

Clinical Study Manager

As the rapid growth of our company continues, we are looking for a Clinical Study Manager to join our team. This is a new position at our company, and you will get the opportunity to shape it based on your expertise. As the Clinical Study Manager, you will be responsible for the performance evaluation studies required during the product development and commercialization processes of new products. You will also monitor our existing products on the market throughout their life cycles. Additionally, you will participate in the development of new products for example by mapping customer needs and wishes.

Your primary tasks will include recruiting clinical laboratories for *in vitro* diagnostic (IVD) product evaluation studies, organizing the studies with ethical and regulatory aspects in mind, and analysing and reporting the results. You will also conduct market research for product development purposes. Together with the sales and marketing teams, you will plan and execute additional studies for existing products and participate in writing of scientific publications based on the studies. Additionally, your work will include the implementation and documentation of the new IVD regulation (IVDR) within your area of responsibility. You will get the opportunity to develop and shape the practices related to the performance evaluation of our assays. We expect you to have a proactive, open-minded, and punctual attitude towards your work. As the Clinical Study Manager, you will be a part of the product development team and work in collaboration with other teams.

We expect you to have

- Experience of clinical laboratory working environments; we particularly value knowledge of infectious disease diagnostics
- A suitable university degree in bio- or medical sciences (e.g., in the field of microbiology, virology, or diagnostics)
- Ability to track and understand the needs of customer laboratories and report them to the team
- Experience in PCR technology
- Excellent communication skills
- Fluent verbal and written communication skills in Finnish and English

We see as advantage

- Experience in organizing clinical studies in an IVD (or MD) environment
- Existing professional network/contacts in clinical laboratories
- Experience of IVD products for infectious diseases and/or point-of-care testing
- Experience in writing scientific publications
- Willingness to acquire knowledge of Abacus' products and to deepen your expertise in product development and manufacturing
- Previous experience of working in a growth company
- Experience of ISO 13485 standard and IVDR

We offer you

- Interesting and meaningful work
- Close-knit and supportive team that completes tasks within agreed schedule
- Organization where changes can be implemented fast
- Competitive salary and great employee benefits
- A newly renovated office at Kupittaa, Turku, and/or option to work remotely
- Opportunities for personal and professional development
- Open-minded work community with a sense of humour welcoming you as a part of the team

ABACUS

Abacus Diagnostica Oy is a rapidly growing Finnish company specialized in rapid molecular diagnostics of infectious diseases. We manufacture, develop, and sell the GenomEra® system, which is based on our proprietary technology. Our customer base consists of clinical laboratories and their distributors around the world.

Our goal is to provide cost-efficient and easy-to-use products that enable high-quality diagnostics regardless of the time and location. We are constantly expanding our already wide portfolio of tests for infectious disease diagnostics. In addition to that, we are currently developing a next-generation IVD system.

Due to the high demand of tests for Covid-19 diagnostics, we experienced a tenfold growth in sales during the year 2020 and expect the growth to continue. The number of our employees has also increased and currently there are almost 30 of us. As a relatively small company, we can offer flexibility and a relaxed working environment despite the often-demanding work tasks. We aim to keep the hierarchies low, so that everyone has a chance to influence the ways things are done. Our employees think that the best things about Abacus are the co-workers and the team spirit.

For further information, please contact recruitment consultant Marjut Kolu, Kolu Consulting Oy, +358 40 720 2549. Please send your CV and application with your salary requirements by 6.6.2021 to marjut@koluconsulting.com.