



NN
Ph.D., KTH Stockholm

Senior Consultant
Specialist within Biological Safety

ID1039

Direct (+45)
nn@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

- Profound proficiency within regulatory requirements including design controls (ISO13485), risk management (ISO14971), biological testings (ISO10993-*) and IEC 60601-1.
- Alignment of test system — qualification, verification, validation — of products, supporting biological safety.
- Process Validation within an ISO 13485 environment comprising IQ, OQ and PQ, according to GHTF/SG3/N99-10:2004.
- Lifecycle Analysis according to applicable standards.
- Coordination of global network within biological safety.

Software/Standards

- Microsoft Windows
- Microsoft Office 365
- Multivariate analysis (MANOVA)
- JMP Software

Extensive knowledge in:

- ISO13485
- ISO14971
- ISO10993-* (Class IIa)
- US FDA regulation 21 CFR Part 820
- IEC 60601-* regulation impacting medical device

Key results

2017-2022

Instrumental in the development of Biological Safety system at GN Hearing.

2007-2018

Accountable for the biological safety at GN Hearing.

1999-2007

Founder of start-up company CytaCoat AB (www.cytacoat.com)

1995-2000

Implementation of test strategy.

Personal Characteristics

I am a devoted principal for operations within biological safety, while considering the soft needs for customers. Very keen to meet the necessities of customers, both in time but also personal inter-relations.

I have 15 years of experience in medical device whereas the biological safety transformed from 'nice to have' to 'a must'.

I have also been instrumental in the start-up company CytaCoat AB (www.cytacoat.com) operating within medical device products.

I am furthermore expert ('*udvalgsmedlem*') at Dansk Standard (S-258).

References

GN Hearing AS, (2007-2022)

Specialist in Regulatory and Materials

- Material and supplier selections enabling smooth transition into biological safety.
- Materials Characterization
- Risk analysis, both FMEA and acc. to ISO14971
- Biological Safety according to applicable standards within the ISO10993-1.

CytaCoat AB, (1999-2007)

Project Manager

Schneider Electric, (2003-2004)

Project Manager

- Accountable for some 250 injection moulding machines at 7 sites.

Allgon, (2000-2002)

Specialist in Materials and Innovation

- Implementation of material selection for optimal antenna performance produced by injection moulding.
- Development of antenna products.
- Collaboration with sub-suppliers.

Cromtryck AB, (1995-2000)

Development and Quality Manager; Surface Chemistry.

- Implementation of ISO9001
- Surface Chemistry
- Accountable for test program