



Stine Balchen
Laboratory & Quality, Chemistry

Senior Consultant

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medicologic®

Medical Device Development

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Competences

- Verification & Validation, Laboratory testing
- Quality Assurance, Medical Devices
- Audit Management, Internal Audits, ISO 13485
- Quality Systems Implementation
- Design Control
- Nonconformance and CAPA Management
- Post Market and Complaint investigations
- Stop Shipment Evaluations
- HACCP and traceability documentation

Software/Standards

Extensive Knowledge in:

- **ISO 13485** Medical Devices – Quality Management Systems
MDSAP
- FVST Guidance no. 9006 / 10th of January 2023, Feeding and HACCP
- **ISO 11608-1:2022 / ISO 11608-1:2014 / ISO/FDIS 1008-1:2021** Needle based injection systems for medical use – Requirements and test methods
- TrackWise

Knowledge in

- **CLSI guideline EP17-A2** Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures
- **ASTM D4169-22** Standard Practice for Performance Testing of Shipping Containers and Systems
- **EN ISO 23640:2015** In vitro-diagnostics of Medical Devices
- **ISO 10993-1** Biological Evaluation of Medical Devices
- **ISO 14971:2019** Medical Devices – Application of Risk Management to Medical Devices
- **21CFR820.20(f)** Code of Federal Regulations
- **FDA-2020-D-0957** Design Control – Guidance for Medical Device Manufactures

References

Mediologic A/S (2024 – present)

Senior Consultant

Consulting for Medical Device Companies

Freelance Consultant (1 year)

Consulting for Medical Device and Medico Companies, e.g. Design control and technical file documentation for clinical trial projects.
HACCP and traceability documentation for compliance.

Novozymes (7 years)

Laboratory Technical Staff

Testing and release of product, customer auditing and development of laboratory testing procedures.

Key results

- Nonconformance and CAPA management in certified Medical Device Company
- Certified Internal Auditor ISO 13485
- Support on Notified Body audits and Customer audits
- Post market control of nonconforming products and Root Cause Investigations
- Extensive laboratory experience in ISO 13485 and FDA labs
- Technical documentation for clinical trial projects

Personal Characteristics

Well structured, with a strategic approach on complicated tasks. Strong coordination skills, with an eye for details.

Focused and goal-oriented mindset combined with a positive and holistic and inclusive approach, to ensure that chosen solutions include the best solution for stakeholders.

In her freetime, Stine is spending time with the family and working on her family farm, and breeding and training horses.

Over the last 16 years my main focus has been on measurement, analysis and improvement in various job roles.

Variation from documentation and validation of test methods in laboratories as well as product release, validation and recalibration of equipment and documentation for QMS and audits relating.

Over the last years the focus has transitioned to control of nonconforming products in relations to MDR, MDSAP and ISO

13485 with branches to design control, change control, risk management, design verification and revalidation and recalibration of machines and equipment.