

Are you at a medical device company that think quality management system sounds complicated, or do you need support with your current QMS to be compliant with ISO 13485? It doesn't matter if you work in a start-up that needs help to build up the entire QMS, or if you work at an established medical device company, **LINE VIKINGSSON** will provide hands-on support with your QMS and guide you all the way to a compliant system. Line has experience and knowledge to build up a very good quality management system for medical devices and she can perform audits according to the ISO 13485.

Do you have concerns about the clinical evaluation of your medical device and need support to make it stand up to regulatory requirements? Or do you have a previously approved CE marked device under the MDD and not sure how to make the transition to the new MDR 2017/745 regulation? Line can help you with that, by deliver GAP analysis of your current clinical evaluation report, evaluate literature data or simply write your entire clinical evaluation report.

Before starting to work with quality management and regulatory affairs, Line worked as senior scientist and obtained her PhD at the Faculty of Biomaterials and Tissue Engineering in Valencia. Line is an open-minded, driven and creative person with a lot of ideas and doesn't hesitate to think outside the box. Line is a team-player, a fast learner and good at communicating. Finally, Line is efficient, thorough and has an eye for details.

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QUALIFICATIONS

Quality and Regulatory Affairs for medical devices

Tools & Methods

Scientific Research
Quality Management System

- Internal Audit
- Clinical Evaluation

EMPLOYMENTS

- Mediteq Svenkebo AB, 2022
- Promimic, Quality Manager, 2018
- Promimic, Senior Scientist 2016
- Astra Zeneca, Consultant Senior Scientist 2015

EDUCATION

- PhD Biomaterials, Centre for Biomaterials and Tissue Engineering, Polytechnic University of Valencia
- M Sc Biotechnology, Faculty of Engineering, University of Lund

Courses & certificates

- QMS, Internal audit and ISO 13485

LANGUAGES

- Swedish – mother tongue
- English – fluent
- Spanish – fluent