WEBINAR

3 WAYS MEDICAL DEVICE COMPANIES WORKING REMOTE ARE LEVERAGING QMS SOFTWARE TO FOSTER INNOVATION & COLLABORATION

Jon Speer
Co-Founder & VP of QA/RA at Greenlight Guru

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ABOUT THE PRESENTER

Jon D. Speer
Co-founder and VP of QA/RA of Greenlight Guru

- **22+** years in medical device industry
- Product development engineer, quality manager, regulatory specialist
- **40+** products to market
- Expert at QMS implementations
- Dozens of ISO audits & FDA inspections

Greenlight Guru produces beautifully simple quality, design control and risk management software exclusively for medical device manufacturers.

jon.speer@greenlight.guru
+1 317 960 4280

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Topics We'll Cover Today

- Product development & QMS challenges intensified by COVID-19 & remote work
- Leveraging a single source of truth for design control & risk management activities to drive collaboration for remote team
- How a connected quality system enables demonstrating closed-loop traceability in order to assure near real-time audit readiness
- How to streamline quality & doc control processes across internal teams & external stakeholders

MANAGING PRODUCT DEVELOPMENT & QUALITY ACTIVITIES WERE ALREADY FRAGMENTED WHEN TEAMS WERE IN THE SAME LOCATION

AND NOW COVID-19 HAS ADDED THE COMPLEXITY OF MANAGING THESE ACTIVITIES ACROSS REMOTE TEAMS

50%

FDA device-surveillance inspections requiring formal action due to quality system failures

MCKINSEY&COMPANY: CAPTURING THE VALUE OF GOOD QUALITY IN MEDICAL DEVICES

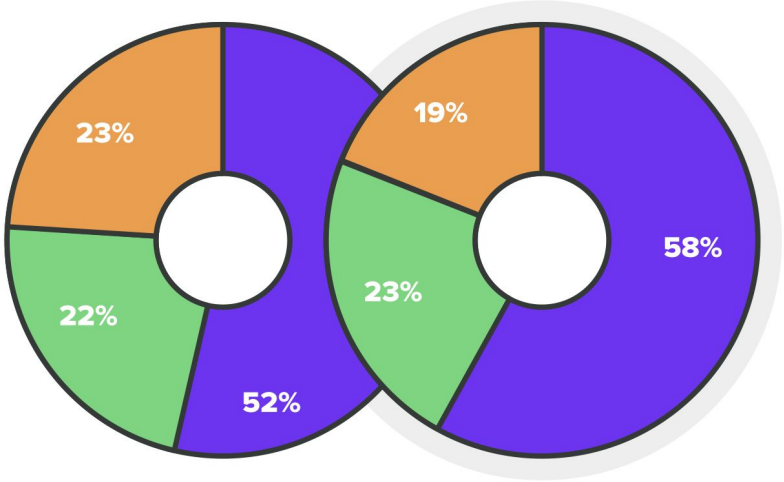
50+%

Medical device companies still using traditional paper or electronic document-based “paperless” systems to manage quality

GREENLIGHT GURU: STATE OF MEDICAL DEVICE PRODUCT DEVELOPMENT AND QUALITY MANAGEMENT 2020 REPORT

COINCIDENCE?

Design controls & risk management technology | Quality management processes technology



- **52%** We use legacy tools
- **22%** Use more specialized tools, but not best-in-class
- **23%** Use best-in-class tools

- **58%** We use legacy tools
- **23%** Use more specialized tools, but not best-in-class
- **19%** Use best-in-class tools

Source: Greenlight Guru | 2019

What percentage of product development teams consider themselves to be **highly efficient throughout the process of bringing a device to market?**

7%

Of product developments consider themselves to be highly efficient when bringing a new device to market

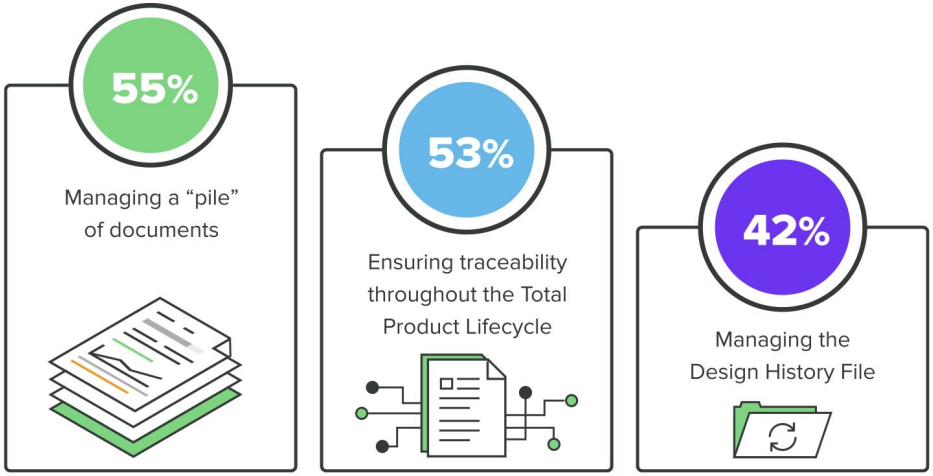
212

Hours

The average time it takes to compile a Design History File - equating to 5.5 weeks of work hours.

Top 3 Pains of Design Controls

What are the specific pain points related to documenting and managing design controls?

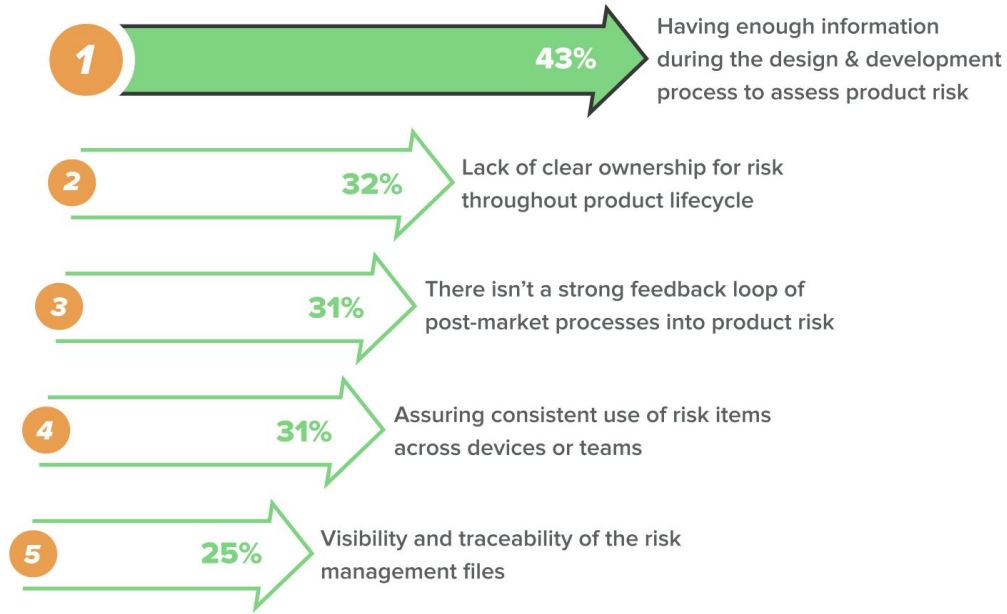


Source: Greenlight Guru | 2019

> ***One of the greatest challenges of the job is “the amount of simple tasks that take time and distract from being proactive.”***

> ***The most frustrating aspect of the job is the “level of manual operations in collecting quality data.”***

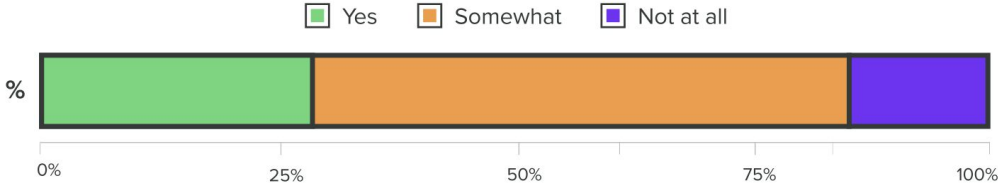
Top 5 Challenges in Managing Risk



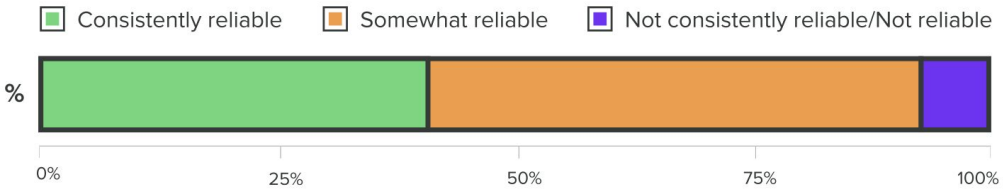
Source: Greenlight Guru | 2019

Data Access & Reliability

Is the data collected from your company's Quality System considered easily accessible in real time?

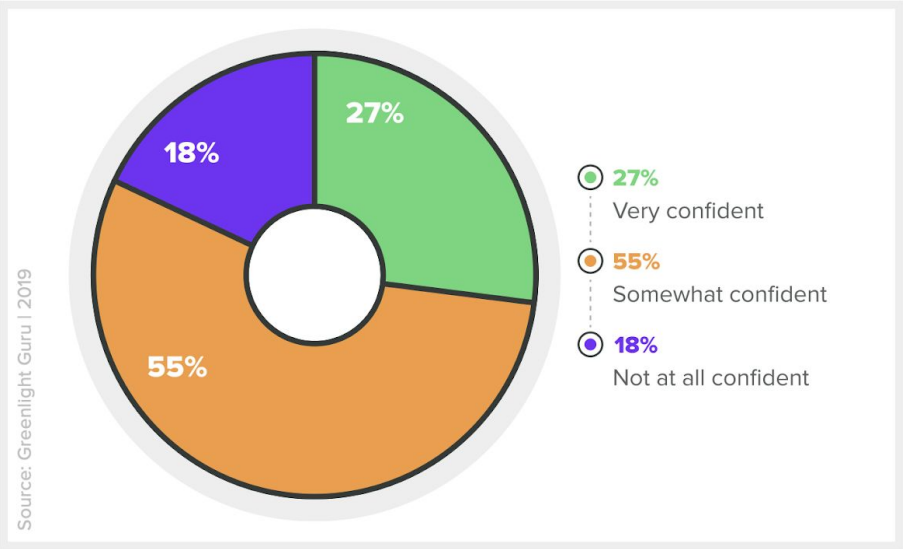


How reliable is the data being generated by the quality system?



Source: Greenlight Guru | 2019

If a government agency or notified body showed up for an unannounced audit tomorrow, how confident are you that you could demonstrate total produce lifecycle traceability?



1 IN 4
are “very confident” in demonstrating traceability in an unannounced audit

Competitive organizations are **2x as likely** to ***need less than a day to prepare for an audit***

It doesn’t have to be this way.

For product development teams tired of managing a pile of documents...

FOR NIMBLE TEAMS THAT MOVE FAST AND ARE COMMITTED TO QUALITY

PHOTONICARE is an early-stage company where their team members are always wearing multiple hats to maintain their agility. They were looking for a purpose-built QMS solution that would increase their efficiency and have the controls in place to get their device to market and achieve compliance with industry regulations.

Since adopting Greenlight Guru, they have accelerated their time to market, feel confident about their QMS for future audits and inspections, and **achieved 510(K) clearance.**

PhotoniCare

GREENLIGHT GURU HAS BEEN INSTRUMENTAL FOR US WHILE WE EFFICIENTLY NAVIGATE THE QUALITY MANAGEMENT PROCESS AND WITH DEVELOPING OUR FDA SUBMISSION.

Ryan Nolan, Co-founder & VP of Clinical Operations at Photonicare

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FOR EXPERIENCED TEAMS LOOKING TO ACCELERATE COMMERCIALIZATION

CENTESE is an early-stage company that spun out of a leading medical device incubator. After initially reverting to a paper-based quality system, they immediately began searching for a digital quality system that **would allow their small team to focus on value added activities, while also avoiding the need to hire someone to oversee a paper-based quality system.**

By implementing Greenlight Guru's MDQMS, Centese simplified the effort required to **achieve ISO 13485 certification, received 510(K) clearance for their device, and set themselves up to scale commercialization efforts by adopting a modern QMS solution.**

CENTESE

I HAVE A HIGH-DEGREE OF CONFIDENCE THAT AS CHANGES OCCUR, I WON'T HAVE TO WORRY ABOUT BEING OUT OF COMPLIANCE BECAUSE WE ARE USING GREENLIGHT GURU.

Evan Luxon, Co-founder & CEO of Centese

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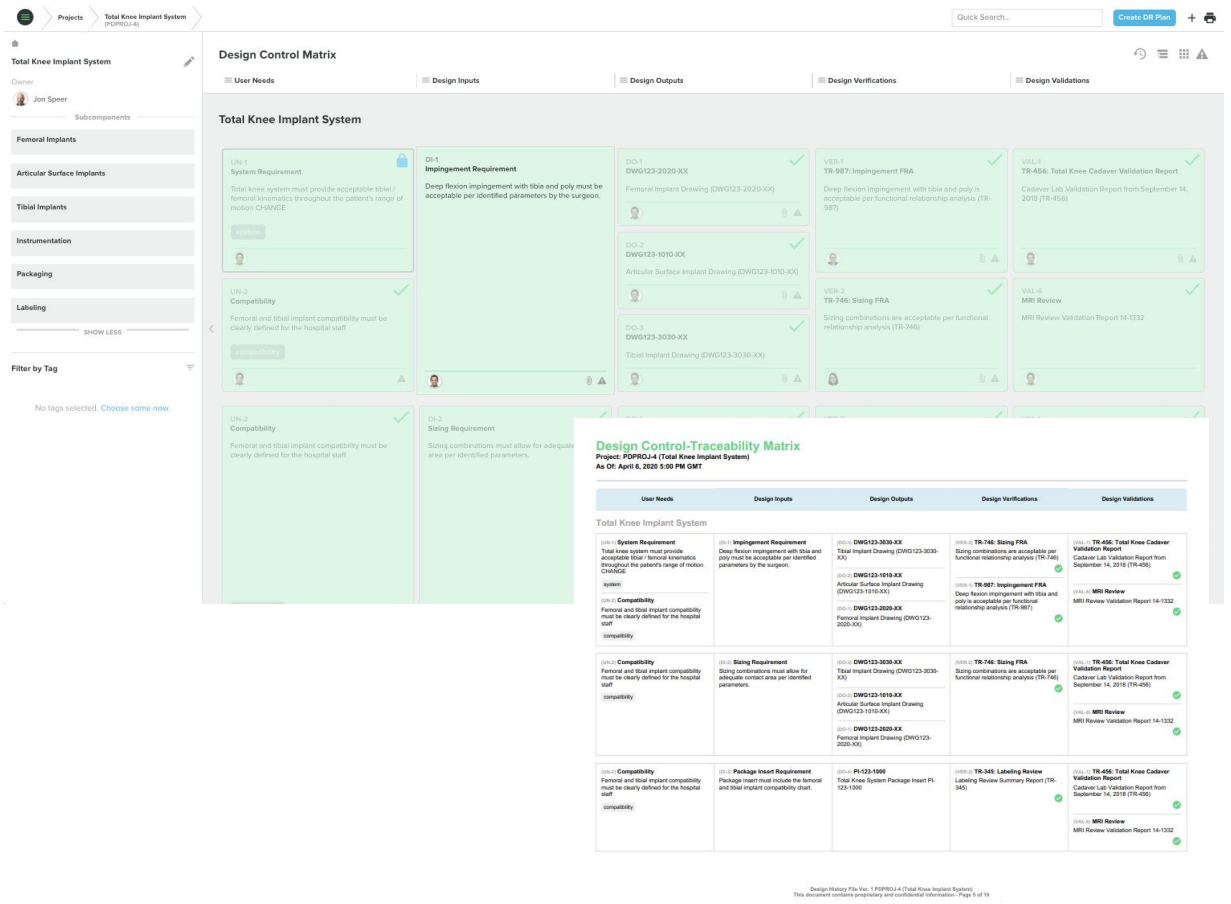
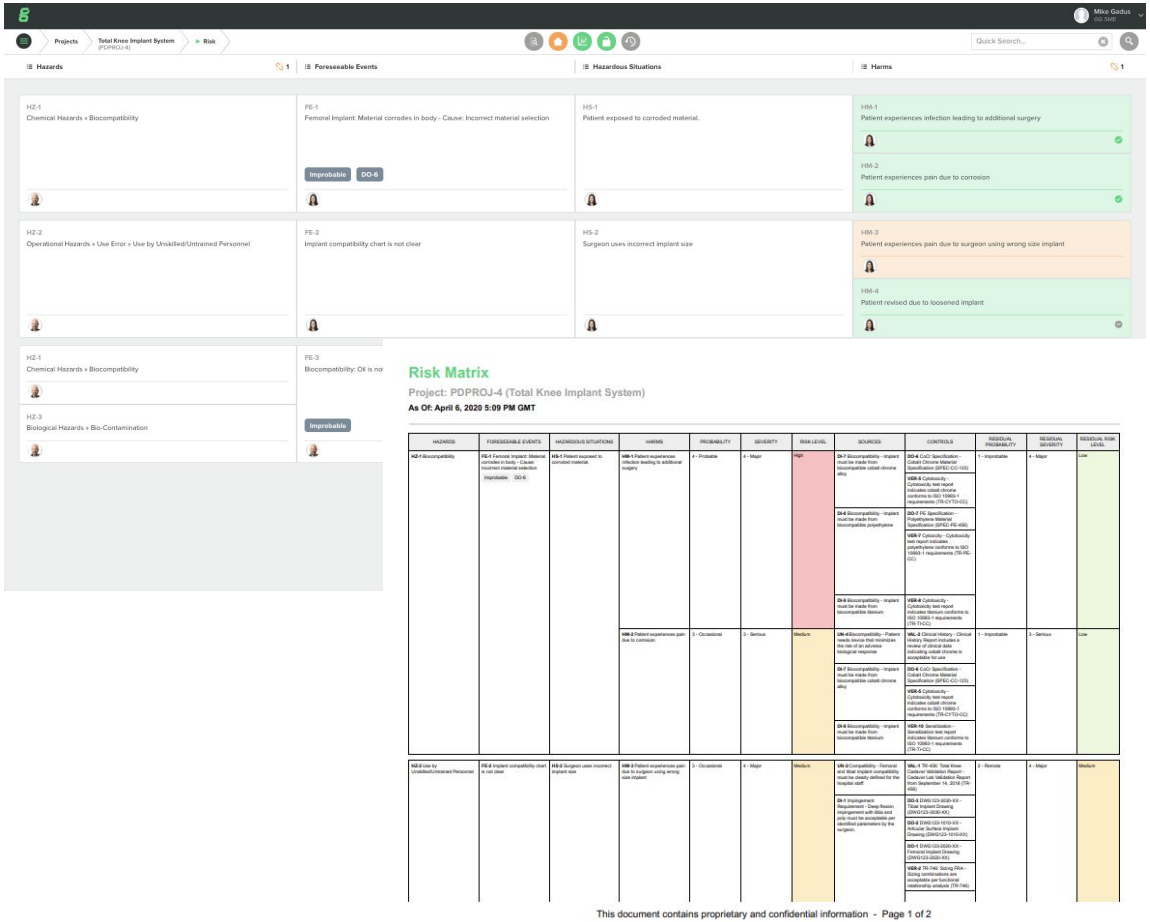
Maintain a living traceability matrix and generate a DHF on demand



Simplify risk analysis by linking to Design Controls in a traceable system with a paperless, living risk management file



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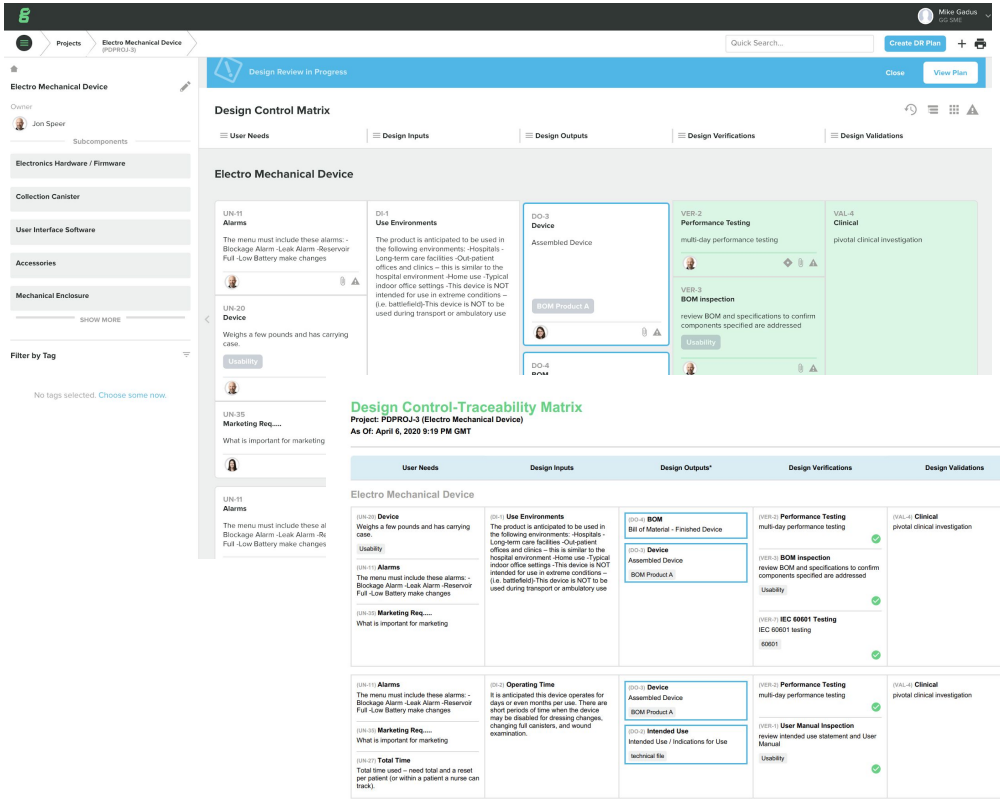
Allow teams to easily plan, conduct, and document design review activities with actionable feedback, with artifacts automatically included in your Design History File

From anywhere.



For quality leaders looking to easily demonstrate closed-loop traceability by streamlining quality and document control processes across internal and external stakeholders in order to scale efficiently...

FOR ESTABLISHED COMPANIES SELLING DEVICES INTERNATIONALLY

Stryker veterans at **C2DX, Inc.** prioritize quality in everything they do. They knew the limitations of other solutions (i.e. paper) which led them to implementing a purpose-built medical device quality management system (MDQMS) right from the start.

With Greenlight Guru they have been able to streamline their processes and achieve MDSAP and ISO certifications – ***all while impressing auditors during a paperless audit***

C2Dx
CRITICAL CARE DIAGNOSTICS

WE WANTED A QMS SOLUTION THAT WAS ROBUST ENOUGH TO GROW WITH US, BUT SIMPLE ENOUGH TO GET US STARTED.

Kevin McLeod, CEO of C2DX, Inc.

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FOR COMPANIES GROWING INTO NEW REGULATORY MARKETS

LUCERNO DYNAMICS has a Class I device commercially available in several markets, but is moving into the EU market for the first time.

A gap analysis revealed areas for improvement in order for them to achieve ISO 13485:2016 certification. After considering 8 different systems, they chose to implement Greenlight Guru.

By implementing Greenlight Guru's MDQMS, they were able to streamline quality processes and document controls to ***experience their first-ever paperless audit while achieving their ISO 13485:2016 certification***.

LUCERNO DYNAMICS

I HIGHLY RECOMMEND GREENLIGHT GURU. THEY HAVE TAKEN A COMPLEX INDUSTRY AND MADE IT INTO A PRODUCT THAT IS SIMPLE TO USE.

Tonia Bryant, Director of QA/RA at Lucerno Dynamics

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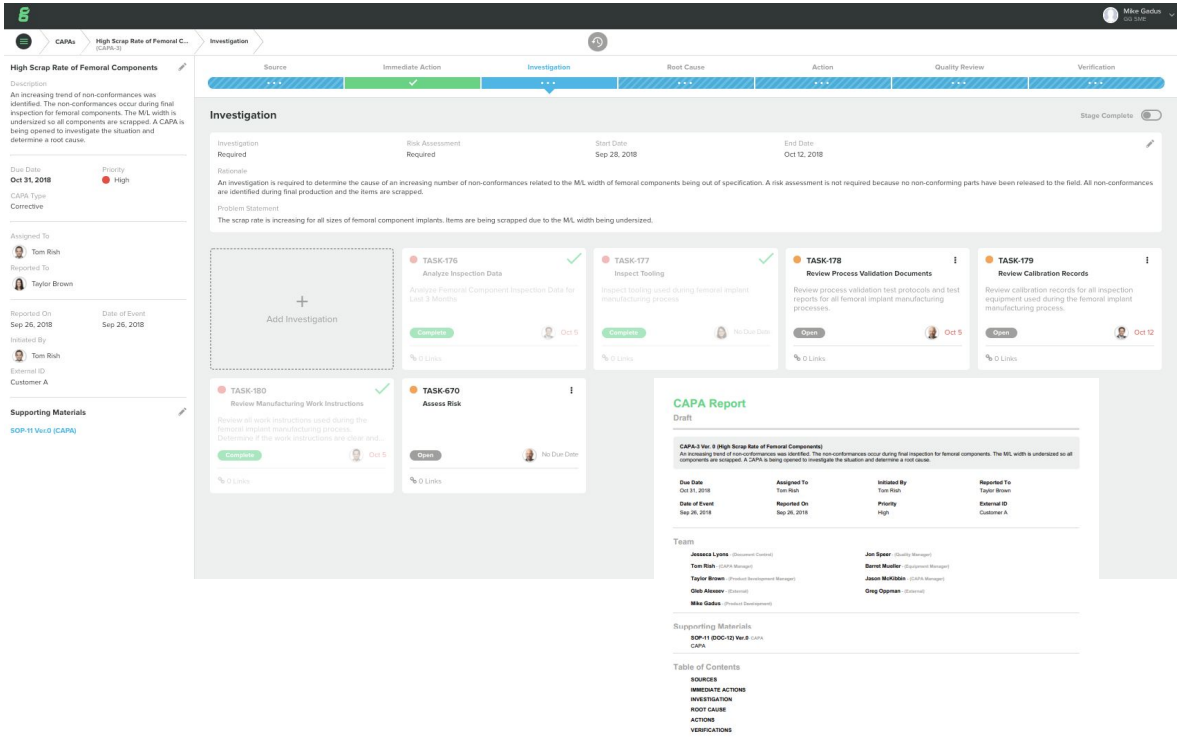
Manage risk-based quality processes in a connected ecosystem that unites internal and external stakeholders



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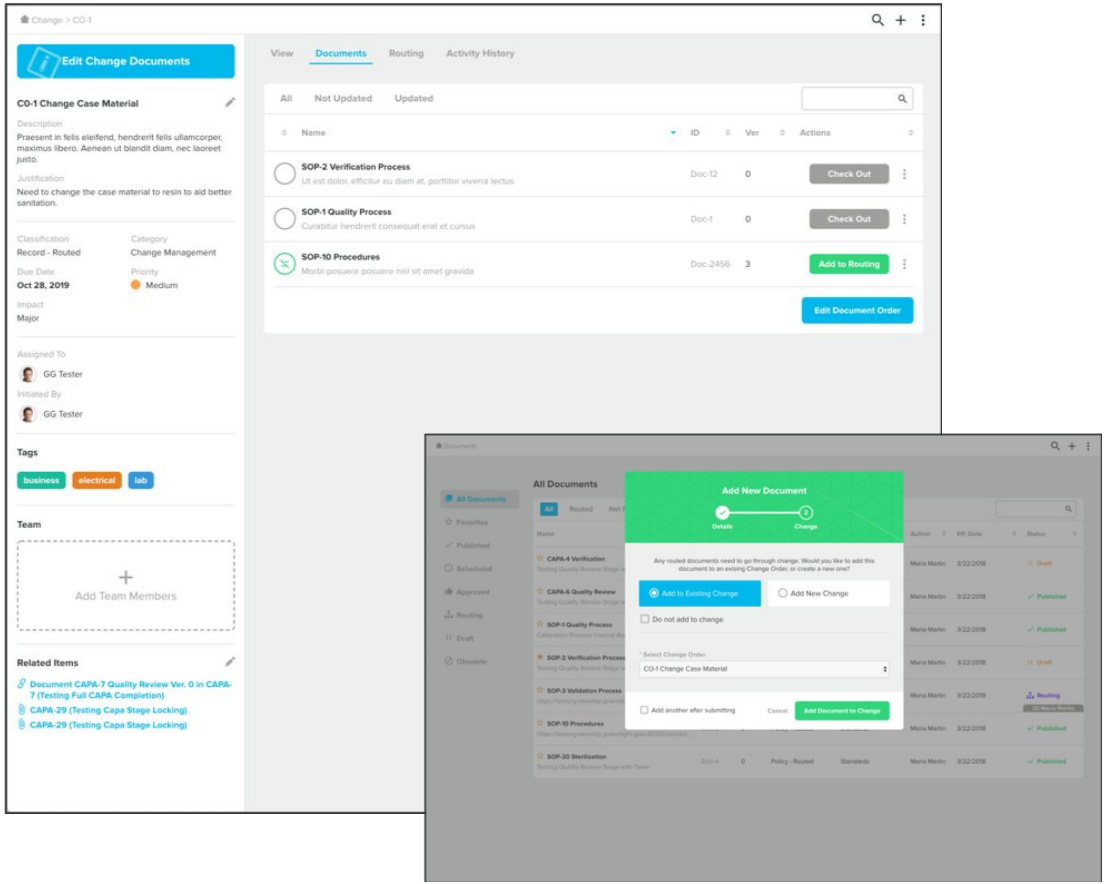
Streamline document control and change management in a cloud-based, Part 11 compliant workspace



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A MODERN, CLOSED-LOOP QUALITY SYSTEM THAT GIVES YOUR TEAM FULL TRACEABILITY BETWEEN DESIGN CONTROLS, RISK, DOCUMENTS, AND QUALITY EVENTS AS CHANGES OCCUR

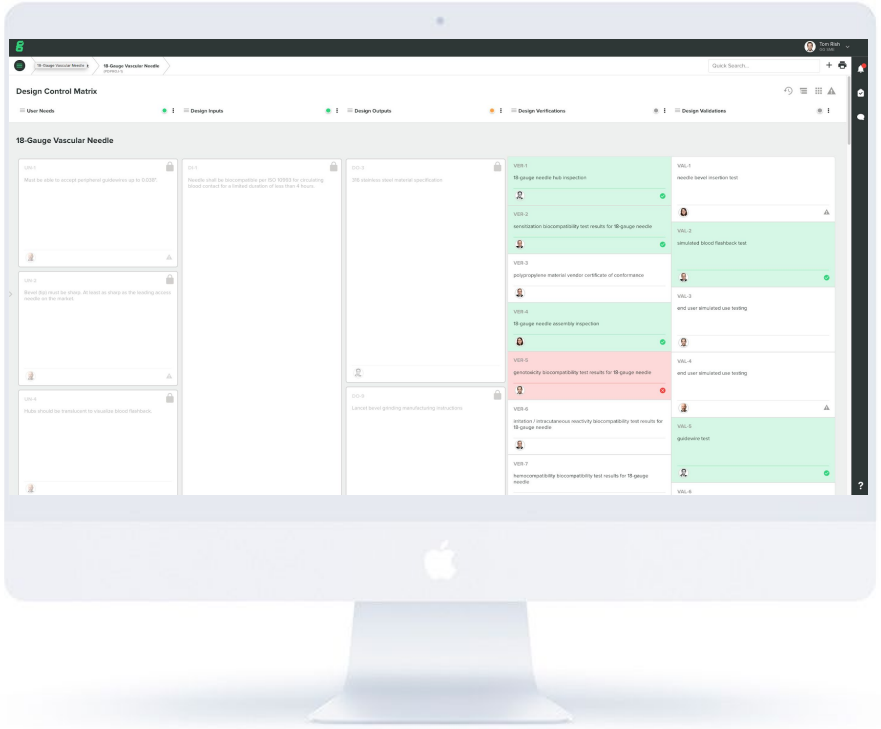
CONNECTED

What about those that use modern, best-in-class systems? What specific benefits are associated with purpose-driven solutions when compared to those organizations using legacy systems?

- **3x more likely** to call themselves *"highly efficient"* when bringing a device to market.
- **2x as likely** to say they are *"very confident"* about demonstrating total lifecycle traceability in the event of an unannounced audit
- ***Significantly* more likely** *to be EU MDR ready.* Roughly half of those using best-in-class tools are either "ready today: or confident they will be ready (compared to fewer than 1 in 3 inside organizations depending on legacy solutions).

MDQMS PLATFORM CAPABILITIES

- **Built-in controls** that align with 21 CFR Part 820 and ISO 13485:2016
- **Flexible review & approval workflows** with Part 11 compliant e-Signatures
- **Fully integrated risk** aligned to ISO 14971
- **LinkAnything** drives full lifecycle traceability
- **Zero effort** system validation
- **Drive collaboration** with task management, comments, and notifications



GREENLIGHT GURU IS THE ONLY MEDICAL DEVICE QMS SOLUTION PROVIDER TO BE NAMED A CATEGORY LEADER BY G2 CROWD FIVE QUARTERS IN A ROW

G2 CROWD helps businesses discover, buy, and manage software by providing real reviews, from real users, in real time.

The Grid Report for Quality Management Systems highlights the leading QMS solution providers ranked by customer satisfaction (based on user reviews) and market presence (based on market share, vendor size, and social impact)

Greenlight Guru's Medical Device Quality Management Software has been named a Leader in the Quality Management Grid Report five consecutive quarters based on receiving a high customer satisfaction score and having a large market presence.

BASED ON REAL USER REVIEWS:

92% of users believe the solution and company are headed in the right direction

89% of user reviews rated it 4 or 5 stars ★★★★★

91% of users said they would be likely to recommend Greenlight Guru

QUESTIONS?

Jon Speer
jon.speer@greenlight.guru