Quality Assurance Specialist to Quality Assurance department at Euro Diagnostica AB / Wieslab AB

Location: Malmö, Sweden
Reports to: Quality Assurance Director

Euro Diagnostica AB and Wieslab AB are looking for a quality assurance specialist who wants to be part of developing our quality system together with the QA team.

The function involves alternating quality work in the QA department. You are a true quality ambassador with high integrity, naturally taking responsibility, demonstrate very good interpersonal skills and enjoy working with others.

The main tasks will be at the Wieslab AB facility that functions under ISO 17025, OECD GLP, and ICH GCP and partly to support QA at Euro Diagnostica AB in selected processes.

Your main tasks will be

- Being appointed responsible for some of the quality processes with focus on Wieslab AB ISO 17025, OECD GLP, and ICH GCP
- Keep up to date regarding current regulations in the areas mentioned above
- Develop, drive, improve, train and secure compliance for quality processes
- Participate in projects (inhouse or external) as quality representative
- Review and approve quality documents such as SOPs, validations/qualifications, change requests, deviations, CAPAs and complaints
- Execute internal audits
- Participate and contribute at external audits and inspections
- As GLP/GCP QA you are responsible for monitoring all studies subject to QA audit and issue Quality Assurance Statement/Certificate for inclusion in final study reports
- Quality support to the organization by giving input on quality requirements
- Develop the quality system along with current regulations and the rest of the QA department
- Support Euro Diagnostica AB under ISO 13485
- Review batch manufacturing records and analytical results to make disposition decision of batches

Expected qualifications

- Minimum a Master degree; in biochemistry / molecular biology / biomedicine or equivalent
- Experience from quality assurance in relevant quality management systems, preferably from OECD GLP and ICH GCP
- Knowledge of cell-based assays and immunological techniques such as ELISA and RIA
- Experienced user of Microsoft Office (Excel, Word, PowerPoint)
- Fluent in Swedish and English (oral and in writing)

Expected personal characteristics

- A thorough, logical and analytical mindset and problem-solving capabilities
- Ability to work proactively and independently and to make decisions
- Ability to assess, motivate and train the organization in the quality management system and regulations
- Skills in risk analysis, root cause analysis and process optimization
- Demonstrate good interpersonal and communications skills as well as customer focus
- You should be driven to continuously improve systems and processes, and efficient in implementing the ideas to reality.
- Demonstrate understanding of fundamental quality management systems, concepts, regulations, standards and practices
- Prioritize tasks to accomplish goals and objectives.

To Apply

In this recruitment, Euro Diagnostica and Wieslab collaborates with Roi Rekrytering, you apply by submitting your application and CV here. We will process the applications on an ongoing basis and call for interviews as soon as possible. Last day for application is January 22nd, 2018.

For further information about the position you are welcome to contact Marie Gersbo, Quality Assurance Director, on +46 (0) 40 53 76 05. Union representative (Unionen): Gunilla Jönsson,
+46 40 53 76 28, Union representative (Akademikerna) Elsa Grenmyr, +46 40-53 76 54.

About Euro Diagnostica and Wieslab

Euro Diagnostica's goal is to constantly develop solutions to aid clinicians in diagnosis, prognosis, monitoring and treatment of autoimmune and related diseases. Euro Diagnostica is providing a large portfolio of kits, laboratory as well as drug monitoring and customized assay development for measurement of biological activity in various biological and biosimilar drugs.

Wieslab is a specialist laboratory that offers bioanalytical services as well as clinical diagnostics testing for clinicians and laboratories worldwide. Wieslab Laboratory Services is an integral part of Euro Diagnostica and offers ISO 17025, GCP and GLP compliant services ensuring regulatory requirements are met. Wieslab offers a range of Bioanalytical services for non-clinical as well as clinical studies for pharma, biotech and CRO customers.

Wieslab has experience within a wide range of immunoassays including ELISA, MSD, RIA and cell based assays. With more than 20 years of experience in developing and running immunoassays our service offering includes method development, optimization, validation and sample analysis.

For additional information visit www.eurodiagnostica.com and www.wieslab.com