



**NN**  
BSc. ME DTU

Qualification and Validation

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**medicologic®**

Medical Device Development

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## 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

## 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)

## References

### Medicologic A/S

#### Senior consultant

### 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.

### 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

## 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.

## Personal Characteristics

He 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).

He 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

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

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

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

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

### 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.

### 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