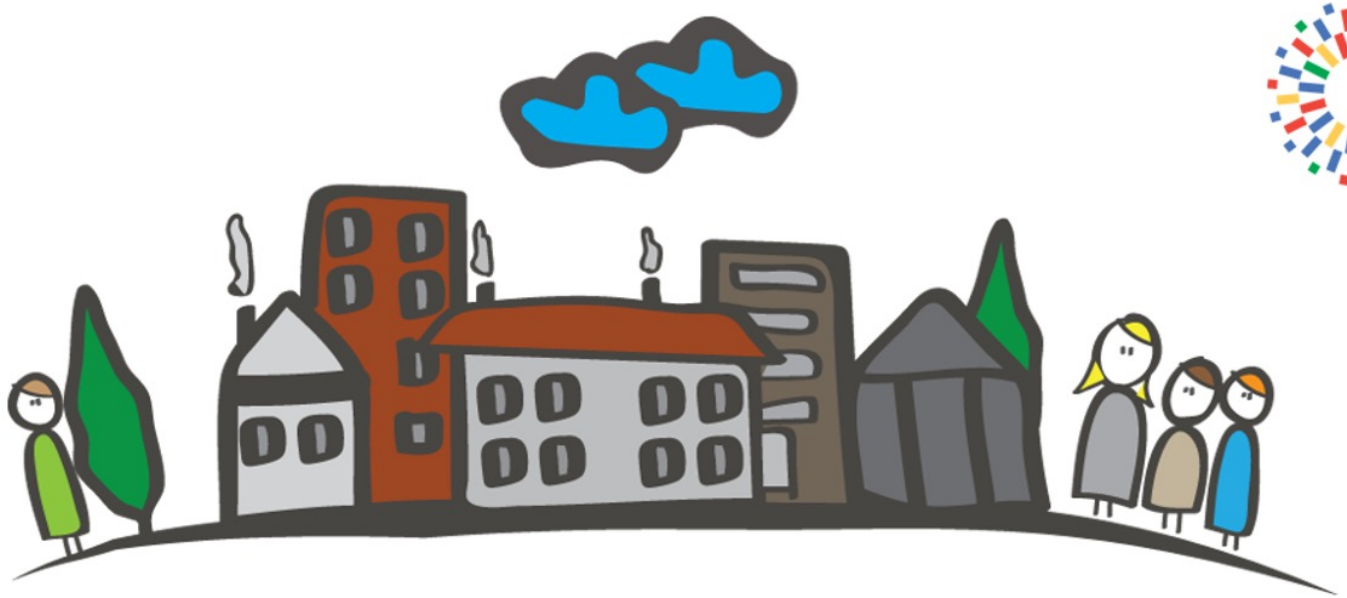
QMS og ISMS



NORWEGIAN
SMART CARE
LAB

Tjenestepakken leveres av underleverandør
Egde i samarbeid med NSCL

Medical Device Quality Management System & ISMS (Information Security Management System)

A structured approach to QMS and ISMS will help your organization achieve the level of corporate governance required to bring medical devices or services to market.

This service package offers access to experts with extensive experience in Quality Management Systems and Information Security Management Systems (ISMS).

Practicalities

- Target group: members/partners/clients of NSCL
- Preliminary work facilitated by Egde, with inputs from company:
  - Identify the focus area of the workshops
  - Identify the companies needs, set expectations, plan and pre-pare the three steps of digital workshops that will enable you to leverage off-the-shelf standards-based solutions, conform to national requirements and recommendations and maximise your product interoperability with patient journals and other national and international health solutions.
- Governance: All participants must sign an NDA

Quality Management (QMS) and Information Security Management (ISMS) implementation

ISO/IEC 27001 is widely known, providing requirements for an information security management system (ISMS). Using this standard enables organizations of any kind to manage the security of assets such as financial information, intellectual property, employee details or information entrusted by third parties in a secure manner.

ISO/IEC 13485 is the internationally recognized standard for quality management systems in the medical device industry. It specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices, and that related services consistently meet customer requirements and applicable regulatory requirements. It is designed and intended for use by organizations for the design and development, production, installation, servicing and sales of medical devices.

Step 1 – Initiation Workshop

A workshop between the company and the subcontractor to define an initial overview of the scope of organizational requirements, data requirements and data flows for the Device or Service.

The company will be expected to share any relevant background information about their technology organizational context. **Workload: 1-2 hours.**

During the workshop it is expected that the company will present their organizational structure, product, technology and objectives, as well as key milestones and delivery dates that need to be met. **Subcontractor** will facilitate a discussion on the potential standards and requirements the company and its medical device or service. **Workload: 3-4 hours.**

Outcome for this step will give the Company recommendations for:

- Which security standards and regulation the organization should follow
- Which Organizational processes need to be implemented to comply with the standard
- If the Company should get certified, or if the Company should limit the scope to follow the standard

Step 2 – Gap Analysis Workshop

This workshop is a collaboration between the Company and **subcontractor** to define main areas of improvement

With the output from this workshop the Company and **subcontractor** will have:

- An overall picture of the challenge areas.
- List of main processes that need to be defined and implemented
- List of documentation and record requirements
- List of controls to be implemented according to standard

***Company input/ workload*:** technical and product input to a workshop of 2 to 3 hours plus follow-up questions.

Step 3 – Planning and implementation

This step consists of collaboration between the company and **subcontractor** to define the content of each organizational process to be followed and how to operationalize the processes.

With the output of this step the Company will have:

- Defined scope of each process that needs to be implemented
- Plan for implementation and operationalization of each process
- Plan for deployment of training and awareness program
- Plan for certification of notifying body (if applicable)

***Company input**:* answer questions via email and online meetings as required. **Workload: 2-4 hours.**

***Outcome**:* will be presented to the company in a c.1 hour meeting and as a PowerPoint presentation.

Preparation & Execution - Summary

Egde

Ta kontakt dersom du ønsker mer informasjon om hva pakken inneholder og hva laben kan tilby din bedrift.

Marit Hagland
Leder
Norwegian Smart Care Lab
+47 452 61 799
Marit.h@valide.no

Karoline Blikra Mokleiv
Forretningsutvikler
Norwegian Smart Care Lab
+47 92 414 043
karoline@valide.no