QA Specialist Immunovia

Job description

As a QA Specialist at Immunovia you will play an important role in the work related to Immunovia's QMS system, high emphasis will be put on QMS maintenance and overall Software documentation for the products during development and continuously maintenance.

The position will report to the QA/RA Director.

Tasks and responsibilities include, but are not limited to:

- Develop, implement and monitor company-wide quality system based on EU IVDD regulations, IVDR 2017/746, US FDA regulations and international standards such as ISO 13485, IEC 62304 and ISO 17025
- 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 requirement
- Active participate in all stages of Software Risk management, Software safety classification, Design Control and Software maintenance procedures for the products
- Provide support for QA release of Software and products
- Participate in all stages of process and instrument validation and qualification and validation of IT processes
- Coordinate and maintain the Validation Master Plan
- Review and approve technical documentation and quality specifications
- Participate in all stages of Change Control and Corrective and Preventive Action (CAPA) procedures
- Active participate in the preparation of regulatory documents and reports
- 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

Requested qualifications

- MSc in natural sciences like biology, biochemistry, chemistry or medicine or equivalent.
- Substantial experience from QA and working with Software, within the Medical Device/IVD field and/or the life science industry
- Strong communication and presentation skills in both written and oral forms
- Proficient with Microsoft Office products.
- Fluent in English

Personal characteristics

- Driving personality with ability to prioritize tasks to accomplish goals and objectives
- You have excellent communication, presentation and intercultural skills
- Ability to work in a team and share responsibilities and tasks
- Ability to analyze data, interpret results and translate outcome to action
- 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.

Contact

For inquires and more information about the position, please contact:
Annika Andersson, QA/RA Director, e-mail: annika.andersson@immunovia.com

Application

Please send your application, CV and personal letter to: hr@immunovia.com.
Last day to apply: 2019-09-13. We are working continuously with the applications.

The position is based at Medicon Village in Lund, Sweden.

About Immunovia

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.
(Source: www.immunovia.com)

Immunovia's shares (IMMNOV) are listed on Nasdaq Stockholm. For more information, please visit www.immunovia.com.