Quality, Regulatory Affairs, Medical Device & IT

When you need advice or support regarding market access, regulatory requirements or evidence strategy for medical devices, SOFIA BLAD can support you. It can concern early research on medical devices, product development, CE marking, clinical investigations, clinical evaluation, post market clinical follow up, classification, regulatory strategy, notified body or competent authorities,risk analysis or compliance to standards for medical devices.

During product design she can lead projects or support the evidence strategy work as well as all other items associated with generating the Technical Documentation.

Sofia has the ability to work both operational to perform activities or strategically to develop and implement processes and procedures to support the activities listed above. Activities and processes are often included into a quality management system.

After more than 17 years of experience from early scientific research to market launch and post market clinical follow up of medical devices, she has specialised into medical and regulatory affairs for medical device industry. The last two year she has worked as Technical Documentation Reviewer and Clinical Specialist at Notified Body. Some of the product types she has worked with are; fetal monitoring system, ECG, medical devices for in vitro fertilization, wound care products and surgical devices.

Sofia is a flexible, structured and performance driven person with strong scientific knowledge. She works well both in teams and with individual tasks and can lead with positive and energic impact.

QUALIFICATIONS

Evidence strategy and Medical and Regulatory Affairs for medical devices and systems.

Tools & Methods

- Scientific Research
- Pre-Clinical Evaluation
- Clinical Investigations
- Clinical Evaluation
- Review of Technical Documentation
- Education and Training
- Market approvals; CE-marking , 510(k), PMA etc.

EMPLOYMENTS

- Mediteq, 2018 -
- Intertek Semko AB, 2017-2018
- Mölnlycke Health Care, 2013-2017
- Vitrolife AB,2007-2013
- Neoventa Medical AB, 2001-2007

EDUCATION

- M Sc in Biology University of Gothenburg,
- Doctor of Philosophy in Physiology, Institute of Neuroscience and Physiology at Sahlgrenska Academy, University of Gothenburg

Courses & certificates

- Certified Technical Documentation Reviewer at Notified Body
- Project Management
- Research methodology
- Evidence based medicine

LANGUAGES

- Swedish – mother tounge
- English – fluent

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