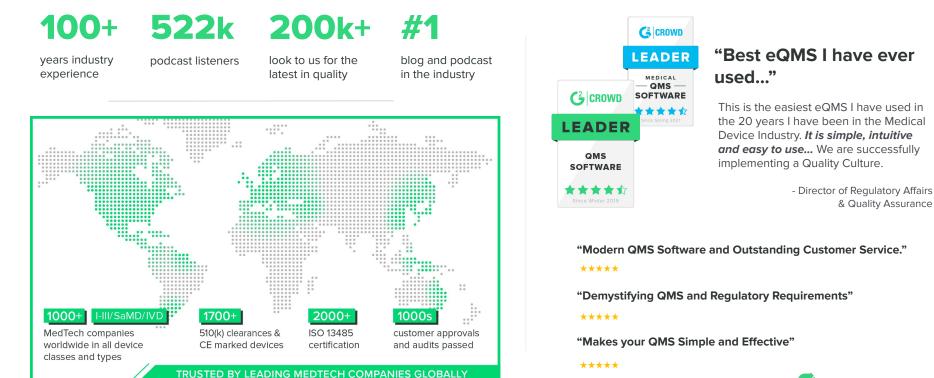


### The Ugly Truth About Paper-Based QMS Making the Switch to eQMS

### BUILT FOR MEDTECH. TRUSTED BY MEDTECH.





### **TODAY'S PRESENTERS**



#### Amanda Fedderson

Quality Assurance Manager *Monitored Therapeutics, Inc.* 



Etienne Nichols Medical Device Guru Greenlight Guru



### Savannah Sitton

Director of QA/RA Milliken



#### **Alfonso Canto**

Quality Assurance Manager Tenacore

Laura Maher Medical Device Guru Greenlight Guru



# **613** MedTech Professionals

2023 MedTech Industry Benchmark Report

# What the Industry has to say

- 1 in 3 medical device industry professionals say they are not well equipped to meet quality and product development standards in 2023
- **1 in 3** MedTech companies are still using general-purpose tools like Microsoft Word or Excel, and even using paper, for key product, quality, and clinical activities.
- **1 in 4** medical device companies say they lack competence in key compliance areas.
- Only 15% have a high level of visibility into quality problems



### THE RESULT.

MedTech companies are spending too much valuable time on administrative and mundane tasks, and that can dramatically slow down the product life cycle.

Making the work even harder to get a medical device to market and keep it on the market as well as having a major impact on company growth and competitiveness.

#### And that's why 75% of medical device companies fail.



### Most companies start with paper.



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

#### **Expectations vs. Reality**

- $\circ$  **Resources**
- Cost
- Downstream effects

## Downfalls of paper.

#### **Expectations of Paper**

Low Starting Cost

We can make it compliant and it is flexible to my needs.

Low resources needed

Quick way to get started

#### **Reality of Paper**

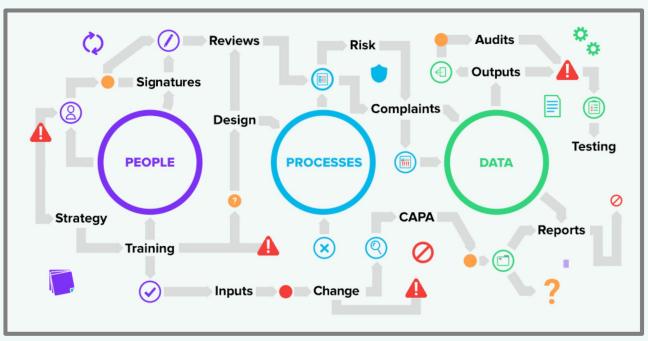
Expensive down the road, need to hire additional employees to keep up with manual work.

Prone to mistakes, clunky processes, not flexible

Lots of resources - Time, \$, employees

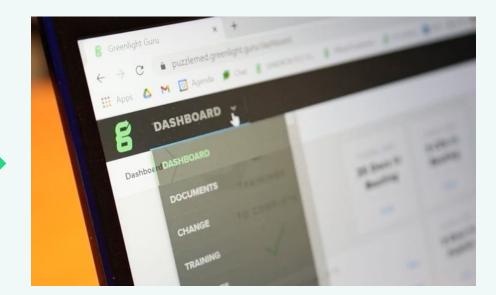
The downstream effects of not having a compliant and traceable eQMS can directly impacts the lives of your patients.

### What fills the gaps?



### Fear of change





### **Need for modernization**

#### Lack of Insights

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

#### Lack of Capabilities

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

### Work Smarter, Not Harder Scale efficiently



### What makes a QMS modern?

Recipe for a Modern QMS → eQMS

- 1. Cloud-based ecosystem
- 2. Built-in Compliance
- 3. Automated
- 4. Validated

# What makes a QMS powerful?

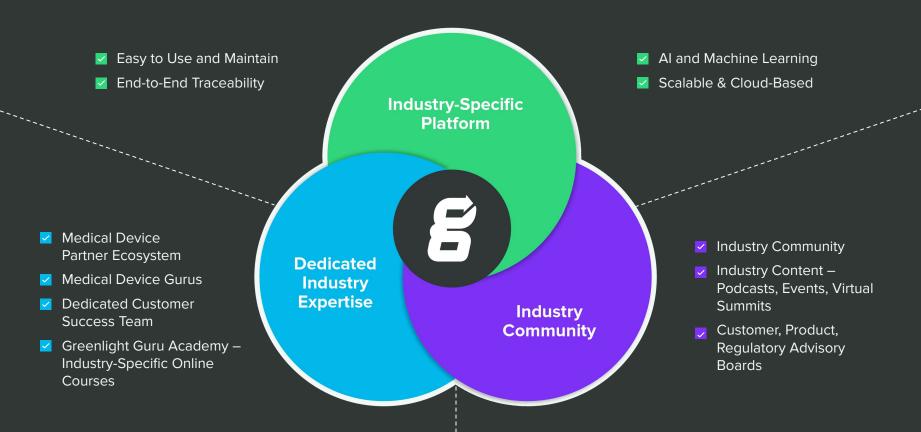
- 1. Traceability and connectivity across the eQMS
- 2. Onboarding and training programs
- 3. User friendly, easy to use
- 4. Support team
- 5. Templates
- 6. Efficient



#### 87% of Market Leaders use

purpose-built solutions to manage their QMS

### More than just software.





### Greenlight Guru's Modern QMS Built for Medical Device Companies

Audits Risk Management SOP (SOP Source					
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Jon Speer (Suspended)	·				
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#### MAKE THE SWITCH TO BECOME A MARKET-LEADING ORGANIZATION

<u>GET YOUR PERSONALIZED DEMO</u> <u>TODAY →</u>

# Panel Time!