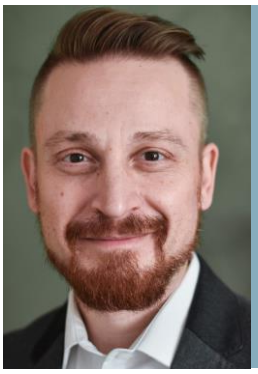

Frederik D. Hjort
BSc. ME DTU

Qualification and Validation

ID1020

Direct (+45) 20 15 99 73
Frederik.hjort@medicologic.com

medicologic®
Medical Device Development

Medicologic A/S
Arne Jacobsens Alle 17
Ørestad City
DK-2300 Copenhagen
Denmark

(+45) 48 24 51 13
contact@medicologic.dk
www.medicologic.dk

Competences

- Qualification and validation (process/method/software).
- Risk Management
- Process validation
- Software and Method validation
- Equipment qualification
- Six Sigma (trained master black belt)
- Applied statistics
- QMS (procedures, templates etc.)
- Team management and coaching

Key results

Extensive Medical Device experience, in particular within non-clinical test and validation disciplines, having worked both in planning, executing and reviewing (QA) protocols, statistical data analysis and reports.
Several post-warning letter remediation projects.
Recreation of lost component specifications.
Used for risk- and statistics-based rationales and justifications for complex problems as well as effectiveness checks for CAPA's.

Regulations/Standards/Software

Extensive knowledge in:

- ISO13485:2016
- IVDR (In Vitro Diagnostic Regulation)
- US FDA regulation 21CFR Part 820
- ISO14971 (Risk Management)
- Certified Validation Manager

- Microsoft Windows
- Microsoft Office 365 (Word, Excel, PowerPoint, Outlook)
- Microsoft project
- Microsoft Visio
- Minitab (statistical software)

Personal Characteristics

Frederik believes that there will be a solution to every problem and will always strive to offer a feasible way onwards (or alternatives with pros and cons in cases where several viable solutions exist).

Frederik is assertive by nature and will listen and look to data to offer the best way going forward, be it in a validation project, in writing up a lean QMS system or assessing the state of compliance and how to remedy any gaps.

Frederik likes to keep up to date with new standards and regulations in the MedTech industry.

In his spare time Frederik enjoys reading and spending time in his toolshop.

References

Medicologic A/S

Senior consultant

Manager, Quality Assurance – Process Engineering Quality Assurance for process, method and software validations

- CAPA handling
- Recall Lead Investigator
- Coaching employees in fields of responsibility

WSAudiology

Manager, System Integration Test
Real-life usage testing of entire system prior to release of new/revised hearing aid/mobile app/firmware.
Planning and execution of test campaigns, often with tight deadlines.

Cook Medical Europe

Manager, Test & Validation

- Warning Letter Remediation (post FDA Warning Letter)
- Coaching in validation methodology and statistical analysis
- Implementation of Master Validation Plan
- Efforts led to successful FDA audit with no observations in field of responsibility.

Agilent Technologies Denmark Aps

Quality Assurance, Validation Specialist

- Quality Assurance for process, method and software validations
- Equipment qualification
- Quality assurance for Process monitoring
- Risk management
- CAPA handling
- Change management

Convatec

Specialist, Design for Six Sigma & QFD

- Internal training in statistics
- Statistics for rationales and risk assessments
- Statistical tolerance chains
- Implementation of MSA
- Method validation
- Reliability Testing
- Off-site project management