Quality Assurance/Quality Control

On behalf of our client Prostatype Genomics – a company on the threshold of an exciting journey within the prediction and treatment choice for prostate cancer patients – we are looking for a QA/QC

THE COMPANY

Prostatype Genomics AB is the legal Manufacturer of in-vitro medical devices (RT-qPCR kit and a cloud-based software) for prognostic evaluation of prostate cancer. The company has an ISO 13485:2016 certified quality management system and is in the process of establishing compliance to IVDR.

The company that today is called Prostatype Genomics AB was founded in 2007 as a spin off from Cancer Center Karolinska (Karolinska Institutet, Stockholm, Sweden) in order to transfer the research results of the research group into clinical reality.

PRODUCTS

The Prostatype® Test System combines gene expression information with currently used clinical parameters (PSA, Gleason Score, and Tumor Stage) and calculates the so called P-score. The test is based on a unique database containing prostate cancer patients and provides decision support for patients and doctors when making a treatment decision.

Several studies have proven that Prostatype significantly improves the accuracy in predicting mortality compared to current clinical tools. The system is based on a gene expression test, which measures the expression of three carefully selected embryonic stem cell genes in prostate cancer core needle biopsies. In conjunction with currently used clinical parameters, the **PrTS** predicts overall survival in prostate cancer.

RESPONSIBILITIES

- Lead and drive the IVDR-implementation (in progress)
- Ensure ongoing compliance with ISO 13485:2016 and IVDR, and provide day to day support and leadership necessary to ensure product development
- CAPA-management

- Manage change control, document control, writing & reviewing SOPs
- QC test and release of product (RT-qPCR kit)
- Establishment and the continuous optimization and refinement of QC routines
- Coordinate with contract manufacturing organization and support quality agreements
- Follow-up and reporting of QC activities at Management Reviews
- As the Management representative, coordinate the reporting of the effectiveness of the quality management system at Management review meetings
- Lead and participate internal and external audits
- Promote quality awareness throughout the organization and provide Quality training
- Supplier management including supplier evaluation
- Be the primary contact person for Prostatype Genomics notified body, external auditors, and regulatory authorities

COMPETENCE REQUIREMENT AND ABILITIES

- M. Sc., or Ph. D. in a relevant Life Science subject
- At least two years of professional experience in QA relating to in vitro diagnostic medical devices
- At least one year of experience on maintaining QMS in an ISO 13485 regulated medical device industry setting
- Several years of experience in authoring Quality documents such as SOP:s, instructions for use, audit plans and study documents
- Preferably experience from Quality Control laboratory in the diagnostic industry
- Preferably experience on RT-qPCR technique and other relevant biomedical laboratory techniques
- Formal training in the EU IVD 98/79/EC and EU IVDR 2017/746
- Experience from working with e-QMS is preferable

Interested?

If you want to know more, please contact Brice Group who is supporting Prostatype Genomics in this recruitment;

Anders Larsson, Partner, +46 73 203 46 91 or anders.larsson@brice.se or

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Or submit you application:

https://pnty-apply.ponty-system.se/brice?id=62

We are meeting candidates continuously, so please make yourself heard as soon as possible.