NORBIT

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MEDQDOC eQMS CASE STUDY: NORBIT

Project overview

Contract manufacturer and niche research and development specialist NORBIT approached MedQdoc looking for a solution to meet their goal of achieving ISO 13485 certification.

MedQdoc proved to be the ideal choice and was easily adopted by their team, enabling them to put robust internal processes and documentation in place to support the certification. Read on to discover how MedQdoc enabled NORBIT to achieve their ISO 13485 certification in less than six months.

"I would absolutely recommend MedQdoc to other companies in the medical device world. Without a doubt, using MedQdoc has been a key factor in the success of our ISO 13485 certification process."

Kristian Nisja,
QA & HSE Manager, NORBIT EMS Selbu

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Aiming for ISO 13485 certification

"NORBIT is a supplier of tailored technology to carefully selected niches. We operate in several business segments, and the medical sector is a strategically interesting segment for us going forward. NORBIT has strong experience in both the design and manufacture of various medical devices."

Per Jørgen Weisethaunet, CEO, NORBIT ASA

As the contract manufacture of medical devices has become an increasing business focus for NORBIT, they wanted to add ISO 13485 certification to their other certifications, to demonstrate evidence of their expertise and regulatory compliance specifically for medical devices.

NORBIT hold long-standing certification for several other standards including IATF16949 for the automotive industry, as well as the more general ISO 9001 and ISO 14001 for environmental management and quality management respectively. They were therefore already familiar with quality management systems and the clauses required for the different standards.

Moving to an eQMS

One of the key challenges presented by NORBIT's plan to achieve ISO 13485 certification was the moving of their QMS documentation from their in-house server and file structure across to a new eQMS, and the potential impact this might have on their team in terms of time and training required. NORBIT previously had an in-house resource that used AM System, so were ideally looking for an eQMS solution which would be compatible with this.

"During this process we discovered that AM System had a partner in the medical device industry in MedQdoc."

Having discovered that MedQdoc could provide the perfect solution for NORBIT's requirements, the system was introduced to the team.

"There was a common perception after the initial management training that MedQdoc would totally change how NORBIT works with QMS documentation for the better. With this early positive attitude from the project team, which was quickly embraced our NORBIT colleagues, we got a flying start to our project."

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Improving processes with MedQdoc

One of the greatest benefits to NORBIT was the improvement to their processes as a result of using the MedQdoc templates. The templates allowed them to create the required documentation straight away, knowing that it would conform with the requirements of ISO 13485.

"Since we could use the templates that we knew satisfied the standard, we could compare our our existing documentation with MedQdoc and merge our system with MedQdoc without needing to spend time on understanding the standard first.
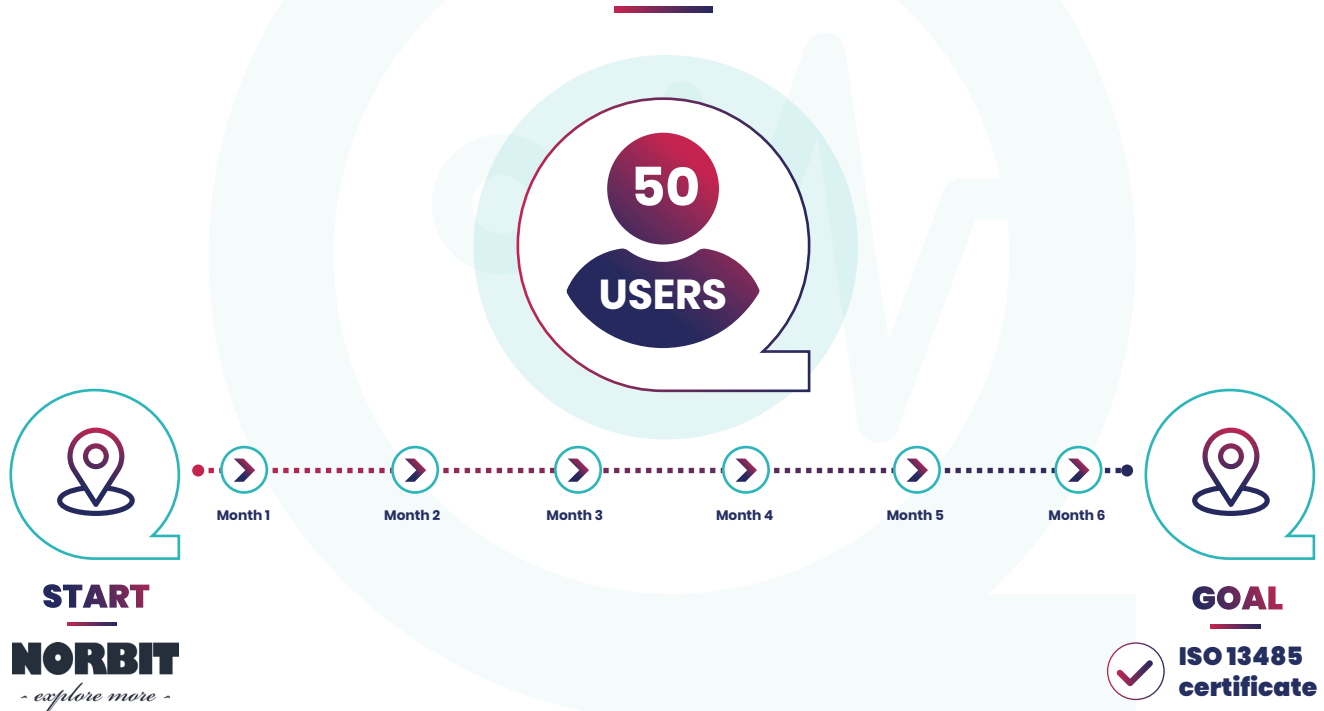
The templates in MedQdoc helped us understand the different clauses in ISO 13485."

MedQdoc was embraced across NORBIT's team, and has been instrumental in providing them with the tools they need to streamline their processes and create the documentation needed by each department.

"For each department and process we have standard operating procedures which are supported by work instructions. With the ability to easily make company adapted flowcharts, related documents and full document control, MedQdoc is an easy-to-use eQMS."

"MedQdoc contained all the QMS templates we required and much more."

50
USERS

Month 1   Month 2   Month 3   Month 4   Month 5   Month 6

START

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GOAL

✓ **ISO 13485 certificate**

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A fast journey to certification

Due to their previous use of AM System, NORBIT's administrator and project team were already familiar with the underlying system, reducing time needed for training on the MedQdoc add-on module.

This meant that the NORBIT team were able to get up and running with MedQdoc very quickly. As a result, they successfully obtained their ISO 13485 certification in less than six months from first starting the project.
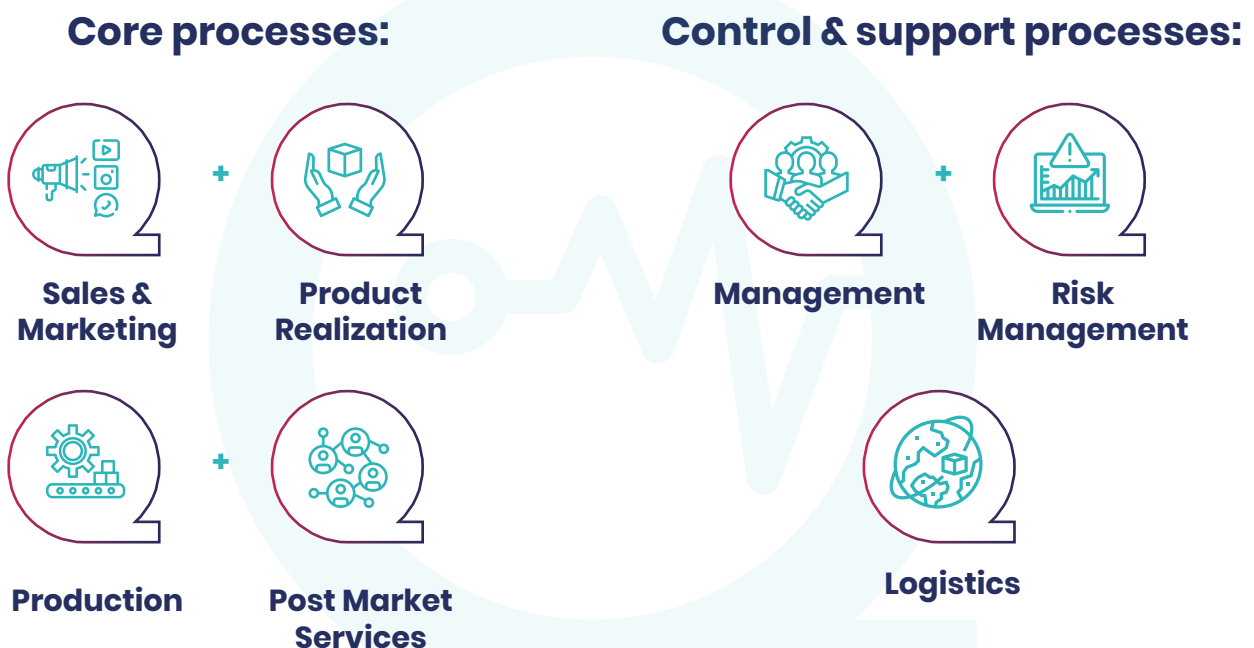
"There is no doubt that the investment we made in MedQdoc secured the progress of our project and enabled us to reach our goal of an ISO 13485 certification in six months."

Kristian Nisja,
QA & HSE Manager,
NORBIT EMS Selbu

How is NORBIT using MedQdoc?

MedQdoc is being used in processes across NORBIT's business.

Core processes:

Sales & Marketing + **Product Realization**

Production + **Post Market Services**

Control & support processes:

Management + **Risk Management**

Logistics

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ABOUT
MEDQDOC

MedQdoc is a software solution based on the AM System platform for a medical device focused quality management system. Created by medical device quality and compliance experts specifically for the medical device industry, MedQdoc comes ready to use with over 130 pre-defined templates. The eQMS software allows you to accelerate your quality management system electronically, enabling a faster path to medical device compliance.

Contact us for a demo and to find out how MedQdoc could support your medical device compliance journey.

COMPLY EASILY WITH

- ☑ **ISO 13485**
- ☑ **ISO 14971**
- ☑ **MDR 2017/745**
- ☑ **IVDR 2017/746**

med**Q**doc

Validated eQMS solution

AM System license