Jenny FÄLDT

Executive Advisor | Interim Executive | MedTech Executive Leadership

ABOUT JENNY

Senior MedTech executive with more than 20 years of experience leading Clinical Affairs, Research, Regulatory Strategy and Innovation within global medical device organisations.

Extensive experience building organisations, developing international teams and establishing evidence strategies supporting regulatory approval, market access and commercial success.

Today I provide executive advisory and consulting services through JeFa Group AB, supporting MedTech companies with clinical evidence generation, regulatory strategy, Quality Management Systems (ISO 13485), and organisational development. I also co-founded Structura MedTech Partner AB, a strategic collaboration focused on supporting MedTech companies with regulatory, quality and clinical expertise.

Available for senior consulting assignments through JeFa Group AB, as well as interim executive leadership roles.

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PERSONAL SKILLS

- Strategic leadership with strong operational execution
- Clinical and regulatory evidence strategy
- Business-oriented decision making
- Organisational development and change management
- Leadership, coaching and team development
- Cross-functional collaboration and stakeholder management

KEY KNOWLEDGE

- Clinical Affairs Leadership
- Medical Device Regulation (MDR)
- In Vitro Diagnostic Regulation (IVDR)
- ISO 13485:2016
- Clinical Evidence Strategy
- Clinical Development
- Clinical Evaluation (CEP/CER)
- QMS
- Regulatory Strategy
- Innovation Management
- Organisational Development
- Executive Leadership

CLINICAL EVIDENCE & REGULATORY STRATEGY EXPERIENCE

Evidence strategy & Planning

Developed clinical and pre-clinical evidence strategies integrating regulatory requirements, market access and clinical acceptance.

Defined evidence generation roadmaps supporting product development from early research through commercialisation, including successful transition from MDD to MDR.

Clinical Evidence Evaluations

Prepared and directed Clinical Evaluation Plans (CEP) and Clinical Evaluation Reports (CER) for medical devices.

Ensured compliant and timely clinical evaluations supporting regulatory submissions and product lifecycle management

Clinical Evidence Generation

Designed and led clinical studies ranging from registry studies to international multicentre randomised clinical trials.

Directed clinical operations, statistical planning, data management and clinical compliance throughout the complete study lifecycle.

Regulatory Compliance & Quality Management

Led regulatory activities supporting CE marking and implementation of Quality Management Systems (QMS).

Completed accredited ISO 13485:2016 Lead Auditor training.

Supporting MedTech companies in designing, developing and implementing scalable Quality Management Systems aligned with ISO 13485 and MDR requirements.

EXECUTIVE EXPERIENCE

Research Strategy & Innovation

Established new research platforms and strategic collaborations with universities, healthcare providers and scientific partners.

Successfully translated research into commercially relevant innovation platforms across medical devices and consumer healthcare.

Evidence Governance

Designed governance models ensuring effective prioritisation of clinical evidence investments while aligning regulatory, commercial and business objectives.

Leadership & Team Development

Built and led global Clinical Affairs organisations covering Clinical Operations, Clinical Evidence, Clinical Data Science, Statistics, Clinical Compliance and Safety.
Recruited, developed and coached international leadership teams while driving organisational transformation and cross-functional

JeFa Group

SELECTED WORK EXPERIENCE

2024 – Present

Executive Advisor and Consultant
JeFa Group AB

Providing executive advisory, interim leadership and consulting services to MedTech companies within:

- Clinical Affairs
- Clinical Evidence Strategy
- Regulatory Strategy
- Quality Management Systems (ISO 13485)
- Organisational Development
- Executive Leadership
- Due Diligence and Business Advisory

Supporting MedTech companies from early-stage development to established global organisations in strengthening their clinical, regulatory and quality capabilities through strategic leadership, expert guidance and hands-on implementation.

Co-founder
Structura MedTech Partner AB

Co-founded Structura MedTech Partner AB together with Stefan Book to combine complementary expertise in clinical, regulatory and quality disciplines supporting MedTech companies with strategic advisory services.

Acting CEO
CerInvent AB

Serving as Acting CEO of an early-stage MedTech company, responsible for strategic and operational leadership, coordinating external development partners and driving product development towards regulatory and commercial milestones.

2018 – 2024

Global Director Clinical Affairs
Mölnlycke Health Care AB

Established and led the global Clinical Affairs organisation comprising Clinical Operations, Clinical Evidence Evaluation, Clinical Evidence Strategy, Clinical Data Science & Statistics, and Clinical Compliance & Safety.

Developed governance structures improving strategic prioritisation of clinical investments across Wound Care, Surgical, Gloves and Antiseptics while supporting successful MDR transition.

Built and developed the Clinical Affairs leadership team, strengthening cross-functional collaboration across the global organisation.

2014 – 2018

Global Research Director – Absorption & Skin Health
Essity

Led the global research organisation within Absorption & Skin Health.

Developed innovation platforms and introduced new collaborative ways of working linking research with commercial business needs.

JeFa Group

2005 – 2013

Director Biological & Clinical Systems
Nobel Biocare AB
Built the biological research capability supporting future treatment concepts and innovation.

Established strategic scientific collaborations strengthening innovation and clinical credibility.

2002 – 2005

Postdoctoral Research (Post doc)
University of Gothenburg
Established interdisciplinary research combining immunology and obesity research while developing new experimental models and translational research approaches.

AVAILABLE FOR

- Interim Executive Leadership
- Executive Advisor to CEOs, Executive Management and Leadership Teams
- Clinical Affairs Leadership
- Clinical Development & Clinical Investigations
- Clinical Evidence Strategy & Clinical Evaluation (CEP/CER)
- Regulatory Strategy & MDR Transition Support
- Quality Management Systems (ISO 13485)
- Clinical, Regulatory & Quality Organisation Development
- MedTech Scale-up Support
- Due Diligence & Business Advisory

EDUCATION

Postdoctoral Research
University of Gothenburg
Research Centre for Endocrinology & Metabolism

PhD, Medical Microbiology
University of Gothenburg

MSc in Biology
Linköping University

Additional qualification
ISO 13485:2016 Lead Auditor Training (2025)