standards and requirements.

You are goal- and results-oriented, have a structured approach and enjoy working in teams.

Required Qualifications and Skills

- MSc in natural sciences like biology, biochemistry, chemistry or medicine or equivalent. PhD is an advantage.
- Substantial experience from QA, QC management or similar positions within the life science industry
- Excellent presentation skills in both written and oral forms
- IT skills, proficient with Microsoft Office products
- Fluent in English and Swedish

Professional and Personal Competences

- Driving personality with ability to prioritize tasks to accomplish goals and objectives. Initiates and generates activity.
- Sets clearly defined objectives, plans activities and projects well in advance and takes account of possible changing circumstances
- Ability to analyze data, interpret results and translate outcome to action such as clear recommendations to management
- Excellent communication, presentation and intercultural skills. Gains clear agreement and commitment from others by persuading, convincing and negotiating. Ability to translate and communicate QA requirements to all staff.
- Analytical with ability to tackle problems and take actions, act on opportunities and generate new ideas
- Capacity to translate QA requirements into procedures in a dynamic and relevant QMS system
- Ability to work in a team and share responsibilities and tasks.
- Adapts to changing circumstances and works productively in a high-pressure environment

Opportunities with the role

You will have the opportunity to work together with a dedicated team towards Immunovia's vision to *significantly improve the survival rates, choice of treatment and life quality of cancer patients and their families.*

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.

Contact

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

Catharina Herbertsson or Eva Runnerström, Recruitment consultants at PeakSearch.

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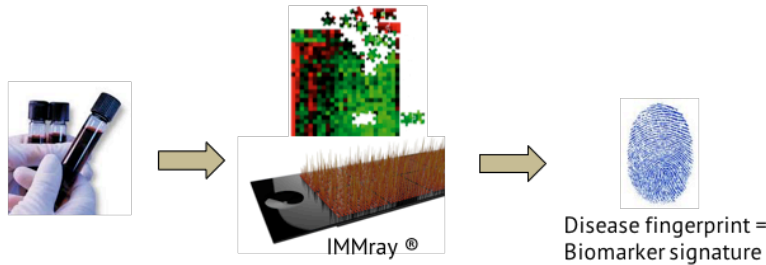
www.peaksearch.se

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.

IMMray®
mäter immunsystemets respons på sjukdom



Immunsystemet:
Ett blodprov innehåller tillräcklig information för att läsa av komplexa sjukdomar, såsom cancer och autoimmunitet

Find the answers of a generation in a single drop of blood

We went through the work of a generation of researchers, mapping the immune system response to cancer, molecule by molecule. We pinned down a combination of 25 clinically relevant markers for successful early stage diagnosis of pancreatic cancer. Using antibodies on a single multiplex chip, we measure them all in one go. All you have to do is to apply a drop of blood.

