



Product development process and testing

With an electronics and embedded software development background, I have worked with all aspects of the device development process – from requirement specifications to system test execution.

I have been responsible for introducing and maintaining software methods and tools for qualified software development in embedded software.

Being a developer, tester and internal auditor, lately focus has been on

CE marking

of device design and manufacturing in compliance with

- Medical Device Regulation EU 2017/745 (IEC 60601)
- Machine Directive 2006/42/EC (IEC 61508)

with special attention on the new issues of

- Risk assessment (ISO 14971, EN 12100)
- Software development (IEC 62304, IEC 61508-3)

This includes making the **technical file** and doing the corresponding checklists.

Being qualified as ISTQB Certified Software Tester, testing of software is a strong competence.

Experience

2020- : **Consulting**

(Medical devices), consultant

CE marking of

- Blood gas analyser

2014-2019: **Consulting**

(Medical devices), consultant

CE marking of

- Respiratory exercise system
- Infusion pump for analgesic drug
- Biomarker device for blood samples
- Accessories for MRI/PET scanning
- Hearing aids
- Sending tubes of blood samples through a compressed air system (pneumatic discharge)

(Industry consulting), consultant

CE marking of

- Ship engine safety system
- Lithium battery control (automotive)
- 3D printer and material recovery system
- Controller for refrigeration compressors
- Smoke ventilation panels for the French market (NFS61-938)

Further experience

- 2014-2016: **Upfront Chromatography** (Milk protein separation), consultant
Developing a dairy process unit for separation of milk protein (IEC 61508)
- 2014-2015: **ePower Technology** (Fitness machines), consultant
Evaluation of software documentation for Medical CE marking (IEC 60601)
- 2013-2014: **Novo Nordisk** (Medical devices), consultant
Validation of R&D test equipment for internal certification of product design
- 2012-2013: **Philips Healthcare** (Medical devices), consultant
Updating technical file for CE marking and system testing (IEC 60601)
- 2011-2012: **Siemens Flow** (Flow measurement devices), consultant
Product integration and system testing with focus on functional safety (IEC 61508)
- 2002-2011: **Novo Nordisk** Process architect of development methods and tools.
System test manager with focus on CE marking (IEC 60601) and FDA 510(k) pre-clearance inspection
- 2000-2003: **ITU** Examination censor in "IT platforms and organisation"
- 2000-2002: **Baan CRM** Software process manager of methods and tools for Windows software development and project management
- 1994-2000: **BarcoNet** Software group manager of methods and tools for software development and project management
- 1993- : **Eldotek** Personally owned company for freelance development, technical consultancy and project work
- 1990-1992: **GN DataCom** Project manager of programmable Dankort card readers and embedded software for transfer of CNC programs through local network
- 1988-1996: **Bocodan** Personally owned company for development and sales of yacht electronics (switchboard and alarm system)
- 1987-1989: **Scantest** Development of the Scantest burn-in system comprising VME data acquisition and work stations with UNIX, C and SQL database
- 1983-1987: **Infolog** Project manager for real-time data acquisition together with programming of mini frame computers: PDP11, VAX, HP1000, HP9000
- 1976-1983: **GN Elmi** Project manager of test equipment for two-tone signalling (MFC), and for digital telephony (PCM)
- 1975-1976: **University of Leeds, England.** Development of mini computer application for real-time digital signal processing (military sonar application)
- 1974-1975: **Forsvarets Forskningstjeneste.** Development of sub water data acquisition equipment

Professional skills

Education

Master of Science (EE), DTU (1974)
Lieutenant, Research Centre of Defence (1975)
Master of Philosophy (EE), University of Leeds (1979)
ISO9001 Internal Auditor (1994)
ISEB/ISTQB certified software tester (2000)

Publications

CE marking – the Technical File (HI exhibition 2015)
Acceptance test of medical devices (Tecpoint 2013)
Risk-based testing – a must for medical devices (EuroSTAR 2010)
Coaching – an inspiration from team sports (EuroSTAR 2004)

Methods and Tools

CMMI, Bootstrap, UML, RUP, MSF
Microsoft Visual Studio, Visual Source Safe, Visio
IBM Rational RequisitePro, ClearCase, ClearQuest, Rose
HP Mercury Quality Center (Novo eTims, Siemens TMS)

Personal information

Born July 4th, 1949
Languages: Danish (native), English (fluent), German
Myer Briggs Type Indicator: **ENFJ**

I am a keen team player:
Singing bass in a classical choir
Playing handball (now on a low level)
Coaching basketball for young people
Coaching on active family summer camps