Pernille Eilersen
M.Sc. in Molecular Biomedicine

Principal AdvisorMedical Device QA/RA

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Competences

- ISO13485 Medical device lead auditor
- QMS management: ISO13485, FDA 21 CFR part 820 and In vitro diagnostics and medical device regulations (MDR/IVDR)
- GMP and Quality Assurance (QA)
- CAPA and non-conformance handling
- Process- and test method validation
- Risk management
- Supplier quality management
- Quality Control (QC)
- Design control and transfer
- Change control
- Project management
- People management

Key results

Revised and optimized the entire QMS system under the merger between Widex and Sivantos Hearing Aids companies into WS Audiology and contributed greatly to the successful accomplishment as the first MDR certified company in the hearing aid industry. The new QMS ensured not only regulatory compliance but also the benefit from synergy effects which reduced costs and optimized the processes in the new global company with +10.000 employees worldwide.

Reduced the batch release lead time and backlog by 50% within 3 months by implementing a shopfloor system in collaboration with key stakeholders as production- and procurement teams including clear roles and responsibilities between the teams.

Personal Characteristics

Pernille is a highly skilled QA/RA consultant with five years' experience in safety, quality and regulation of in vitro diagnostics and medical devices, with a background in research, shop floor management and business development.

She holds a unique profile, combining a strong process- and business-oriented mindset with solid QA/RA knowledge which enables her to successfully translate regulatory requirements and legislations into practical processes and simple procedures. The key to her good results is her pragmatic approach, fast understanding of complex matters and engaging key stakeholders delivering lean but high-quality solutions.

References

MEDICOLOGIC (2021 - present)

Senior Consultant and principal Advisor
Medical devices and in vitro diagnostics.

Nunc A/S – part of Thermo Fisher Scientific

External consultant – *In vitro diagnostic & medical devices*

- Project Management: Implementation of in vitro diagnostic and medical device regulatory requirements (MDR/IVDR) in QMS; transitional provisions for Post-market surveillance, vigilance, economic operators, and all related procedures including clinical/performance evaluation, risk management, data analysis, complaint handling, CAPA, UDI-DI etc.

ZOETIS Animal Health

External consultant - *In vitro diagnostic devices for veterinary use*

- Daily Support: QC associate manager supporting the QC team in shopfloor with prioritizing and executing tasks and non-conformance reports, facilitating root cause analysis meetings and improvement actions in the test methods and procedures used in the laboratory. Further, assist the Supplier Quality Manager in risk assessments including training.
- Project: Facilitating pFMEA meetings, write protocols and other validation documentation to the complete process validation of a semi-automated production line in the design transfer of a manufacturing process from R&D in order to launch a new product.

Atlas Antibodies AB

External consultant - *In vitro diagnostic devices*

- Support: Advise in the regulatory strategy and training of an R&D organization in the technical file documentation requirements including classification and subsequently registration of research use only (RUO) products.

WS Audiology (previous Widex and Siemens Hearing Aids)

QC Manager and Supplier Quality – *Medical devices*

- Managed the QC team consisting of 7 employees responsible for incoming QC of raw materials and batch release and supplier quality.
- Responsible for supplier qualification & evaluation, supplier audits and participating in inspections and internal audits (MDR, FDA 21 CFR 820 and ISO13485) as well as responsible for training of the organization.
- Responsible for cross-functional MDR and merger projects; Implementation of production processes and procedures from Headquarter in Singapore to DK site including training of the organization.
- Conducting internal audits and participating in Notified Body audits and regulatory inspections. Contributed to WS Audiology was the first hearing aid company in the industry to obtain the EU MDR certificate. In addition, effectively completed an FDA readiness program resulting in a successful FDA inspection short after.

AGILENT TECHNOLOGIES

Quality Assurance Specialist – *In vitro diagnostic devices*

- QA Project lead in the design transfer of a class III IVD from US to DK manufacturing site.
- Part of the FDA Compliance validation program incl. class II and III legacy IVD products. Creation of and re-assessment of pFMEA's, design validation documentation, review and approval of stability-, feasibility- and robustness study protocols to update DHF, review and approval of validation protocols and reports.
- QA support to daily operation and several R&D projects; Review of non-conformance reporting, CAPA, design changes and raw material specifications.