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PUBLIC WEBINAR

Modernizing Your QMS to Reduce Risk, Improve Quality & Drive Innovation

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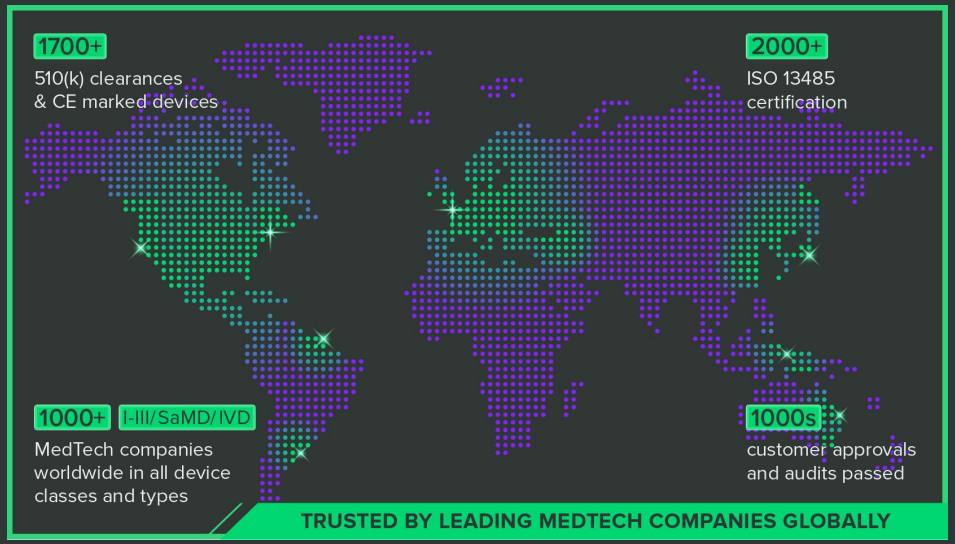
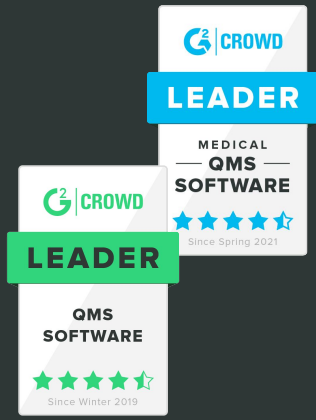
100+
years of industry experience

522k
podcast listeners

200k+
look to us for the latest in quality

#1
blog and podcast in the industry





"Best QMS I have ever used..."

"This is the easiest eQMS I have used in the 20 years I have been in the Medical Device Industry."

- Director of RA/QA

"Modern QMS Software and Outstanding Customer Service."

★★★★★

"Demystifying QMS and Regulatory Requirements"

★★★★★

"Makes your QMS Simple and Effective"

★★★★★

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Meet your Presenters:

Moderator

Etienne Nichols
Medical Device Guru

Presenter

Laura Court
Solutions Engineer

Quick Poll

Agenda

1. Problems with Present Solutions
2. Why is it so hard?
3. Need for Modernization
4. Recipe for a Modern QMS
5. Importance of Data Sharing Between Tools
6. What you should be asking your QMS vendors
7. Leading with Quality

A lot of medical device professionals start out like this...

And that is ok!

THE PROBLEM WITH MANY SOLUTIONS

Expectations vs. Reality

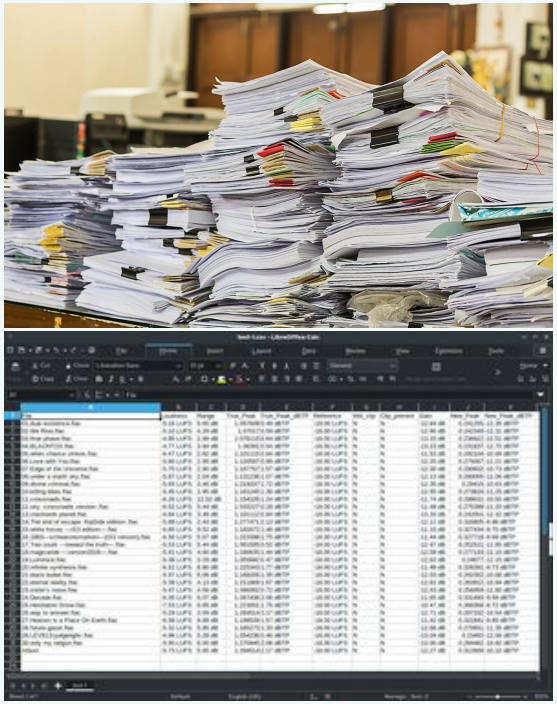
- Resources
- Cost
- Downstream effects

1 out of 3 Medtech companies are still using paper even though it correlates with lower performance.

Downfall of Choosing the Wrong Solution

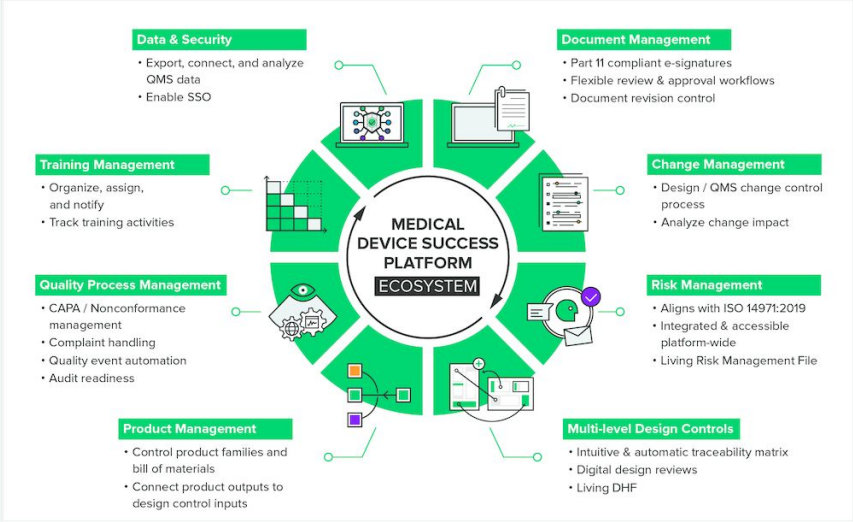
Expectations	Reality
Low Starting Cost	Expensive down the road, need to hire additional employees to keep up with manual work.
We can make it compliant and efficient even though it's lacking capabilities	Prone to mistakes, clunky processes, not flexible
Low resources needed	Lots of resources - Time, $, employees
Quick way to get started	The downstream effects of not having a compliant and traceable eQMS can directly impacts the lives of your patients.

Fear of Change



#1 Top cited challenge for MedTech companies is fear of change/resistance to change efforts

Greenlight Guru | 2023 Medical Device Industry Benchmark Study



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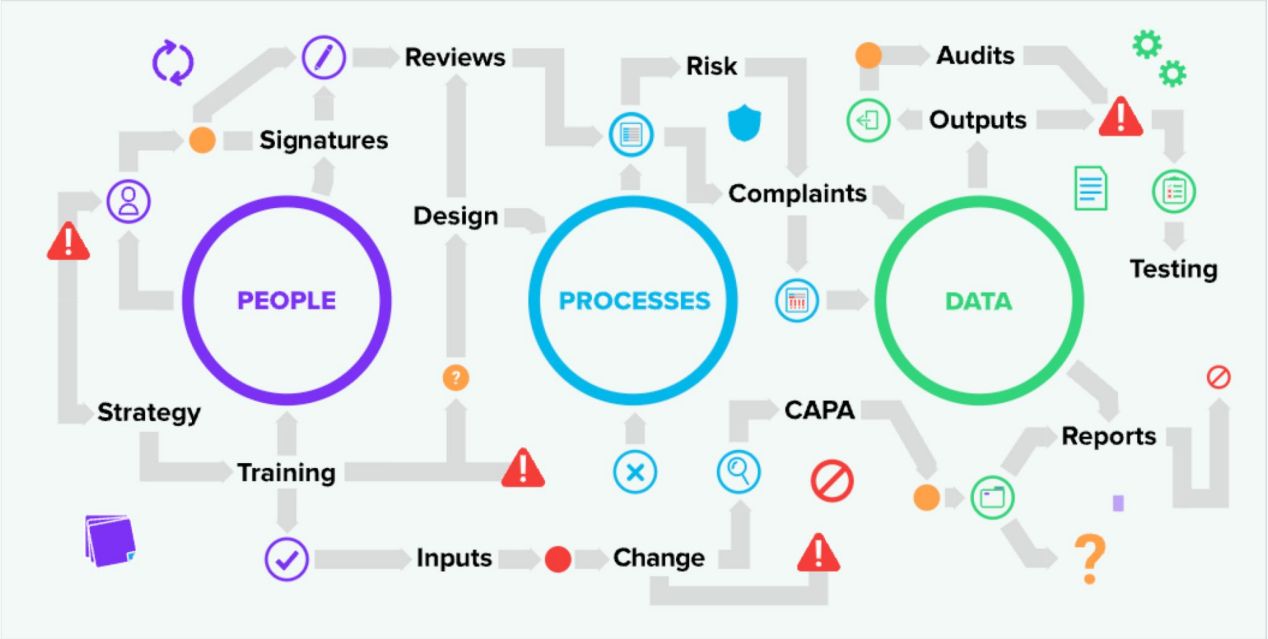
How Many Companies Do It Today:



What do you have to lose?

Insights

Visibility and traceability are lost. There's no easy way to identify gaps and downstream impacts

Capabilities

Manage product lifecycle while navigating ever-changing regulatory requirements. With the wrong tool, this can get messy.

Efficiency

Scale your business, pass audits, and reduce risk.

Work Smarter, Not Harder

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What Makes a QMS Modern?

Recipe for a Modern QMS

Validated
Automated
Built-in Compliance
Cloud-based ecosystem
Connectivity and Traceability
UX that anyone can easily learn
Data Sharing & Migration Capabilities

Cloud-Based Ecosystem

Data & Collaboration

- Enables remote work and remote access
- Data & Security Options

Efficiency

- Reduce expenses that come along with manual work
- High ROI, especially as you scale

Validated Software

- Risk-based approach to validation
- Keeps up with regulatory changes, guidance
- Saves time: Reduces burden of validation testing for you

#2 Top cited challenge for MedTech companies is the cost/effort of validating new digital tools

Greenlight Guru | 2023 Medical Device Industry Benchmark Study

Automated Software

- Automatically generates auditable reports and records
  - Ex: DHF, Quality Reports, Risk, etc.
- Supports training compliance: Automated training reminders based on due dates
- Does the tedious work for you

Built-In Compliance

Compliance for You

Leverage a software partner that is also ISO certified

ISO 9001 - for Quality Management
ISO 27001 - for data security

Compliance for MedTech

- ISO 13485
- Part 11 compliant e-signatures
- ISO 14971
- EU
- Provides industry education and training

Connectivity & Traceability

Make Compliance Easier

- Activity History & Change History
- Connects pre-market work with post-market surveillance processes

Make Your Life Easier

- Link anything across the software
- Helps scale business efficiently
- Reduced Risk

Easy User Experience

- Robust and time efficient implementation training
- Intuitive software
- Clearly see status of work
- Task-based QMS
- **Better usability = better team engagement = better performance**

Data Sharing

Data sharing across systems is critical as teams leverage more than just a QMS to manage their product lifecycle.

Integrations and ability to share data via API are the new norm and requirement for MedTech to succeed

Quick Poll

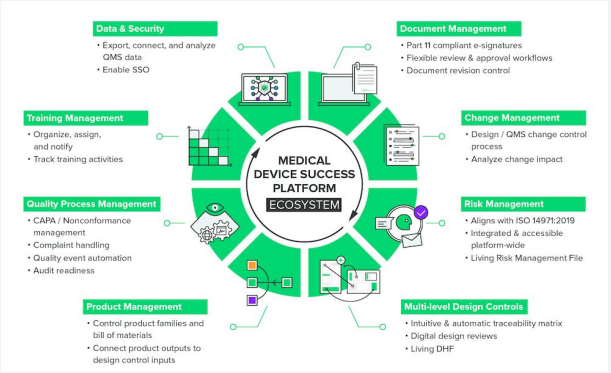
Outcomes of a Modern QMS

- Reduce Risk ✔
- Scale Efficiently ✔
- Drives Innovation ✔
- Focuses on Quality ✔
- Streamline Compliance ✔
- Stay Competitive in your Market ✔

What Else Should You Ask a QMS Vendor?

1. How they support medical device companies specifically?
2. Support both Quality & Product Development?
3. Onboarding and training programs?
4. Audit-tested Templates?
5. Support team?

Coming Soon: Extensive QMS Vendor Checklist



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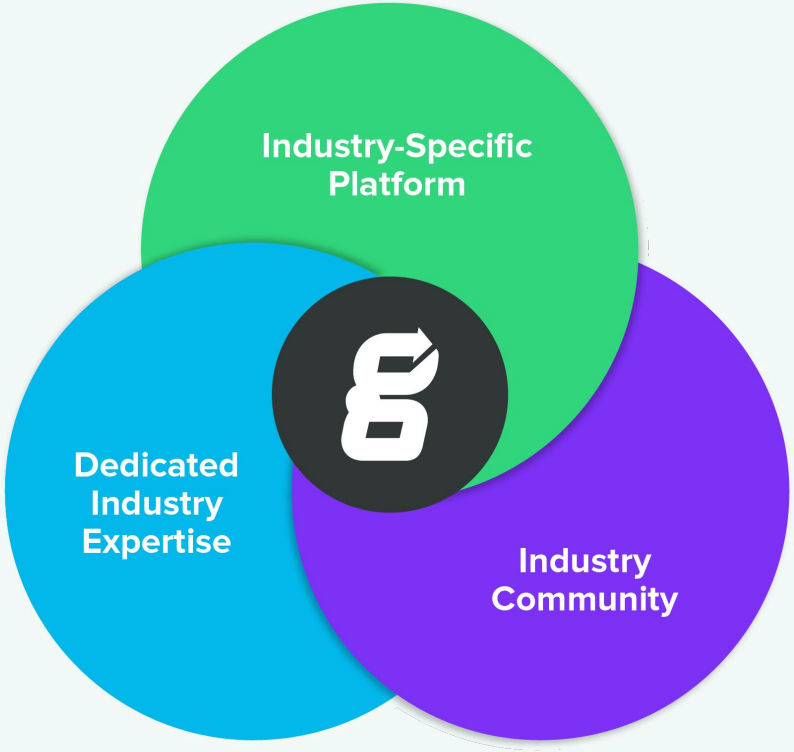
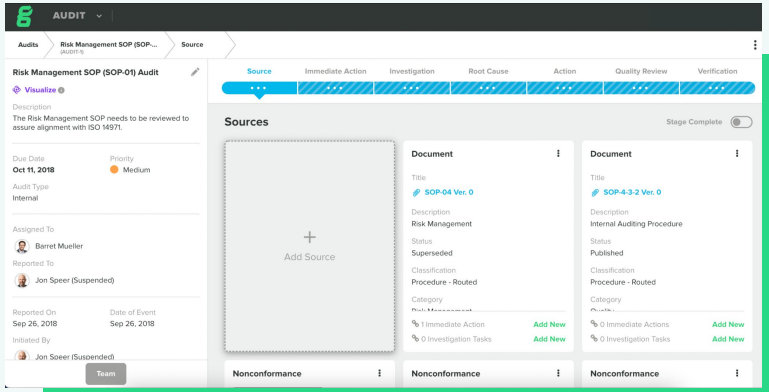
WHAT MAKES A QMS SUCCESSFUL FOR *YOU*?

Lead with Quality with a QMS that specializes in MedTech



87% of Market Leaders use purpose-built solutions to manage their QMS



MAKE THE SWITCH TO A MODERN QMS BUILT FOR MEDTECH

LEARN ABOUT GREENLIGHT GURU'S API TODAY →

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Q&A