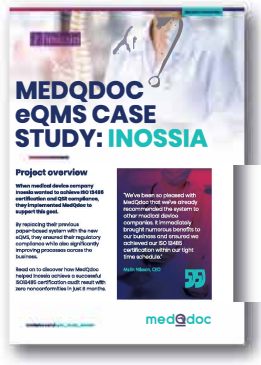
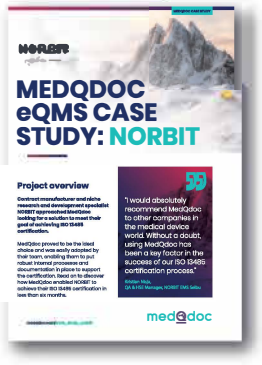
A QUALITY MANAGEMENT SYSTEM (eQMS) DESIGNED FOR THE MEDICAL DEVICE INDUSTRY

Read the eQMS case studies:



Inossia case study



NORBIT case study

Aidee case study

COMPLY EASILY WITH

- ISO 13485
- ISO 14971
- QSR
- MDR IVDR

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medqdoc

The intuitive eQMS created by medical device quality and regulatory compliance experts.

Reach your quality goals quickly and effectively.

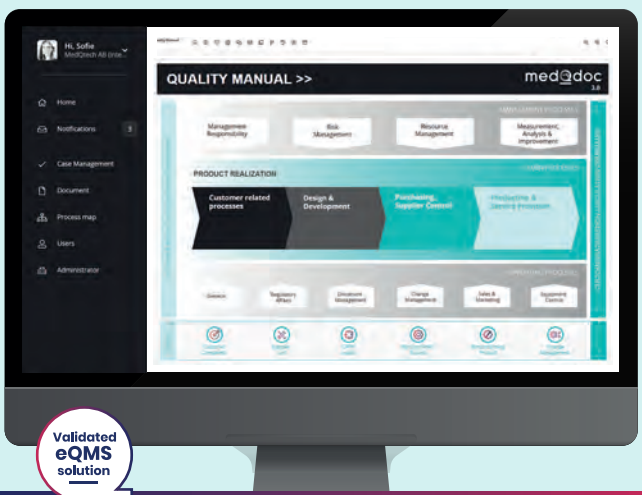
A simple, ready-to-use eQMS that adapts to your needs.

MedQdoc is designed to make life easy for our customers by providing a logical workflow. Functions and information you use daily are just a click away. The search query tools help you quickly find what you are looking for. Your documents, process maps and case management intelligently link. It is ready-to-use and user-friendly, but still comprehensive enough and adaptable where needed.

Making your medical device eQMS journey simple to achieve

A user interface created with medical device compliance expertise – utilising pre-defined templates logically.

MedQdoc effectively applies quality procedures for:



- Management Responsibility
- Risk Management
- Resource Management
- Measurement, Analysis & Improvement
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- Customer Related Processes
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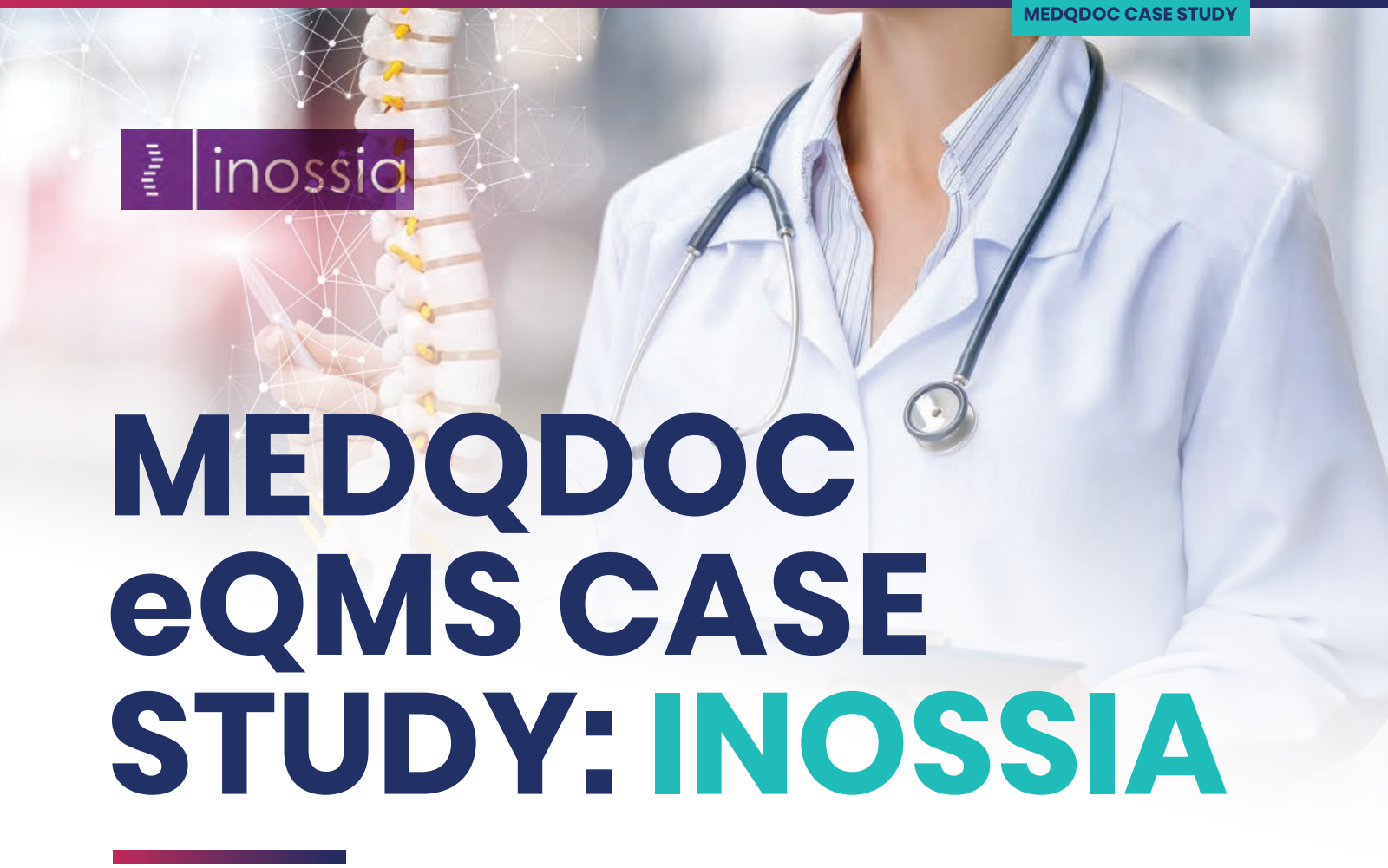


MEDQDOC eQMS CASE STUDY: INOSSIA

Project overview

When medical device company Inossia wanted to achieve ISO 13485 certification and QSR compliance, they implemented MedQdoc to support this goal.

By replacing their previous paper-based system with the new eQMS, they ensured their regulatory compliance while also significantly improving processes across the business.

Read on to discover how MedQdoc helped Inossia achieve a successful ISO13485 certification audit result with zero nonconformities in just 6 months.

Inossia background

Founded in 2013, Inossia has invented a softener to better treat osteoporotic fractures in the spine.

The softener is added to bone cement to avoid unnecessary, painful fractures. Their main focus is on improving fracture treatment for osteoporotic patients and to support active aging.

As part of the process of bringing their new product to the medical device market, Inossia implemented MedQdoc to ensure their regulatory compliance.

"We didn't want a large, overly-complex system that would force us to work in a restrictive way, so MedQdoc has been exactly what we needed and works with us rather than against us."

Malin Nilsson, CEO

Choosing an appropriate eQMS

With Inossia's product in an early realisation stage, achieving ISO 13485 certification formed an important step towards preparing to launch the bone cement softener onto the market.

With the company also targeting the American market, Inossia additionally needed to comply with FDA 21 CFR Part 820, also known as the Quality System Regulation (QSR), which is the equivalent regulatory requirement for medical devices in the USA.

Implementing a robust electronic quality management system (eQMS) was therefore a key part of this process.

When choosing an eQMS, Inossia had three key criteria:

Size and scalability

They wanted a system that would work for their company size but could also be expanded to suit changing requirements and users. Alternative systems are often unsuitable for use at the smaller scale required for start-up businesses such as Inossia, whereas MedQdoc works for companies of all sizes, providing the ideal, futureproof solution.

Flexibility

Inossia didn't want a system which was too restrictive, so finding a flexible system to suit the business was vital. It was important to be able to personalise and configure the system to suit their specific requirements, so MedQdoc was the perfect option to create a system tailored to Inossia's business.

Easy to use

The Inossia team wanted a clear, intuitive eQMS which was easy to learn and use, to ensure it would make their lives easier and suit the way they work. MedQdoc's straightforward interface makes it simple to navigate and find documentation quickly, and means users can update and edit information at the click of a button.

Moving from paper-based documentation

Inossia were initially using paper-based records and documents and had to sift through binders of paperwork to find the documentation they needed.

The administration work with hard copy paperwork and hand-signed records had become a burden to the business, and it was taking valuable time to update documents, sign off changes and locate documentation when it was needed.

The complexity of their product and the challenges of conforming with the Medical Device Regulations meant that Inossia needed a system that could significantly help them with their daily workload and improve their business operations, as well as supporting them to meet the quality and regulatory requirements.

They engaged the services of a medical device consultancy that recommended MedQdoc as a more efficient alternative to their paper-based system.

The MedQdoc team provided training and support to ensure the process of transferring the paper-based documentation across into the new eQMS ran very smoothly.

Inossia were then able to build on their existing documentation using MedQdoc's range of helpful templates, which saved them a significant amount of time. Using these, the system was expanded further to create a comprehensive, personalised quality management system encompassing everything Inossia required to achieve ISO 13485 certification and QSR compliance.

Quickly adapting to the new eQMS

MedQdoc proved to be quicker and more user-friendly than other systems Inossia's team had used previously. For some, it was their first user experience of an eQMS, and they found it clearly structured, logical, and very simple to navigate. This made it easy for the business to adopt the regulatory requirements and allowed Inossia to experience the overall benefits of having an effective quality management system.

Inossia quickly noted the wide-reaching benefits of MedQdoc and began to use it comprehensively across the business. They found the MedQdoc documentation templates particularly useful for helping them to meet the regulatory requirements. In particular, the technical documentation templates made a significant positive impact in enabling them to meet the MDR requirements.

MedQdoc now drives Inossia's business as their primary software system, with their full technical documentation, procedures and records to meet the requirements of QSR and ISO 13485 now stored in a smart, accessible way.

While other businesses keep their research in separate systems or only retain certain information, Inossia uses MedQdoc to record and store everything documented by the business, for full traceability and easy access to their important documents.

In addition to their main ISO 13485 and QSR documentation, they use MedQdoc for managing other information relevant to the business, such as lab notes which are now recorded using Inossia's own predefined forms in MedQdoc and input straight into the system.

"After using the system a lot and seeing the benefits and simplicity, we decided to put everything in MedQdoc to keep it organised. We now keep all our documentation in there so we know we can easily access it again at any time."

Alejandro López Landa,
Product Realization Manager

Significantly improving document control

Inossia are finding MedQdoc's document control and case management features particularly useful for increasing their productivity and efficiency.

With document comments created and stored in the system, the team can easily see any notes left by colleagues, and make the required amendments within MedQdoc. With no need to check documents in and out, and no need to download and work with documents outside the system, Inossia are finding that the process is much faster and easier to manage while providing a clear audit trail.

With staff in different locations, getting documents reviewed and signed often previously involved paper copies being driven between cities. MedQdoc has significantly changed this process, saving time and money and making everything much easier to manage through the system.

Inossia are also finding MedQdoc's case management features exceptionally useful for increasing their productivity and efficiency, and it has had a very positive impact on their business.

Five key benefits for Inossia

Inossia found five key benefits of implementing MedQdoc:

The **ready-to-use templates**, configured for the medical device industry, have provided significant value to Inossia's team.

MedQdoc has made it **easier to find and control documentation** by moving Inossia away from the old paper-based system.

The overall **time savings for the business** have allowed the team to focus on other projects and tasks to drive the company forward.

By having all **documentation easily accessible**, communication and processes have been improved across the team, reducing logistical challenges.

Regulatory compliance has been achieved, with a strong system and processes now in place to support this long term.

New innovations and learnings

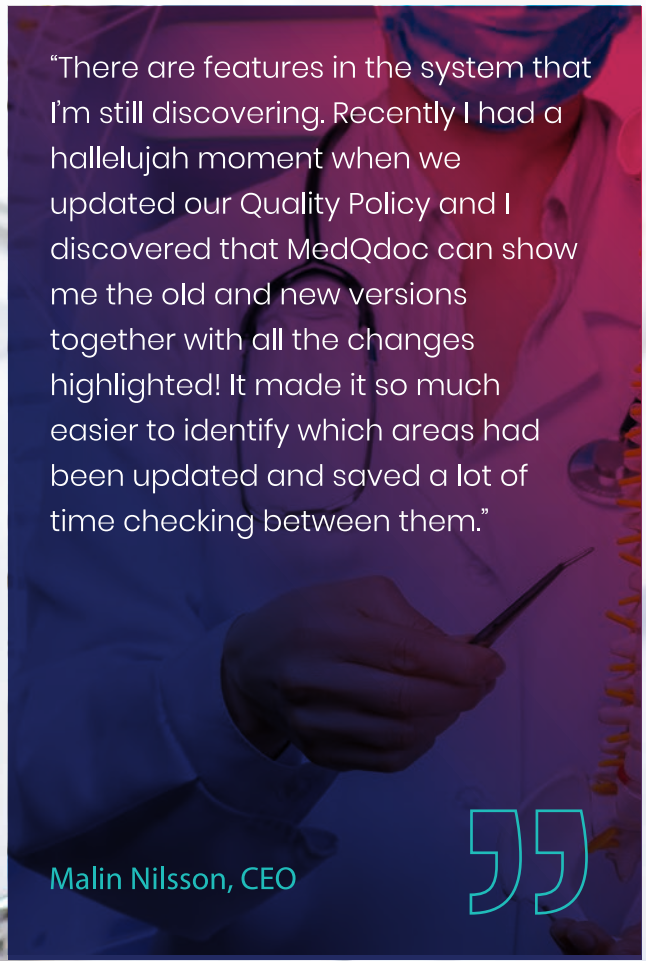
Inossia are constantly finding new features in MedQdoc which are improving their ways of working.

They are also benefitting from the extensive expertise of MedQdoc's team, who they are able to contact whenever they have questions about the system or the medical device standards and regulations in general.

First class training and support

Inossia have been very pleased with the training and support provided for implementing and using MedQdoc to achieve the requirements of ISO 13485 and QSR.

The eQMS provider AM System, which MedQdoc is based on, have also impressed Inossia with excellent, quick customer support when needed.



"There are features in the system that I'm still discovering. Recently I had a hallelujah moment when we updated our Quality Policy and I discovered that MedQdoc can show me the old and new versions together with all the changes highlighted! It made it so much easier to identify which areas had been updated and saved a lot of time checking between them."

Malin Nilsson, CEO

"MedQdoc has provided us with great support. One of the top reasons we chose the system was because it was created by regulatory experts, which seems to be unique in the market. We asked a lot of questions, not just about the system but also about the certification process, and they were always happy to explain about the regulations and requirements. They have been able to advise us on setting up our processes in a compliant way, as well as how to use MedQdoc for it, and we've always received proper, evaluated answers tailored to our business."

Malin Nilsson, CEO

ISO 13485 audit success

Inossia's ISO 13485 certification journey was an impressive achievement and was completed in just 6 months.

To help prepare Inossia for their ISO 13485 audit, the MedQdoc team helped scope out the project to establish a realistic timeline to suit the company's goals and ambitions. They then supported Inossia with weekly meetings to help keep them on track with the project's timeline.

The 6-month time period from the start of the project to Inossia's successful audit was exactly on target and was made possible by the dedication of both the Inossia and MedQdoc teams, as well as the system itself.

When the day of the final audit arrived, it was a very well-prepared team that met with the auditor. The auditor was particularly impressed with the intuitive process maps, case management features and how quickly they could find and access documents due to MedQdoc.

The auditor also highlighted Inossia's commitment to fully implement a quality management system and optimising it so well for their business.

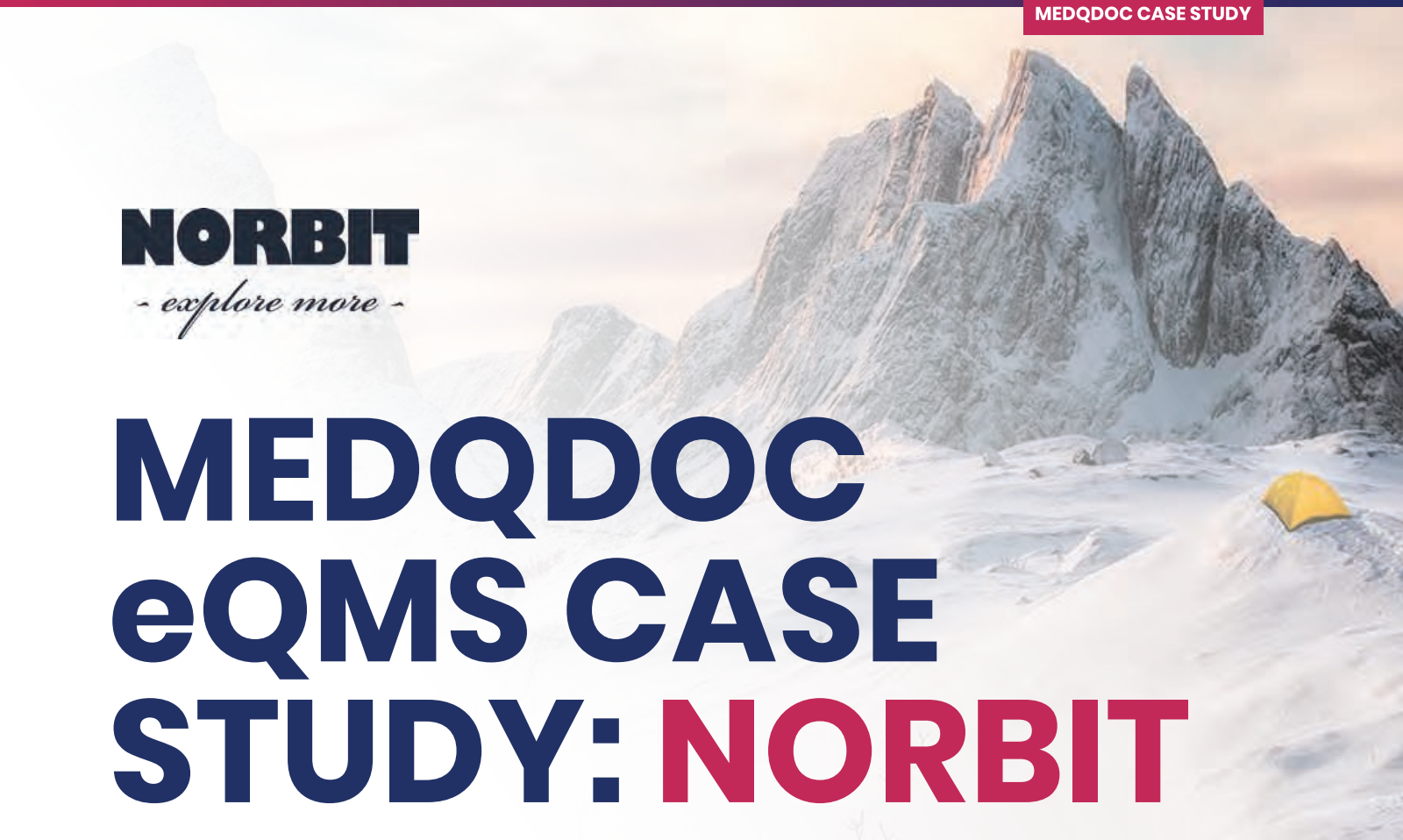
Inossia completed their final ISO 13485 audit with zero nonconformities, which is an outstanding result.

Key project stats

5 multi-tasking users

6 months from implementation to successful ISO 13485 audit

0 nonconformities



NORBIT
- explore more -

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

medqdoc.com/eqms-case-study-norbit/

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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 that 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."

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."

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

aidee.io

HOW MEDQDOC HELPED MEDTECH START-UP AIDEE ACHIEVE ISO 13485 CERTIFICATION WITHIN 12 MONTHS

Project overview

Executive summary – how Aidee achieved ISO 13485 certification

Aidee Health are a MedTech start-up that needed an eQMS to help them navigate the regulatory requirements of the industry to bring their innovative blood pressure monitor to market.

With MedQdoc, a specialist eQMS for the medical device industry, Aidee were able to establish a robust quality management system and develop the necessary documentation in a fraction of the time without starting from scratch, leading to ISO 13485 certification being awarded within 12 months of implementing MedQdoc.

> MedQdoc gave us the perfect head start as a business with relatively little experience in the MedTech industry. The eQMS was simple to use and it was packed full of practical guidance to help us gather and produce the necessary documents needed to demonstrate compliance. We would not have achieved our goal of ISO 13485 certification so quickly if it weren't for MedQdoc guiding us every step of the way.
>
> Susanne Ludvigsen,
> CEO, Aidee Health

medQdoc

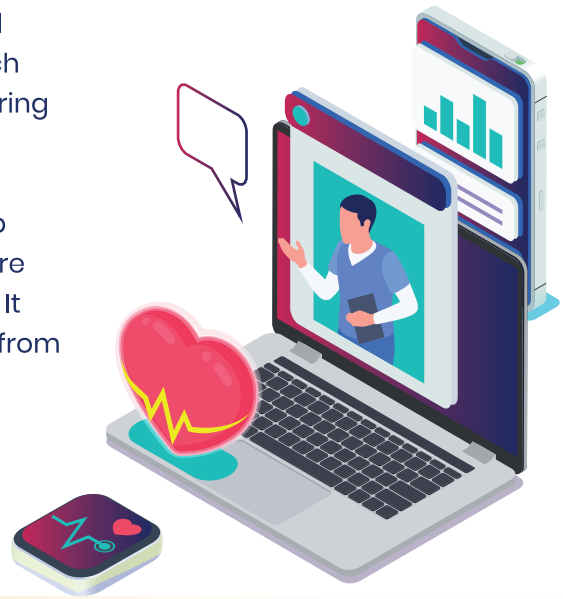
Who are Aidee?

aidee.io

Aidee Health AS are a Norwegian-based start-up developing cutting-edge blood pressure monitoring technology to combat hypertension more effectively.

The innovative solution moves away from the traditional inflated cuff method for measuring blood pressure, which can induce stress on the body during the process and bring about measurement inaccuracies.

Aidee's innovative monitor is a comfortable chest strap that provides continuous, round-the-clock blood pressure monitoring without the discomfort of a constricting cuff. It feeds electrical (ECG) and optical (PPG) measurements from the chest strap to a complex algorithm that accurately calculates blood pressure, which is displayed alongside other monitored parameters within a mobile app.



"We did not expect the audit process to go so smoothly and quickly, but MedQdoc was so logically structured and easy to navigate that anything the auditor asked for, we could produce with ease without any running around. We are green to the industry, so it is a real achievement to come out of the audit with only 3 minor and easily resolvable non-conformities. Using MedQdoc's framework gives me confidence that we will always be audit-ready."

Espen Westgaard,
CTO, Aidee Health

How Aidee benefitted from using MedQdoc

Using MedQDoc, Aidee were able to:

+ **Understand and satisfy the regulations more quickly and easily by using the intuitive, ready-to-use and customisable templates.**

+ **Ensure nothing slipped through the cracks by relying on the robust document controls.**

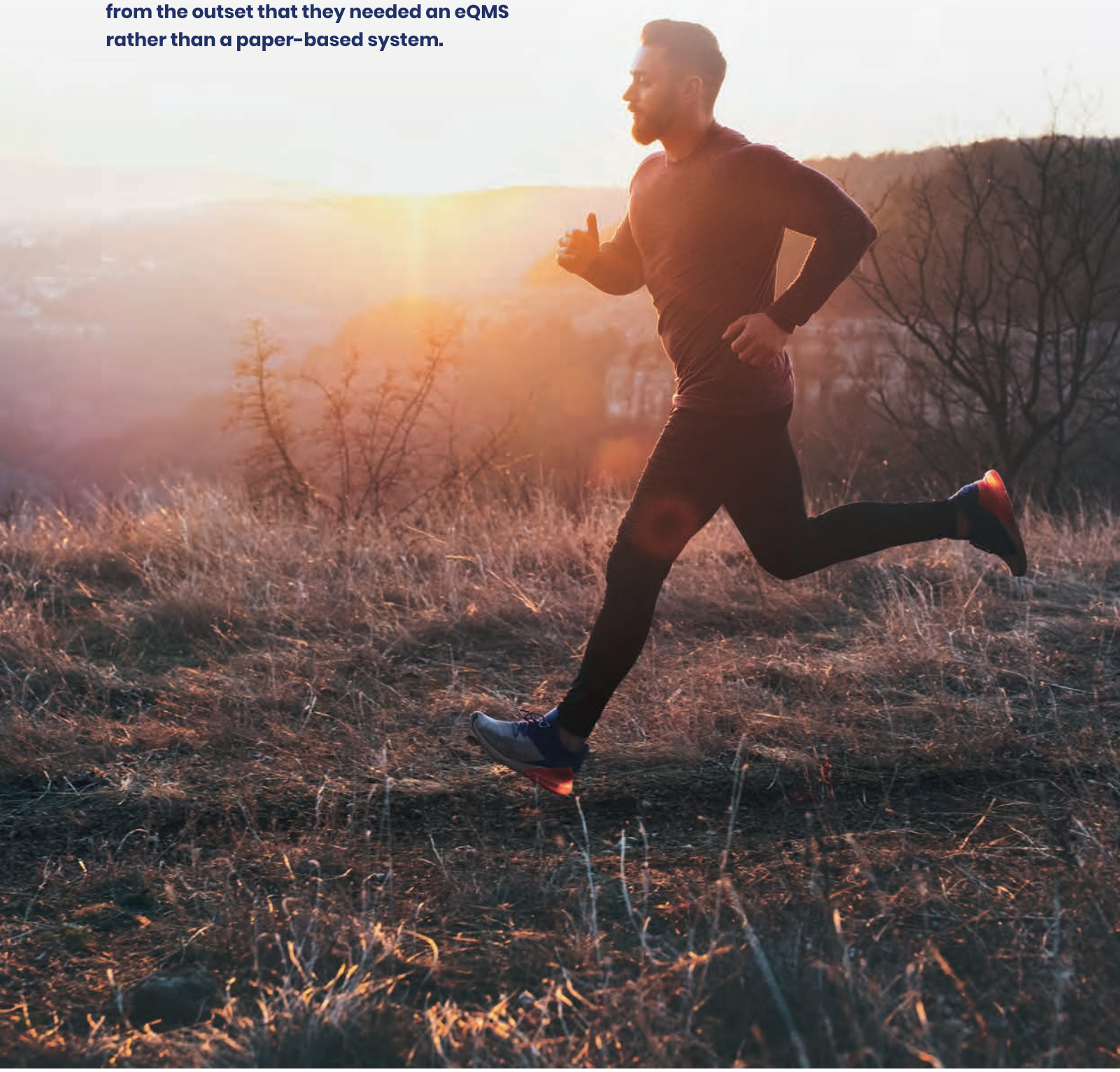
+ **Implement a compliant eQMS efficiently.**

+ **Become audit-ready quickly, which reduced potential delays in the certification process.**

+ **Embed a quality management-oriented culture within the organisation from the outset of the project.**

Not all eQMS solutions are the same

Aidee needed to become certified to launch their blood pressure monitor on the market. Their first step was to demonstrate they had a quality management system that facilitated ISO 13485 compliance. And being in the digital solutions world, Aidee knew from the outset that they needed an eQMS rather than a paper-based system.



Aidee were using a competitor's eQMS at the beginning of their product development journey, being initially attracted to their large international presence and clever design for automatic design control and risk management.

Aidee were looking for templates to help them kick-start the development of their quality procedures and documentation but found that these were an add-on module that came at additional cost. The templates were also based heavily on US regulations with little focus on ISO 13485 certification — required to achieve CE marking for launch in the EU market.

Aidee needed an eQMS that aligned better with their processes and objectives and so got in touch with the MedQdoc team after learning about the eQMS.

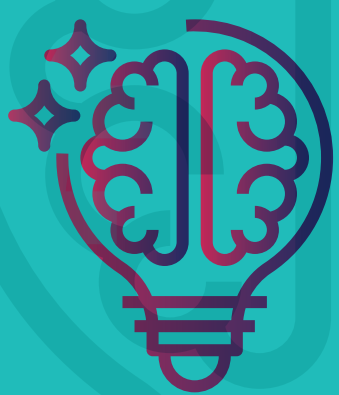
Discovering the value of MedQdoc

As a company in its early stages in the industry, Aidee did not have existing documentation or processes to use as a reference. And with little prior experience within MedTech and its compliance requirements, Aidee needed a robust eQMS that could provide a starting point and give practical guidance on what they needed to do to demonstrate compliance.

They revisited their vendor selection process and reviewed what the requirements of their eQMS were:

+ All-in-one digital QMS with workflows and features built specifically for medical device manufacturers, to help incorporate regulatory standards into operations right from the start
+ Easy to navigate, use and understand by new entrants to the MedTech industry
+ Deliver on ISO 13485 compliance and CE marking for the Norwegian and EU markets
+ Support future expansion into wider markets and their local regulatory compliance requirements (e.g. QSR for the US)
+ Easy-to-understand templates that set out a straightforward way to create and maintain records and give practical guidance on how to demonstrate compliance
+ Extensive library of preconfigured templates that make it quick, easy and efficient to get up and running, even for start-ups
+ All-inclusive eQMS with no unexpected add-on modules and hidden costs
+ Proven and established eQMS that is trusted by other like-minded medical device quality professionals and organisations.

Aidee discovered that MedQdoc could deliver on these needs and also guide the team in a straightforward, practical and structured way towards establishing a robust and compliant quality management system.



Fast-tracking ISO 13485 compliance with MedQDoc

After transitioning to MedQdoc, Aidee's team found that it was more intuitive and informative than the previous system they used. Aidee found that unlike other templates on the market that simply copied and pasted text from the regulations, MedQdoc's templates were tailored and written by medical device quality and regulatory compliance experts and proposed practical ways of demonstrating ISO 13485 compliance at no additional cost.

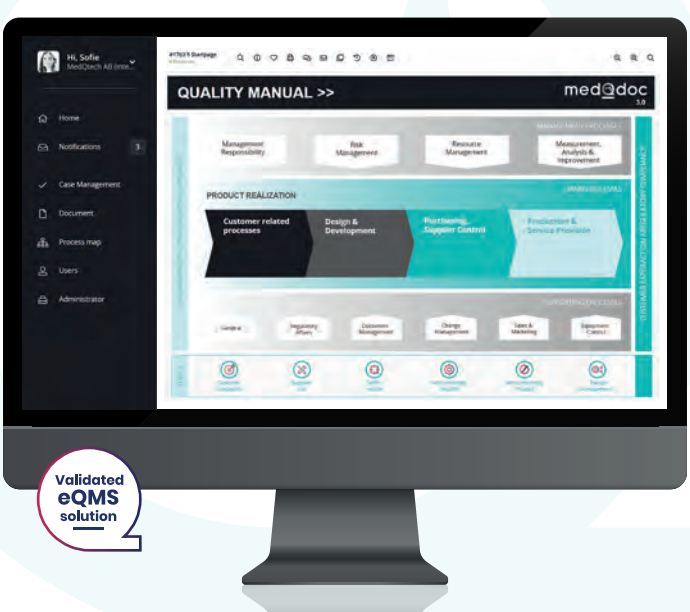
This was a big time-saver for Aidee as they were able to understand the requirements more easily without having to interpret the complex regulations and figure out how to demonstrate compliance themselves. They were also able to generate the required documentation without needing to start from scratch by using the guidance, which gave them more time to focus on other areas of the business.

In addition to MedQdoc's extensive library of templates, Aidee also found MedQdoc's document management system invaluable in improving their efficiency and driving their quality management-oriented culture throughout the organisation. With MedQdoc's document management system, Aidee were able to edit documents without checking them in and out and work directly in the software without needing to download the documents separately onto local drives.

Aidee were impressed by how easy it was to manage the audit-ready system and how it reduced the time spent on admin.

By embedding MedQdoc into their processes since project conception, Aidee became confident that their quality processes and documents could stand against the scrutiny of rigorous auditors without having to worry about retrofitting any documentation or discovering issues at a later stage. This was quickly proven to be the case during their successful audit with BSI for ISO 13485 certification.

MedQDoc now drives Aidee as their primary software system to store all their documentation, procedures and records. They have used MedQdoc to carry out supplier audits and have now completed their manufacturer selection process. Moving forward, Aidee are continuing to use MedQdoc to produce all the technical documents needed as part of their product development.



Templates, technical documentation, validation documents – all included

MedQdoc QMS Templates –
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Learn about the huge variety of QMS templates available through MedQdoc, to help you on your ISO 13485 and QSR journey.

Download at: **medqdoc.com/eqms-tools/**

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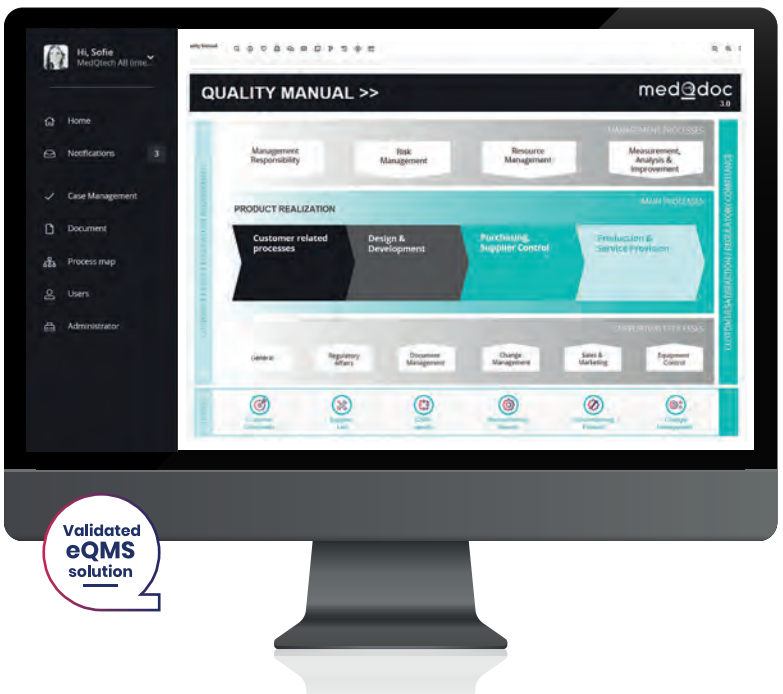

- Direct link to the quality manual
- Overview of process interactions and segmenting processes into sections for clarity
- Logical left to right flow process – with clear input and output
- Intuitive and easy for all department to quickly find their processes and documents of interest
- Direct links to your most important workflows – adaptable to your business needs.

"Can I have a list of all QMS documents and which paragraph in ISO13485 they are linked to?" No problem! And you can also instantly see what paragraphs in QSR and MDR/IVDR they are connected to.

Auditors love MedQdoc

A bold statement! But one we believe in. When MedQdoc is involved with an audit we get a lot of positive feedback. Why? From our intelligent query builder that creates perfects lists of everything from a products DHF or DMR to all SOPs within a specific area or part of the regulation to the logical format of the startpage. Plus the interlinking documents that follow process maps effectively.

MedQdoc ensures that not only everything is in place, it is also easy to find exactly what you need. Both elements are so important.

medqdoc

ABOUT MEDQDOC

MedQdoc is a software solution 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.

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