

Send your application in English to:
jobs@bkmedical.com

Mark the application:
"Clinical Study Lead"

We conduct interviews as we receive
applications



Clinical Study Lead

*Join us in improving surgical outcomes through generation of
clinical evidence for all of BK medical solutions.*

Clinical Study Lead for Clinical Affairs

Leading and driving medical device Clinical Investigations

Do you also love clinical data? Would you like to lead all clinical study activities for super exciting active surgical imaging systems to improve surgical outcomes?

You will be working closely with Clinical Evidence Leads and Product Strategy Directors for the different BK Medical clinical application areas to identify what clinical data is needed to support the products from a clinical, commercial and regulatory perspective.

As the function is brand new you will be instrumental in building the clinical study area in collaboration with the Director Clinical Affairs and other relevant stakeholder across the business. Our ambitions are high and we ensure great team spirit, a scientific but fun environment and value cross functional collaboration to make us a success.

You:

- Drive the availability of clinical data for BK Medical's medical devices to support the business and be responsible for delivering timely and appropriate clinical evidence for both new products as well as legacy products.
- Be responsible for design of all clinical investigations including driving protocol development and discussing our clinical plans with regulatory authorities and investigators
- Develop, maintain, and expand collaborations with outside clinical investigators, researchers and thought leaders to facilitate the optimum performance of clinical development programs.
- Manage the process of screening, qualifying, selecting, and contracting with investigators, sites and vendors required for conduct of clinical investigations and other clinical study activities in collaboration with Clinical Study Specialists and develop timelines and budgets.
- Obtain necessary clinical study approvals from IRBs/ECs, regulatory bodies, and Competent Authorities as relevant and ensure studies are on track for site initiation, patient recruitment and enrolment, and take corrective actions where necessary to address issues.
- Develop SOPs and work instructions to assure internal files and clinical study files (patient; site; country) conform to Good Clinical Practice regulations and standards.
- Help in providing oversight of investigator-sponsored studies.

BK Medical is committed to designing ultrasound systems that help surgeons image, guide, intervene, and navigate inside the human body. Surgeons are our customers, and they range from HPB surgeons, neurosurgeons, and robotic assisted surgeons to urologists, colorectal surgeons, and more.

Our key values:

- We work with great passion and always strive to get to the next level
- We do what we say and say what we do
- We are open, direct and look out for each other
- We are aware of the basic needs and requirements of our customers. At the same time, we see opportunities instead of limitations

At our European headquarters in Herlev the work atmosphere is casual, and our organizational structure is flat. We have a good staff canteen focusing on health and variety, we have private health insurance and pension plans as well as social joint events and several staff clubs.



Clinical Affairs

You will be joining a Clinical Affairs function under development. Our ambitions are high, and we ensure great team spirit, a scientific but fun environment and value cross functional collaboration to make us a success.

We are responsible for generation of relevant clinical data and to elevate clinical evidence of safety and performance to ensure sufficient, timely and compliant clinical documentation to support and drive commercialization of BK Medical's product range.

As the function is brand new you will be instrumental in building the clinical study area in collaboration with the Director Clinical Affairs and other relevant stakeholder across the business.

You are welcome to contact Helene Gustafsson, Director Clinical Affairs, by phone +45 2547 8905 or send an e-mail to hgustafsson@bkmedical.com.

BK Products Guides Procedures for the Surgeon





“By working within these specialties, I realized that I could provide or improve the health care system that way.”

- Rikke von Barm, Specification Engineer



“I chose to pursue a career in the medtech industry because I want to work at a place where both the company and the colleges always strives for achieving better.”

- Rasmus H. Rossen,
Senior Mechanical Engineer

BK Medical

● Global Organization

BK Medical is an international company with sales offices all over the world, and European headquarters in Herlev, Copenhagen.

At BK Medical, we support employees in developing their skills and expertise. We have a professional and informal organization with flexible working conditions and a flat organizational structure. We are effective and can execute our ideas into strong products – these ingredients make BK Medical an exciting and development-oriented workplace.

We look forward to welcoming you to a team that makes a difference – a difference to quality of life.

● Intraoperative Ultrasound

BK Medical is committed to designing ultrasound systems that help surgeons image, guide, intervene, and navigate inside the human body. Surgeons are our customers, and they range from HPB surgeons, neurosurgeons, and robotic-assisted surgeons to urologists, colorectal surgeons, and more.

Our mission at BK is to enable real-time intraoperative guidance during surgical procedures, giving surgeons the information needed to immediately make critical decisions. Our products are designed and customized for surgical procedures, to help surgeons save time and get results.

As market leaders, we work closely with experts and universities to provide the best solutions to clinical challenges.

● Research and Development

BK Medical has development departments in Denmark and the US. The largest development team is based in Denmark. We develop software, hardware, mechanics, signal processing, and advanced algorithms.

When it comes to research, we have collaborated with the Technical University of Denmark (DTU) for more than 20 years. Together, we have completed 2 high technology projects for advanced ultrasound imaging.

We are currently part of a large-scale project with DTU, Danish hospital Rigshospitalet, and the University of Copenhagen concerning extreme high-resolution ultrasound.

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