

Send your application in English to:

jobs@bkmedical.com

Mark the application:

"Senior Regulatory Affairs Specialist"

We conduct interviews as we receive applications

Senior Regulatory Affairs Specialist

Do you want to secure safe and effective new products for Health Care Providers utilizing intraoperative ultrasound imaging around the globe?



Senior Regulatory Affairs Specialist

We are looking for Senior Regulatory Affairs Specialist with drive and energy to join our Regulatory Affairs team. It is a new position in a rapidly increasing organization. You will be part of our global team who are in Denmark (Herlev), USA (Boston) and in China (Shanghai).

We are looking for a new team member with a positive and proactive mindset. You thrive in an international environment with a high pace. You enjoy being part of a committed team and take pride in finalizing the tasks together with the team. In this position you will drive global registrations of innovative products around the globe and be part of the group who ensure that BK Medical products are timely registered to be provided to our global customers. You will plan RA strategy, author and execute documents with the aim of registering products Class I - III globally.

You will work closely with the Global Regulatory team as well as Product Marketing, Sales Distribution and R&D.

You:

- Degree on bachelor level in medical science, engineering or equivalent knowledge
- More than 5 years' experience in a similar position in an international medical device company
- Have experience with making Regulatory Strategies during development of new products as well as ensuring CE marking, FDA clearance and product registration
- Experience in software/digital fields preferred
- Experienced in cooperation with relevant national health authorities, Notified Body
- Ability to communicate well verbally and in writing is essential, as are good organizational and planning skills
- Fluent in oral and written in English as a working language

Who are we in RA

Regulatory Affairs is a part the RA/QA Function belonging to the global organization with offices in Herlev, Denmark and the Global Headquarter in Boston, Massachusetts, US.

The Global Regulatory Affairs Team consists of 13 members: 3 people in US, 1 in China, 9 people in Denmark. The members of the Regulatory Affairs have a strong regulatory background within Medical Devices and are dedicated to development of safe and effective products for our global customers.

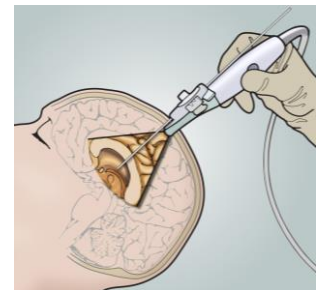
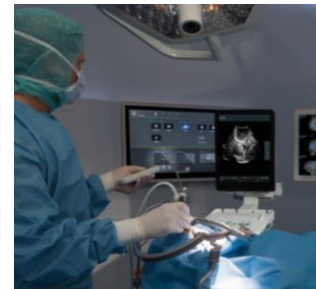
We have a great team that solve challenging tasks together. We value being professional, trustworthy, honest, communicate with one voice and being open minded. We are business oriented and take pride in guiding the organization in the complex regulatory environment.

About BK Medical

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.





Global Regulatory Affairs



Lis Pedersen Mylin
Director Regulatory Affairs
☎ + 45 31 43 24 15

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We are responsible for providing early Regulatory Strategies during development of new products as well as ensuring CE marking, FDA clearance and product registration in 70 countries. We communicate with local Authorities around the globe and secure compliance to local regulation as well as keeping the organization informed about changes.

We work closely with R&D which is located in Denmark, as well as Clinical and Commercial Marketing, Marketing Communication, Product Strategy groups and Global Distribution Sales.

We have a great team that solve challenging tasks together. We value being professional, trustworthy, honest, communicate with one voice and being open minded. We are business oriented and take pride in guiding the organization in the complex regulatory environment.

Does this fit you well? And would you like to be part of our team? Apply for the position today.

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

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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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