Successful QMS digitalisation

Examples from real medtech cases, **plus** my best tips and tricks

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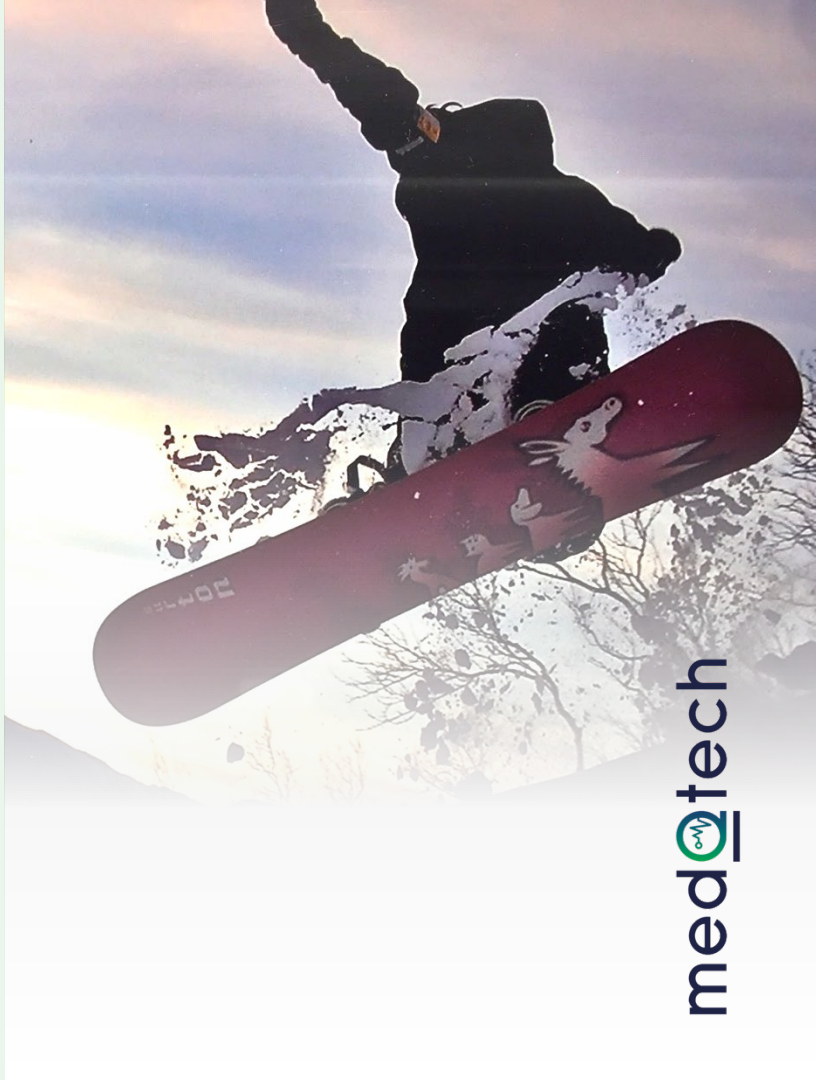
About me:

- **18 years** of QA/RA experience in Pharmaceutical and Medical Device Industry
- **Senior** Quality and Regulatory Advisor in Medtech
- **Helping** MedQtech companies establish a compliant QMS and implement eQMS solutions
- **Acting** as QA/RA Manager, Management Representative and PRRC for small Medtech companies



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About MedQtech and MedQdoc

MedQtech is a consultancy firm focused on the Medical Device Industry

We are regulatory compliance experts and quality management system specialists

MedQdoc is an eQMS solution developed by MedQtech

Sprung from the desire to enable Medtech businesses to accelerate compliance and improve efficiency and innovation

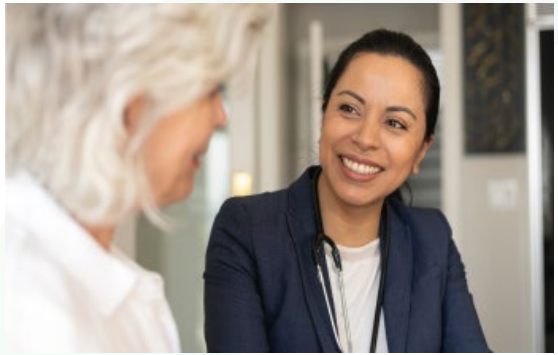
Story 1 –

Medical device software company

Start-up

Background

- Completely new to the Medical Device regulatory landscape
- Realized quickly that they needed an eQMS solution tailor-made for the Medical device Industry
- Only 12 months from start to gaining their ISO13485:2016 certificate
- Wanted a MS that eventually would be compliant with 14001 and 27001 as well



Process

- Implementation project
- Started with a thorough QMS education
- Chose an experienced QA/RA consultant to help them adapt to their unique situation
- Each process owner created the SOP for their area

Success Factors

- Engaged Management
- Sufficient time allocated
- Project leader with QA/RA knowledge

Problems along the way

- Chose an overly complicated eQMS solution to start with

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Benefits of an eQMS for this company

All processes are maintained and up-to-date (very easy within the system)

Accelerated process by using pre-prepared structure and templates

Enables a consultant PRRC to work remotely, even from another country!

Easy to adapt the QMS to a MS compliant with ISO14001 and ISO27001

Early changes such as company name, office moves and product name change are handled through an appropriate change management process, giving complete traceability and transparency

Electronic signatures, compliant and safe storage, and archiving of documents (no paper!)

Easy to navigate in an audit situation; an eQMS enables completely remote audits (during the most recent audit, the auditor was able to navigate around the system himself)

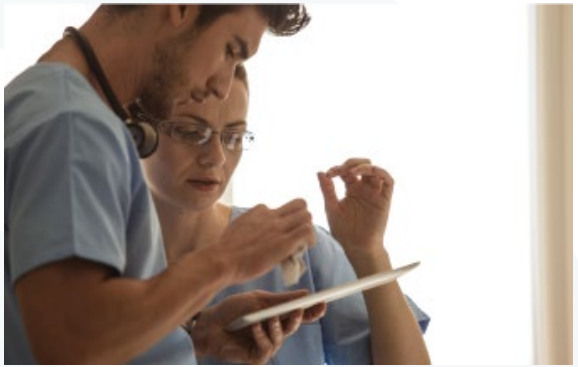
Story 2 -

Research company

Invented a critical component to a Class III Medical device

Background

- No physical office
- Limited Medical device industry experience but a QMS according to ISO13485:2016 is a requirement for a Class III MedTech company
- Documentation from development phase was all paper-based
- Signatures required driving documents around between lab, home offices and contract manufacturer



Process

- Started with a thorough gap analysis
- Implementation plan adapted according to the needs of the business
- Then comprehensive QMS education
- Appointed an experienced QA/RA consultant to help them navigate the specific requirements of their unique situation
- Each process owner created SOP for their area

Success Factors

- Engaged Management
- Sufficient time allocated
- Chose an eQMS that was intuitive and easy for everyone to use

Problems along the way

- Difficulty understanding the differences between document types

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Benefits of an eQMS for this company

Electronic signatures – no more driving around with documents!

Pre-prepared structure and templates provided a boost in the areas where gaps where identified

Remote working from conferences all over the world

All work saved in one place where it is remains accessible even if a key member of the team leaves the company

One system for everything; as a small company it made sense to use their QMS for business objectives, all meeting protocols and project management

eQMS has become part of the company culture; designed and configured with their own company colours and something they are proud to show

Achieved their required ISO13485 certificate within 6 months from implementation project start – using a completely remote audit process due to Covid-19

QUALITY MANUAL >>

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CUSTOMER NEEDS / REGULATORY REQUIREMENT

CUSTOMER SATISFACTION / REGULATORY COMPLIANCE

MANAGEMENT PROCESSES

- Management Responsibility
- Risk Management
- Resource Management
- Measurement, Analysis & Improvement

MAIN PROCESSES

PRODUCT REALIZATION

- **Customer related processes**
- **Design & Development**
- **Purchasing, Supplier Control**
- **Production & Service Provision**

SUPPORTING PROCESSES

- General
- Regulatory Affairs
- Document Management
- Change Management
- Sales & Marketing
- Validation & Equipment Control

TOOLS

- Customer Complaints
- Supplier List
- CAPA reports
- Nonconformity Reports
- Nonconforming Product
- Change Management
- Project Management

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Document no: #SOP-1752:4

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Story 3 –

Class I medical device company

Assistance needed to comply with the new requirements in MDR

Background

- No one in the organization was qualified to meet the new MDR requirements of PRRC
- Technical files according to MDD created but not kept up-to-date
- QMS not well maintained

Process

- Implementation project
- Started with thorough QMS education
- Appointed an experienced QA/RA consultant to help them adapt to their unique situation

Success Factors

- Chose an eQMS system that prevents cutting corners in important areas, and hence drives compliance
- Started with a few key processes to drive implementation of the full QMS

Problems along the way

- Busy management with little time to participate
- Unclear process ownership within the company
- Organizational changes

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Benefits of an eQMS for this company

Built a framework for an external expert to take the PRRC role remotely

Supports remote working – company is based in several locations and works with a numbers of consultants

Accelerated compliance journey facilitated by pre-prepared structure and templates

The eQMS solution they chose was intuitive and easy to understand – busy top management team can sign off on important decisions and the accompanying documents when it suits them

Full traceability of roles, responsibilities and who has participated in meetings and decisions

Requirements regarding environmental and sustainability work incorporates into the system alongside quality and safety.

Summary

Main benefits of an eQMS

- **Saves time** - less administrative work, chasing of signatures and looking for the latest version of a document
- **Enables remote working** – e.g. for companies with one foot still at university or small companies that need a part-time PRRC
- **Supports audits** - enables remote, and first and foremost smooth audits
- **A boost in your weakest areas** - using pre-prepared structure and templates
- **Enables easy maintenance and continuous improvement of your QMS**
- **Organisation-wide engagement** - increases the chance that all departments get involved in the QMS; key in achieving the business advantages that a structured QMS can provide

Summary

Possible pitfalls / warnings

- **You cannot buy an out-of-the-box QMS ready for your company –** you need to adapt any template and structure to you own specific situation
- **Set the expectations right -** an electronic system will never do the work for you, but it will enable you to be more efficient and, crucially, compliant!
- **Beware unengaged management**
- **Choosing the wrong eQMS solution**

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Summary

My best tips and tricks for transitioning to an eQMS

- **Dedicate resources for implementation**
- **If you don't have your own project manager and QA/RA expert, get help** - the ideal situation is a combination of your own dedicated resources and external help.
- **Choose the right eQMS solution for your unique situation –** intuitive and good-looking, yes, but it must provide the features you need. Don't be seduced by cool but complicated features that you don't need.
- **Make sure that top management is engaged and involved**

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Thank you.

Any Questions?

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