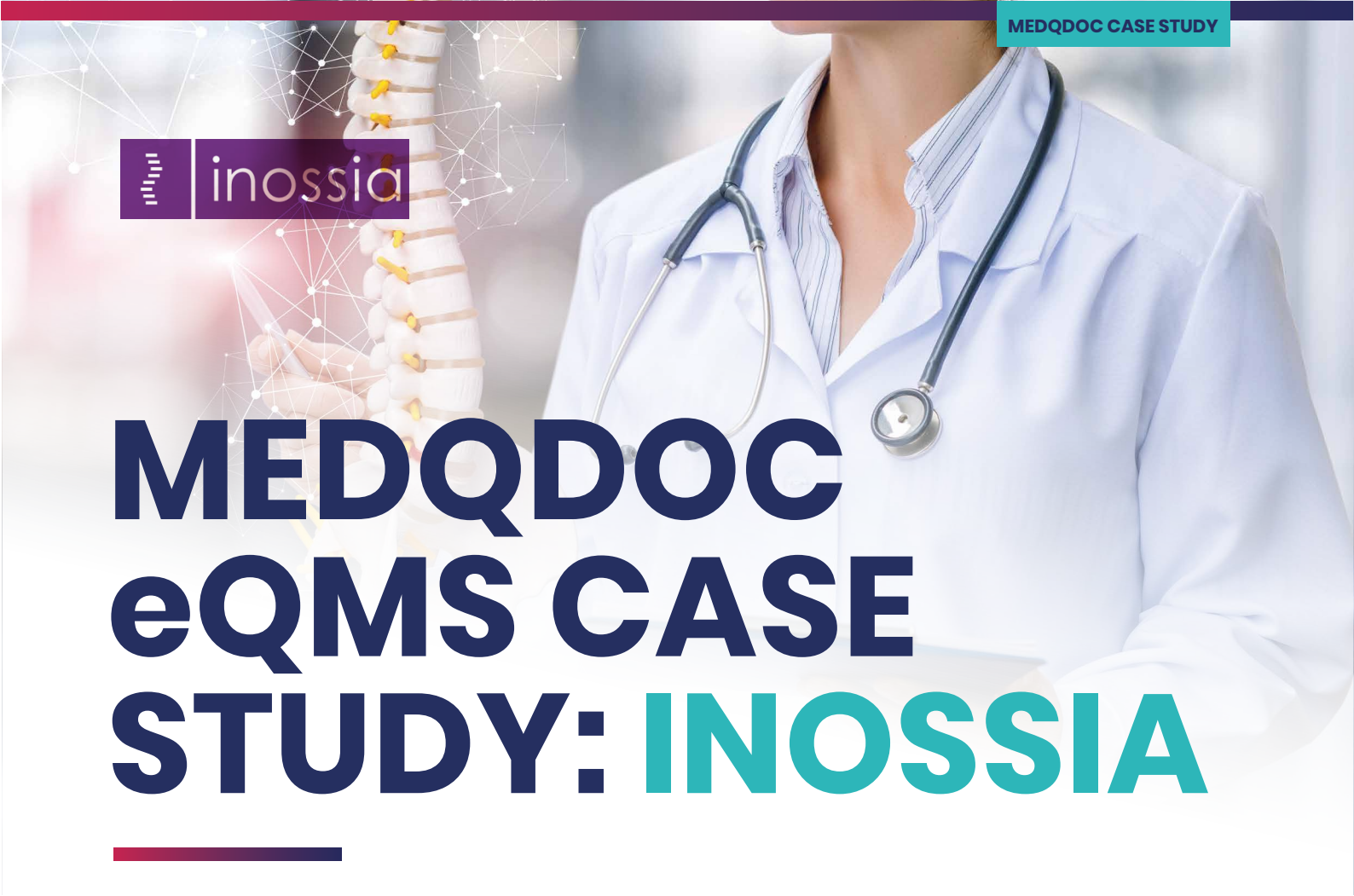


MEDQDOC eQMS CASE STUDY: INOSSIA

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.

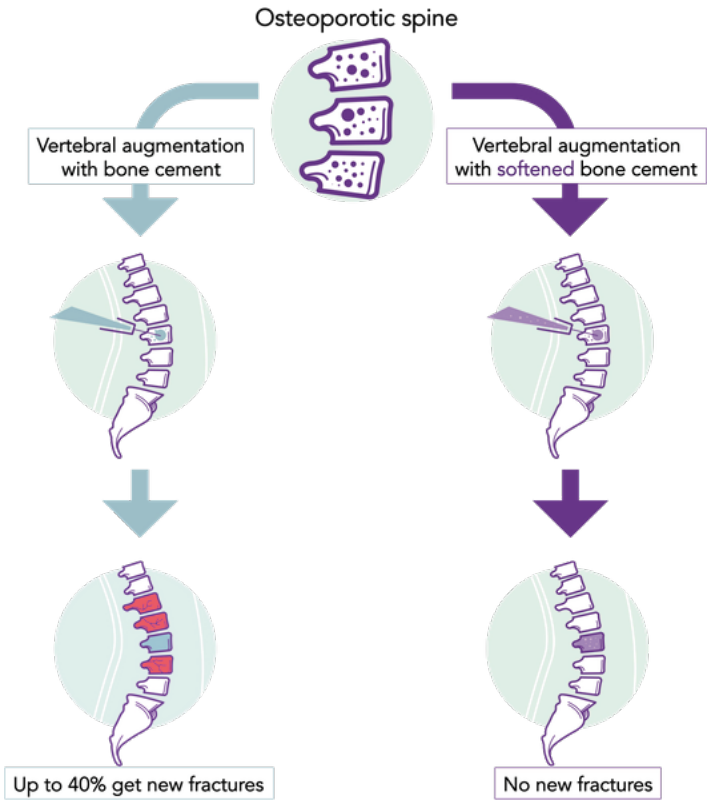
Read on to discover how MedQdoc helped Inossia achieve a successful ISO13485 certification audit result with zero nonconformities in just 6 months.

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 which 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.

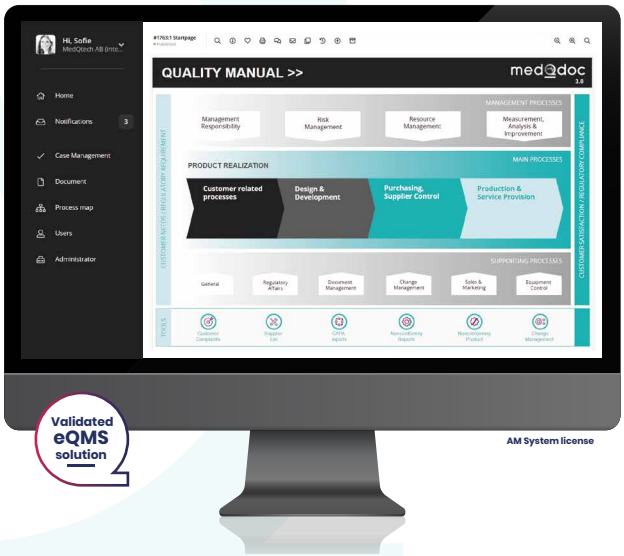
They engaged the services of a medical device consultancy who recommended MedQdoc as a more efficient alternative to their paper-based system.

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.

Paper based

eQMS



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 use 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

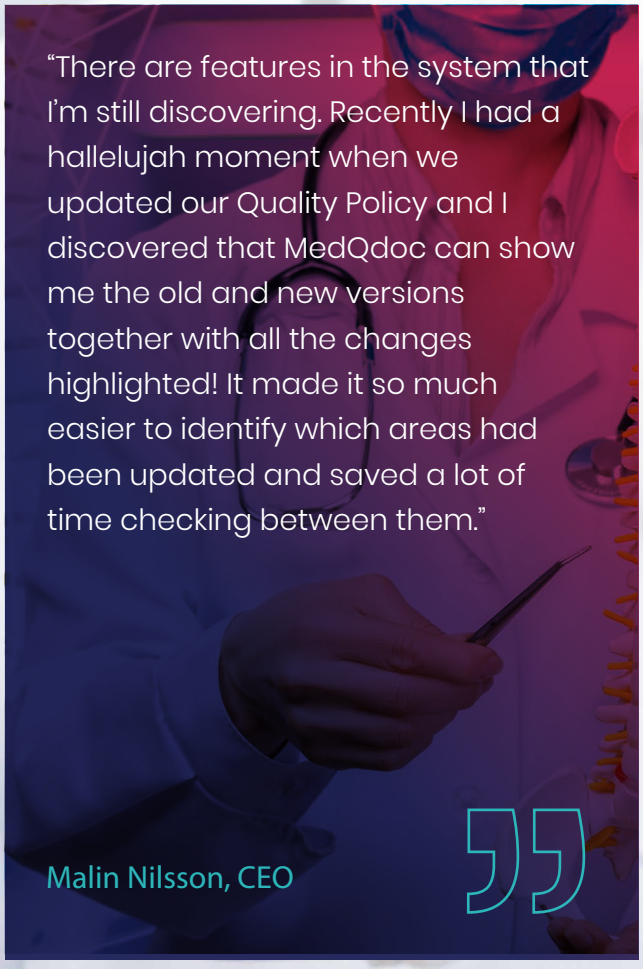
Inossia are constantly finding new features in MedQdoc which are improving their ways of working.

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

ABOUT MEDQDOC

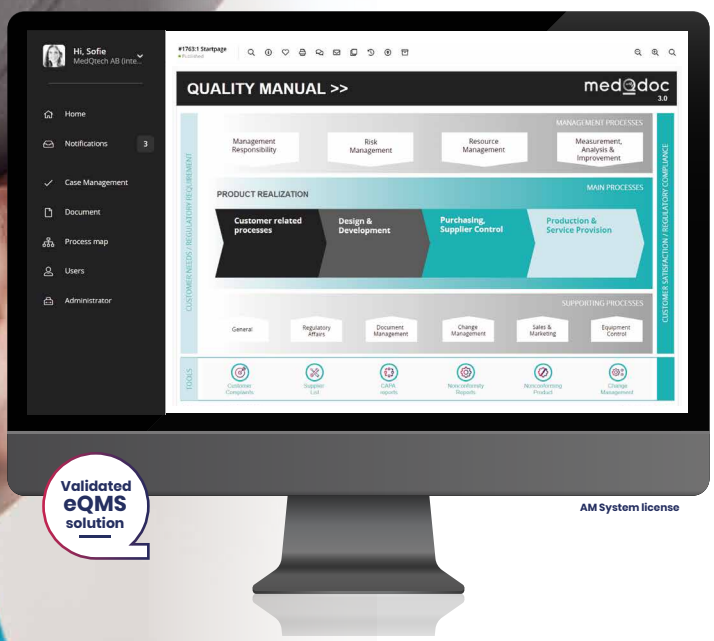
MedQdoc is an electronic quality management system (eQMS) for the medical device industry. Created by medical device quality and compliance experts specifically for the medical device industry, MedQdoc comes ready to use with over 130 pre-defined templates. The eQMS software allows you to accelerate 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

medQdoc



Validated eQMS solution

AM System license