Consultant Presentation – Emilie Andersson

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, regulatory project support including design and development and design control, risk analysis, clinical evaluation, clinical investigation applications or quality management systems.

Emilie has the ability to work in a structured way and has 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 in product registrations, classification, compilation and update of technical files, and can support the development or change of projects. Her experience includes all risk classes and several product types, such as implants, IVF products, and electronic patient records. Emilie is also a member of the 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 enjoys working with an inquisitive mindset towards defined goals. Emilie is a team player, a fast learner and good at communicating and has valuable soft skills and will with excellent results drive the work forward in a team.

Finally, Emilie is efficient, thorough, and not afraid of accepting new challenges.

Emilie Andersson
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TOOLS & METHODS

- Market approval and clearance; CE-marking, 510(k), PMA, pre-submissions UK and registrations in other markets
- Define and implement processes and QMS
- Regulatory project support within design and development and design control
- Risk management and patient safety analysis
- Clinical evaluation and clinical investigation
- Deliver trainings and workshops

EDUCATION

- M.Med.Sci. in Business Creation and Entrepreneurship in Life Science, Sahlgrenska, 2014
- B.Med.Sc. in Biomedicine, Karolinska Institute, 2011

COURSES & CERTIFICATES

- MDD & MDR, IVDD & IVDR
- QMS ISO 13485, Internal Audit ISO 19011
- Lead Auditor ISO 13485
- Risk management ISO 14971
- Member of TK355 under Swedish Institute of standards

EMPLOYMENTS

- Mediteq Svenkebo AB, 2014 -
- Anatomica AB, 2013-2014
- Start-up Extensis, 2013-2014
- Sahlgrenska Academy, 2013

LANGUAGES

- Swedish – mother tongue
- English – fluent

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