Quality, Regulatory Affairs, Medical Device & IT

When you need hands-on support regarding product registrations, quality assurance or regulatory requirements for medical devices, **EMILIE ANDERSSON** is the one to help you. It can concern CE-marking, FDA registrations, project support, risk analysis or quality management systems.

Emilie has ability to work goal oriented in a structured way with an eye for details. She is excellent at performing the activities mentioned above and can help to practically support your team in efficiently executing such activities.

Emilie has experience and knowledge from working with product registrations, compile or update technical, regulatory support in development or change projects or classification assessments. Her product experience includes all risk classes and several product types, such as implants, IVF products, and electronic patient records. Emilie is also a member in standardization committee TK355.

Emilie has an extensive education in medicine and life sciences, as well as in business development, innovation and entrepreneurship. In addition, Emilie has good knowledge about medical research.

Emilie is an open, driven and creative person with a lot of ideas, who enjoy working with an inquisitive mindset towards defined goals. Emilie is a team player, a fast learner and good at communicating. Finally, Emilie is efficient, thorough and not afraid of accepting new challenges.

QUALIFICATIONS

Quality and Regulatory Affairs for medical device or software

Tools & Methods

- Market approval and clearance; CE-marking , 510(k), etc.
- Define and implement processes
- Regulatory project support
- Risk management and patient safety analysis

EMPLOYMENTS

- Mediteq Svenkebo AB, 2014 -
- Anatomica AB, 2013-2014
- Start-up Extensis, 2013-2014
- Sahlgrenska Academy, 2013
- Supersale, Sport & Fritid, 2012
- Vård och Omsorg, Nyköpings kommun, 2008-2012

EDUCATION

- Master of Med. Sci. in Business Creation and Entrepreneurship in Life Science, Sahlgrenska Academy, 2014
- Bachelor of Med. Sci. in Biomedicine, Karolinska Institute, 2011

Courses & certificates

- Medical Devices – MDD & MDR
- QMS, ISO 13485 and internal audits
- Risk management, ISO 14971
- Standardization under SiS

LANGUAGES

- Swedish and English – fluent
- French – basic knowledge

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