



Luuk van den Poll Thomsen

MSc Applied Physics

R&D & Design Control

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Medical Device Development

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Competences

- Medical Device Development
 - Program and project management
 - Radiology software, endoscopes, hearing implants, autoinjectors, IVD point of care testing including reagents.
 - Mechanics, electronics (IEC 60601 series), software (IEC 62304) and connectivity
 - Design Control and QA: MDR, IVDR, ISO 13485, 21 CFR 820.30
 - Risk analysis: ISO 14971 – FMEA
 - Usability ((IEC 62366)
- Technical File and 510(k) preparation, gap analysis
- QMS optimization & development, writing SOP's and templates.
- Regulatory strategy
- Leading R&D organizations
- Holistic understanding of company value chain

Standards

Extensive knowledge in:

- ISO13485
- **MDR 2017/745 and IVDR 2017/746** [Medical Device & In Vitro Diagnostic Regulations]
- **FDA regulation** [CFR part 820]

References

Medicologic A/S

Senior R/D and Design Control

Consulting and Interim Medical Device R&D and Design Control

BluSense Diagnostics

Director of Product Development

Management of assay development team (10-15 persons)
Regulatory strategy, QMS

Phillips Medisize

Senior Project Manager

Development of autoinjector platform

Oticon Medical

Senior Project Manager

Development of cochlear implant sound processor
Development of novel bone anchored implant

Key results

- Implementation of radiology management system in Region North
- Key player in establishment of new endoscopy division and responsible for development of first successful products
- Key player in integration of cochlear implant division after acquisition and responsible for development and launch of the world's smallest cochlear implant sound processor.
- Design of regulatory strategy and project management of initial phases for novel autoinjector platform
- CE marking of 4 point of care diagnostic tests within a year
- Mentoring and advising startup companies in the medical device space, including the winner of Danish Tech Challenge 2023
- Industry fellow for DTU X-Tech program

Personal Characteristics

Luuk is a seasoned program and project manager with 20+ years of experience in medical device and in vitro diagnostics product development.

Improving people's lives through new technology is Luuk's main driver and hence he always focuses on bringing the right product with the right quality to the market. He believes that good working relationships at all levels are the key to doing this.

Luuk is a positive person with a pragmatic mindset, excellent communication skills and a taste for leading diverse and international teams.

Ambu

R&D Project Manager

Development of several generations of single-use endoscopes
Update of training manikin
Development of novel wireless ECG electrode
Development of endotracheal monitoring device

Medical Insight (today Vital Images)

Manager of Projects

Development and onsite implementation of radiology management system (RIS/PACS) in region North