Arnar H. Kristjánsson
Dipl.ing. Industrial Engineering & Mngt.
Technical University of Berlin (TU-Berlin)

Medical Device Manufacturing

ID1052

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medicologic®
PARTNER

Medicologic A/S
Arne Jacobsens Alle 17
Ørestad City
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(+45) 48 24 51 13
contact@medicologic.dk
www.medicologic.dk

Competences

- Medical Device Production Development
- Project Management
- Verification, product transfer, validation
- Product management
- Quality management
- Risk management
- MDR

Key results

2020-22:
Interim-COO: Designed / Sourced / Built / Validated 3 production lines (Class III and biocide)

2018:
COO: Led Development of a Class IIa/IIb Medical Device

2011:
Global Product Manager: Launched 7 Medical Devices (Class I) in 2 years. Responsible for a $40M portfolio of 150+ products

Standards & Regulations/Software

Extensive knowledge in:Software:

- ISO 13485:2016 – Management and Implementation
- EU Regulations: MDR 2017/745
- FDA Regulations 21 CFR part 820
- ISO 62304 – Midecal Device - Software
- ISO 62366-1 – Medeical Device Usability
- ISO 14971 – Medical Device – Risk Management
- ISO 10993 – Biological Evaluation

- Microsoft Office
- Industrial CAD

Personal Characteristics

Arnar has 20 years global experience in Product Development & Management, Supply Chain Management, Regulations, Operations, Entrepreneurship, Project Finance, and Business Consulting within multiple industries.

He is a team player with a “just do it” mentality. When in the role as leader, he empowers, motivates and supports the team to reach maximal results. He gets things done.

Arnar holds a PhD in Engineering Design, MSc Master of Production, and Dipl.ing. in Industrial Design and Management.

He has a global mindset and is fluent in English, Norwegian, and German, as well as proficient in Spanish.

In spare time Arnar plays musical instruments and enjoys cycling and traveling.

References

Medicologic A/S (2023 – present)
Senior Consultant Medical Device Manufacturing

Xybel AS

CEO - Diverse consulting and interim management projects within the Medical Device industry, covering areas such as product development, management, manufacturing, and regulations.
Served as interim COO for a Biocides/Medical Device company in Norway, successfully setting up a Class III medical device production line in a cleanroom setting and scaling biocide production. Also experienced in hiring qualified staff and steering regulatory aspects of production. Portfolio includes advisory roles in diverse MedTech sectors, from wound care to circulatory systems. Demonstrated skills in handling complex projects, such as a continuous glucose monitoring system. Offers invaluable insights into supply chain management, daily operations, budgeting, and Lean implementation.

Otivio AS

COO - Responsible for QA/RA, Product Development, Production and Logistics.
Lead the successful development of a new generation of the FlowOx medical device; with 80% lower manufacturing cost, increased ergonomics, and improved aesthetics and functional performance in general. Lead multi-national development team.
Implemented a new eQMS / LCM system, moving the company from paper based to digital.
Responsible for Quality Assurance and Regulatory Affairs

Össur Americas

Global Product Manager Foot & Ankle | Knee - Lead the Foot & Ankle Braces and Support segment.
Managed a $40 million product portfolio within orthopedic medical devices. Idea gathering, VoC, business cases, regulatory issues, pricing, marketing strategy, etc.
Launched seven products in this time - main ones with multi-million-dollar revenu

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