Gert Andersen
B.Sc Engineering

QA/RA Consultant, Medical Device

ID1018

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medicologic®
Medical Device Development

Medicologic A/S
Arne Jacobsens Alle 17
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Competences

- Quality management
- Design Controls and DHF
- Design and implementation of QMS
- Testing Strategies and Implementation
- Implementation of the V-model
- Design verification – Test protocols/test reports
- Risk Management
- Post Market Surveillance (PMS) and Vigilance
- Management and project management
- Experienced auditor
- Management Representative
- Qualified Person
- Medical Marketing and product launches

Key results

- Implementation of QMS and ISO 134845:2016 certification at RD-Support
- Implementation of QMS at Optoceutics and Measurelet
- Antia Therapeutics AG:
    - CE-Mark Class IIB
    - ISO 13485:2012 → 2016 certification
    - Market introduction and sales of Easyx Liquid Embolic
    - Clinical Studies (Class IIB and Class III)
- Prior to that multiple medical device product launches

Software/Standards

Extensive knowledge in:

- **MDR 2017/745, IVDR 2017/746**
  [Medical Device & In Vitro Diagnostic Directive]
- **ISO13485:2016** [Medical Device QMS]
- **FDA CFR 820** (QSR for Medical Devices)
- **FDA 21 CFR** (Classification of Medical Devices)
- **EN ISO 14971:2019** [Risk Management]
- **EN ISO 19011:2018** [Internal Audit]
- **MEDDEV 2.12-1 rev 8** [Vigilance]
- **MEDDEV 2.7/1 revision 4** [Clinical Evaluation]

Personal Characteristics

Gert believes in practical solutions that works for people.
He has hands on experience in all aspects of startups and large medical device companies including extended Regulatory and Quality experience.
Gert can do the job himself as well as teach and coach.

Gert is an excellent cook and spend his free time mountain biking close to the summerhouse where he is also working on projects.

Gert is married for a lifetime and has two daughters.

References

Medicologic A/S (2020 - present)
Senior Consultant, Medical Device Test and Compliance

Leo Pharma MDR compliance, Verification test reports, shelf life

Radiometer IVDR compliance, Risk Management, STED

Uneeg FDA compliance for submission

Soltech ApS
Implementing and maintenance quality Management System ISO 13485:2016. Responsible for Design Controls
Test and test procedures, Clean room, and Process validation

Antia Therapeutics AG Director
Responsibility for the quality system, certification (ISO 13485), implementation of procedures, internal audits. Responsible for test and implementation of test procedures, Design Control, Clinical Evaluations and establishing of technical file. Supply chain, Manufacturing setup, Distribution management

Opti-Med GmbH
Product Manager, Global Product Launches
Marketing Literature. Part of the executive Management Team

COOK Medical
Product Development of class IIb and III
IP/Licensing
Business Unit Manager
Marketing
Sales & Marketing

RD Support ISO 13485:2016 certification by BSI
Optoceutics QMS, Regulatory strategy and DHF
Measurelet QMS, Regulatory strategy and STED
Wavecare QMS, Regulatory strategy and STED

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