

Send your application on
danish or english to:

jobs@bkmedical.com

Mark the application:
"Design Control Specialist"

We hold interviews ongoing



Design Control Specialist, R&D

*Would you like to be part of an international and innovative working environment,
where some of the worlds best ultrasound systems are developed?*

Design Control Specialist in R&D

For our Headquarter in Herlev, Copenhagen, we are looking for new colleagues to strengthen our competences in R&D within developing products that follow the regulatory requirements for medical equipment.

We are working in a challenging and developing environment with highly skilled and motivated colleagues in multidisciplinary projects.

Maybe you are our next Design Control Specialist, if you have experience from another similar position, have a can-do attitude, can embrace continuous improvements and if you enjoy interacting with a diverse set of stakeholders.

The job:

You will become part of a newly established Design Control & Usability Engineering team in R&D, which has an important and central role in the development of the highly technical and innovative products, and here you will drive and be responsible for adherence to the design control processes.

Most of the daily work will be done in close cooperation with the Project Managers and the many highly skilled colleagues in R&D, but also with other stakeholders as, Quality Assurance, Regulatory Affairs, Production, Marketing and more.

Primary tasks:

Your job will be to work in in a cross functional product development team as a key figure in the planning and follow up of all design control activities. Here you will:

- Drive and document design control activities in various R&D projects
- Provide relevant input to the project planning activities
- Ensure a constant updated design document transparency
- Ensure the quality of the Technical File documentation
- Support the continuous improvements of the standard operating procedures and instructions.

Qualifications:

You have a master's or bachelor's degree in engineering, pharmaceuticals, life science or similar with interest and experience within product development and/or Quality Assurance and Regulatory Affairs.

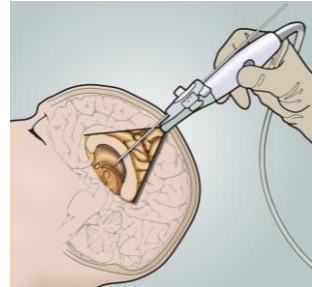
- Passionate about working with leading technological product development
- Are prepared to learn about ultrasound technology
- Experience with regulations, standards and guidelines within the medical device area e.g. MDR, ISO 13485, ISO 14971 and FDA 21 CFR 820.30 is a plus.
- Experience from driving and documenting design control activities such as requirement engineering, design verification and facilitating design reviews.
- Experience from facilitating product risk management activities and creating the risk management file.
- Are fluent in English, spoken and written.

The degree of experience will define the seniority of the positions.

Personal skills:

You are a good communicator who thrives on having an active role in a cross functional teamwork with many different colleagues. You are cooperative and result oriented and value honest and direct communication as well as a positive and humorous outlook on life.

- Pro-active – You see solutions to problems
- A positive attitude with a helpful and curious mindset
- Thrives with many different types of tasks.
- Good communication- and co-operation skills
- Have e strong sense of quality and are highly organized





R&D Projects



Lisbeth Reindel

Manager Design Control & Usability Engineering

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BK Medical's R&D today consists of approx. 100 technical specialists and managers distributed between our main R&D center in Herlev and our transducer development center in State College, Pennsylvania US. R&D is divided into 8 departments, where the newly established Design Control & Usability Engineering is among.

R&D's employees all have a technical background and reflect the broad cultural diversity that is a natural part of a global company. We work in a project environment where the individual projects are managed by a project manager who has extensive experience in developing BK Medicals products. The projects are managed in cross functional product development teams, and it is in these teams that our new Design Control Specialist will be a key figure.

Our development projects embrace broadly e.g. optimizing the image quality of existing transducers, new innovative transducers, SW for our ultrasound platform, upgrading existing scanners with new functionality as well as new scanners and platforms. In addition, we spend a large part of our time on Research in ultrasound.

The project work is carried out in teams, typically with resources from the global BK Medical organization - BK Medical in Herlev, BK Medical in State College in Pennsylvania and BK Medical in Boston. As a natural part of the development of medico technical products, we carry out our projects based on a well-developed and mature development model. Planning and execution make extensive use of visual project management according to the Agile principles.

All production of transducers takes place in Pennsylvania and production of systems in Boston and Herlev.

All project documentation is prepared in English..



Innovative Products

We are looking for employees who are as driven and motivated as we are. Employees who are passionate about developing products that can help surgeons make decisions that can improve outcomes for patients.

Below are some of the many products we are proud to have developed.



Our products are designed for ultrasound examinations in:

- Surgery
- Urology
- Pelvic Floor
- Colorectal

The Robotic Drop-In ultrasound transducer is used during surgical procedures to visualize organs. It is inserted through a trocar in the abdomen and can be controlled by a robot.

The ultrasound images help the surgeon in decision making during surgery.

The bkSpecto one of our latest developments. This unique scanner has very high image quality as well as an easy-to-use glass interface

BK Medical



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 with approximately 100 employees, while there are 11 employees in State College, Pennsylvania. We do development in 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.



Global Organization

BK Medical is an international company with sales offices all over the world, and European headquarters in Herlev, Copenhagen. We have approximately 670 employees, 210 in Herlev. In 2020, we booked revenue of USD 163 million.

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.

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