

When you need advice or support regarding quality assurance and regulatory requirements of medical devices, **Jessica Govik** can help you. It can concern quality management systems (QMS) including eQMS and software validation, business process development, project management, risk management, CE marking (technical file) and regulatory strategies.

She has +15 years of experience from QMS, process and product development (design control), project management and QA/RA for medical devices. Her experience of devices ranges from class I to class III and market entry of electromedical devices, sterile devices and devices containing software in CE, US, Canada, Australia and Brazil.

During product development and regulatory market access, she can act as overall project manager or sub-project lead for QA/RA and work both strategically and operationally supporting risk management, product verification and validation, design review, change management, labelling, product documentation as well as other items associated with technical documentation.

When improving or implementing business processes, she can facilitate the development of clear, compliant processes and act as project manager to ensure effective change management and training.

She has a broad competence where she sees the bigger picture as well as details underneath. She is a communicative, structured team player engaged to ensure the team deliver great and solutions to the tasks ahead.

With her background in tissue engineering, she understands research and development, e.g., in material development and cell culture.



Jessica Govik

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TOOLS & METHODS

- Quality management system and processes, incl. e-QMS
- Risk management, ISO 14971
- MDR, ISO 13485, MDSAP, QSR
- Market approval and clearance; EU, US, Canada, Australia, Brazil
- Training leader

EDUCATION

- Master of Science in Engineering, Molecular Biotechnology, Uppsala University, 2009
- Master of Science, Tissue Engineering, Chalmers University of Technology, 2009

COURSES & CERTIFICATES

- Internal Audit
- Risk Management, ISO 14971

EMPLOYMENTS

- Mediteq, 2025 - current
- Oticon Medical AB, 2022-2025
- Essity AB, 2019-2023
- Knightec AB, 2014-2019
- Chalmers University of Technology, 2009-2014

LANGUAGES

- Swedish – mother tongue
- English – fluent
- German – basic

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