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Clinical Evidence Lead

You will be part of our small but growing team in Clinical Development. Together with Clinical Application and Clinical Outcomes, Clinical Development is one of the three specialized teams that make up Department of Clinical Value Proposition and Evidence.

Clinical Evidence Lead to BK Medical

Clinical Development consist of a team of highly experienced Clinical Scientists and Clinical Evidence Leads. Our main responsibilities are to drive the clinical strategies to ensure timely execution on clinical deliverables to support regulatory submissions and commercial strategies. We are an international team who value cultural and personal diversity in an informal, friendly, and respectful atmosphere. We strive to apply data driven methodologies and evidence-based decision making, in our daily work. At the same time, we value a balanced and pragmatic approach to problem solving in a fast-growing company in a dynamic environment.

Key responsibilities for our new Clinical Lead

- Leads the clinical development and clinical data strategy for an allocated application area
- Lead wording, substantiation, and documentation of clinical claims for regulatory compliance and commercial utilization
- Leads the clinical evidence activities in development projects and gives input to PMCF
- Defines clinical milestones and project deliverables
- Supports clinical evaluation activities and documentation
- Supports post market clinical activities including PMCF
- Collaborates in the development of regulatory strategies for market approvals
- Provides ad hoc support and guidance on activities and documentation requiring clinical competences

Typical tasks to do

- Ensure the development and implementation of clinical evidence strategies
- Develop documentation of clinical claims and their substantiation

- Support Post Market Clinical Follow-up activities
- Author the Clinical Development Plan
- Perform literature search/reviews to maintain surveillance of published literature and clinical results

Your professional background could be

- Ba. or higher degree in the Life Sciences or related disciplines with:
 - A minimum of 5 years direct experience in clinical development of medical devices
 - Demonstrated expert knowledge and comprehensive understanding of applicable GCP, ICH guidelines & FDA, MDR and relevant applicable international guidelines and regulations
 - Excellent interpersonal, written/verbal communication & organizational skills
 - Strong program management and financial skills
 - Fluent verbal and written English language
 - Willing to travel domestically and internationally, as required

We look forward to receiving your application, in which you describe 1) what your motivation is for becoming part of our Clinical Development team and 2) which of your experiences and skills you will particularly contribute.

For more information regarding the position, please reach out to Sr. Manager, Head of Clinical Development, Trine Tølbøll - Trine.Tolboll@ge.com.

We are looking forward to hearing from you.



BK Medical

BK Medical is a market leader within active imaging and has always been committed to designing systems that help surgeons visualize anatomy and lesions, guide interventions, and navigate inside the human body. BK Medical is an international company with sales offices all over the world, a global headquarter in Boston, Massachusetts (US), a European headquarter located in Herlev, Denmark, and a transducer manufacturing site in State College, Pennsylvania, US.

The company employs approximately 800 FTEs globally and almost 300 FTEs in Herlev. In 2021, BK Medical was acquired by GE Healthcare. With this acquisition, GE Healthcare adds the fast-growing and relatively new field of real-time surgical visualization to GE's pre- and post-operative Ultrasound capabilities, creating an end-to-end offering through the full continuum of care from diagnosis through therapy and beyond. Through significant synergies with the benefit of GE's technology and commercial scale, BK Medical will be able to reach new customers and markets around the world.

Our Headquarter in Herlev are placed in lovely and modern buildings. 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.

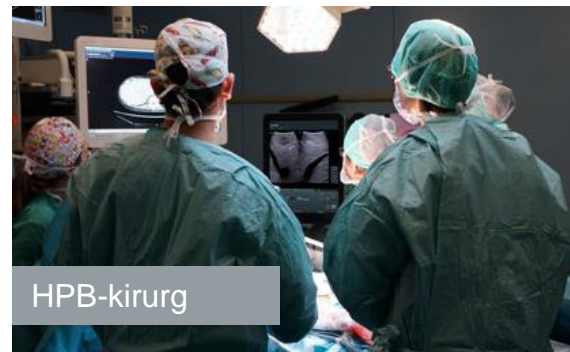
BK designer ultralydssystemer, der hjælper kirurger med at scanne, styre, foretage indgreb og navigere inde i menneskekroppen



Urolog



Neurokirurg



HPB-kirurg



Kolorektal kirurg



Robotkirurg



Andre markedsbrugere



“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 organisation

BK Medical er en international virksomhed med salgskontorer over hele verden. Vores europæiske hovedkontor ligger i Herlev tæt på København.

Hos BK Medical støtter vi, at vores medarbejdere udvikler deres kompetencer og viden. Vi er en professional og uformel organisation med fleksible arbejdsvilkår og en flad struktur.

Vi er effektive og fører vores ideer ud i livet i form af stærke produkter – hvilket gør BK Medical til en spændende og udviklingsorienteret arbejdsplads.

Vi glæder os til at byde dig velkommen i et team der gør en forskel – en forskel for livet.

● Intraoperativ ultralyd

BK Medical er engageret i at designe ultralydssystemer, der hjælper kirurger med at scanne, styre, foretage indgreb og navigere inde i menneskekroppen. Vores kunder er kirurger og spænder fra HPB-kirurger, neurokirurger og robotassisterede kirurger til urologer, kolorektale kirurger med flere.

Vores mission er at muliggøre intraoperativ vejledning i realtid under kirurgiske indgreb ved at give kirurger de nødvendige oplysninger til straks at træffe kritiske beslutninger. Vores produkter er designet og tilpasset til kirurgiske indgreb for at hjælpe kirurger med at spare tid og opnå resultater.

Nu fremmer BK Medical sin mission med GE Healthcare. Sammen vil vi nå ud til flere kunder og fortsætte med at give kirurger mulighed for at træffe kritiske beslutninger, der giver mulighed for bedre pleje, hurtigere procedurer og reducerede komplikationer.

BK Medical er markedsledende og arbejder tæt sammen med eksperter og universiteter for at levere de bedste løsninger til kliniske udfordringer.

● Forskning og udvikling

BK Medical har udviklingsafdelinger i Danmark og USA. Det største udviklingsteam har til huse i Danmark. Vi udvikler software, hardware, mekanik, signalbehandling og avancerede algoritmer.

Når det gælder forskning, har vi samarbejdet med Danmarks Tekniske Universitet (DTU) i mere end 20 år. Sammen har vi gennemført 2 højteknologiske projekter til avanceret ultralydsscanning.

Vi deltager for øjeblikket i et stortilet projekt med DTU, Rigshospitalet og Københavns Universitet om ultralyd med ekstrem høj opløsning.

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