

Digitalizing a Quality Management System Rolling Out the MasterControl eQMS

A global leader specializes in designing medical devices for orthopedic use with a headcount of over 400 staff users expanding operations in domestic and global markets. In order to develop on the international stage and bring their products to market quickly, companies operating in the medical devices sector need to keep up with changing regulations. With the aim of turning red tape into a blue ribbon, client went digital with its QMS.

The company's decision has been rewarded with better quality management and smoother compliance with key aspect of **Quality**, **Regulations**, and **Market Access**



Quality Focus: Improving the QMS by introducing tailored solutions

Regulatory Strategy: Conforming with regulations and standards, including MDR, ISO 13485:2016, and FDA CFR 21 Part 820. Being awarded international certifications such as MDSAP

Development: Supporting Amplitude with its organic growth and development in the international market.

Solution: Mastercontrol as a Tool

MasterControl's software solution is scalable, customizable, and tailored to medical device companies, giving client the benefit of straight forward rollout at its primary location and across its international locations. Modules implemented as part of core solution are **Quality, Document, Training, Change, CAPA, SCAR, Supplier, Audit**

Benefits: Figures since MasterControl was put in place



Improvements in Quality Management:

<p>Streamlining Processes: Management of documented operations procedures. Time saved in getting information during audits and inspections.</p>	<p>Traceability: Full change history for data and documents throughout their lifecycle.</p>	<p>Data security: Access management through electronic authentication and data hosted on certified servers.</p>	<p>Visibility: Real-time indicators and reports allowing decisions to be made based on accurate data and improving risk management.</p>
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Benefits Management:

- Reports and automatic notifications improve response times,
- Real-time overview of indicators, results, and quality incidents improves allow for a better, data-driven decision-making process.
- Electronic storage improves portability and makes work between departments and branches smoother.

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