



NN - Female
Zealand Business College

Senior Consultant
QMS and Supplier quality expert

ID1031

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Medical Device Development

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Competences

- Supplier Management
- Quality Management
- Audit Management
- Trained lead auditor/internal auditor
- Team/Department management
- Management representative
- Quality system implementation

Software/Standards

Extensive knowledge in:

- ISO9001 (Lead Auditor)
- ISO13485
- MDSAP
- Medical device regulation 2017/245 (Internal Auditor)

Knowledge in:

- In vitro diagnostic medical devices 2017/246
- FDA 21 CFR part 820
- ICH guidelines

Software skills:

- SAP QM Key user
- Documentum Key user
- TrackWise
- D4 Key user
- Agile
- MS Office

References

Medicologic A/S

Senior Quality Consultant

- QA Manager
- Supplier/Distributor optimization / IVDR compliance
- Supplier quality optimization / MDR/FDA compliance
- QMS IT system implementation and transfer
- QA support NC/CAPA/CR

Companies I've worked with

Thermo Fisher A/S

ConvaTec A/S

WSAudiology

Toms Group Aps

Boehringer Ingelheim Animal Health

Key results

Have hold titles as QC team manager, Supplier Quality manager, QMS manager and Head of QA.

Holding these titles, the companies have gotten certified or re-certified according to ISO9001, ISO13485, MDSAP, GMP+ and FSSC22000.

Assisted consultant customer in achieving recertification according to ISO13485 and obtaining IVDR certification while I was interim QA Manager

Personal Characteristics

She is someone who:

Helps to create team spirit

Appreciates presence and equality

Looks at the company with a holistic view, as all joints are needed to make the wheels turn.

In her spare time Ann-Kathrine spends time with family and friends, walks her two dogs, rides her bike or enjoy exploring new countries

Positions and responsibilities

Head of QA / QMS Manager / Supplier Quality Manager

- Quality management
- Supplier management
- Employee management and development
- Audit management
- QMS implementation
- QMS responsible
- QMS Training
- Design transfer and DHF approvals
- Cross functional projects management

Team Lead QC and Complaints

- QC management
- Complaint management
- Employee development

Senior Quality Engineer / Senior QA Specialist

- Integration and maintenance of QMS
- QC project in reduction of incoming inspection
- Supplier Qualification
- Supplier audits
- Supplier maintenance
- NC, CAPA, Complaint and SCAR handling
- Complaint investigation and response
- Change control
- Improvement projects