



We are searching for a:

**R&D PROJECT
LEADER**

The cancer diagnostics company BiBBInstruments AB (“BiBB”) is searching for a **R&D Project Leader** to our team based at Medicon Village in Lund.

BiBB has developed EndoDrill®, the world's first market-cleared electric-driven endoscopic core biopsy instrument, and we have several ongoing and future development projects to be managed in an efficient manner. Initial clinical trials with EndoDrill® have been very promising and our clinical partners have named the product as a possible game changer for endoscopic tissue sampling and diagnosis. As a project leader of development and improvement project you will be an important member of our lean organization as part of the technical team of the product family EndoDrill®. You will report directly to our Chief Technology Officer.



Who we are

BiBB is a cancer diagnostics company that develops and manufactures EndoDrill®, a patented product line of the first electric-driven endoscopic biopsy instruments. EndoDrill® works with high precision to take high-quality tissue samples with the aim of improving diagnostics for several types of cancer, such as stomach, pancreatic, liver, lung and bladder cancer. The product portfolio targets the global market for ultrasound-guided (EUS/EBUS) biopsy instruments, which represents the most advanced and fastest-growing segment of endoscopy. The company listed on Spotlight Stock Market was founded by Dr. Charles Walther, cancer researcher at Lund University and senior consultant in clinical pathology at Skåne University Hospital in Lund.

The motorised high-speed rotational EndoDrill® needle enables high-quality core biopsies, overcoming

the limitations of today's standard manual needles. The EndoDrill® system has been designed to be easy to use consisting of a sterile disposable EndoDrill® Biopsy Instrument with an associated EndoDrill® Drive System.

In 2023, EndoDrill® GI, BiBB's lead product, received market clearance from the US FDA as the first electric-driven biopsy instrument for endoscopy in the USA. At the beginning of 2024, CE certification according to MDR was obtained in Europe for the entire EndoDrill® product family. Clinical evaluations of EndoDrill® GI are currently underway at hospitals in Sweden and the US, and the plan is to launch the product on the Swedish market later in 2024.

Together, we can improve cancer diagnostics for better patient outcomes.

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The role

- Leading product development projects through the product life cycle according to BiBB's business strategic plan.
- Cooperating with cross functional team members (QA/RA, CMO, production and product marketing), as well as external consultants and suppliers.
- Leading improvement projects related to non-conforming product and processes.
- Leading design verification activities.
- Responsible for planning design validation as well as participate in design validation activities.



Qualifications

- You have previously worked as a development engineer and then transitioned to a position as a project leader. You have at least 3 years' experience of documented project lead within the MedTech industry.
- You are used to taking responsibility, working independently and have a very driven and forward-looking personality. You enjoy working in a team and have a good ability to communicate both internally and externally.
- You have completed a Bachelor of Science in Engineering degree (preferably Mechanical Engineering or Design and Product Development); other degrees will be considered based on experience.
- You have understanding and experience of medical device development according to ISO13485 as well as medical device regulations in EU and US (MDR 2017/745 and FDA 21 CFR QSR)
- You have experience of working with contract manufacturers of medical devices.
- You have experience of working with sterile medical devices.
- You are fluent in English and Swedish.



A word from our founder Dr. Charles Walther

"Cancer diagnostics is a rapidly growing field. The ability to obtain the most informative type of tumor sample is a cornerstone when deciding if a patient has cancer or not. We have shown we can create great value for the patient with our diagnostic EndoDrill® method, targeting some of the most common cancer types. If you want to be part of the quest for improving cancer diagnostics, our team is the place to be."

Board Member and CMO Dr Charles Walther – Founder of BiBB

For more information about the position, please contact our CTO Esther Brännström (esther.brannstrom@bibbinstruments.com, +46 725 22 00 68).

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