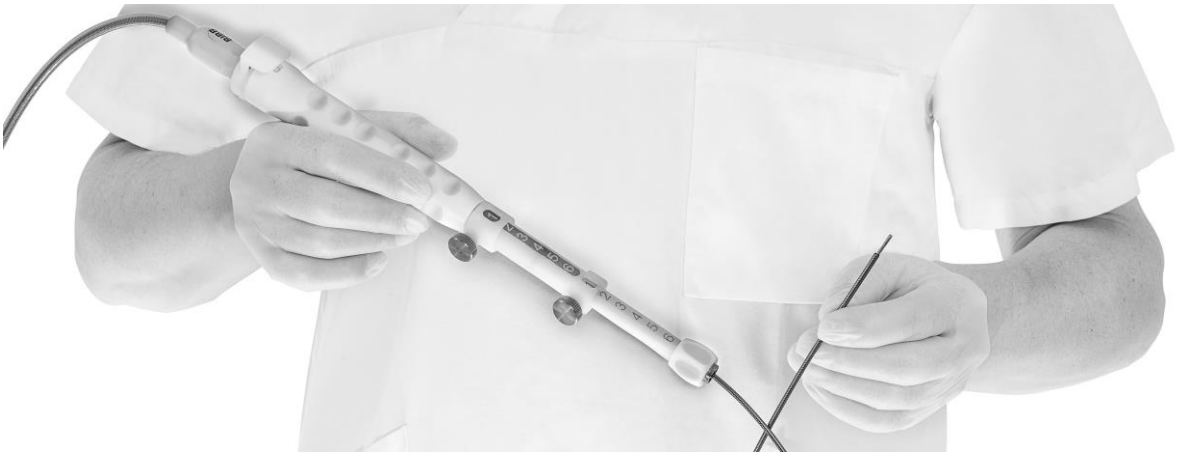
Quality Assurance Engineer

BiBBInstruments AB ("BiBB") is searching for a Quality Assurance Engineer, to our team based at Medicon Village in Lund, Sweden. You will be a member of our small medtech company to ensure that the company as well as the product family EndoDrill® comply with laws and regulations applicable for development of medical devices. You will report to our Quality and Regulatory Assurance Manager.

Who we are:
BiBB is a medtech company that develops endoscopic biopsy instrument for early diagnosis of some of the most severe cancers, e.g. stomach, pancreatic and lung cancer. Our flagship product, EndoDrill® Model X, will be the first electric biopsy instrument for both ultrasound and standard endoscopes. EndoDrill® Model X consists of disposable biopsy instruments with a unique and patented drilling function and a reusable part with motor unit, foot switch and cables.



Responsibilities

- Support with statistics and documents for Quality Review Board and Management Review meetings
- Interact with Technical Department and Sales in e.g. development projects to ascertain that applicable Technical Documentation is written correctly
- Support the Technical Department with e.g. review of instructions for use, validation documents from test laboratories
- Maintaining compliance of BiBB´s Technical Documentation in applicable markets
- Handling of complaints, any recalls as well as handling of deviations (NCRs), CAPAs and Change Orders
- Plan and participate in internal audits and external audits of suppliers
- Participate in qualification of suppliers
- Support collection and analysis of Post Market data for PMS reports/ PSURs

Qualifications

- Experienced in and familiar with quality management systems for medical devices such as ISO13485, QSR etc
- Experienced in and familiar with registration of medical devices in different countries.

- As a person responsible for regulatory compliance, she/her shall also have either of the following qualifications:
  - A diploma, certificate or other evidence of formal qualification, awarded on completion of a university degree or of a course of study recognized as equivalent by Sweden, in law, medicine, pharmacy engineering or another relevant scientific discipline, and at least one year of professional experience in regulatory affairs or in quality management systems relating to medical qualifications.
  - Four years of professional experience in regulatory affairs or in quality management systems relating to medical devices.

A word from our founder

As the methods for treating cancer develop, increasing demands are being placed on diagnostics in today's healthcare. To meet this development, there is an increased need for high quality tumour samples that not only delivers a reliable diagnosis, but also provides information needed for deciding treatment and prognosis. Our EndoDrill® product family is being developed for optimised tissue sampling for many common forms of cancer.

Board Member and CMO Dr Charles Walther – Founder of BiBB

For more information about the position, please contact our QA/RA Manager Marie Grey (marie.grey@bibbinstruments.com, +46 705 90 21 44).