

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

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.

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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+%

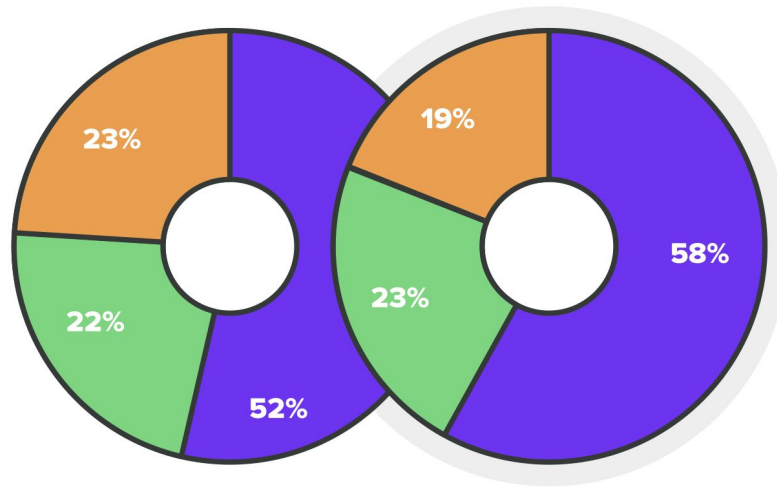
Medical device companies still using
traditional paper or electronic document-
based “paperless” systems to manage quality

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

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?

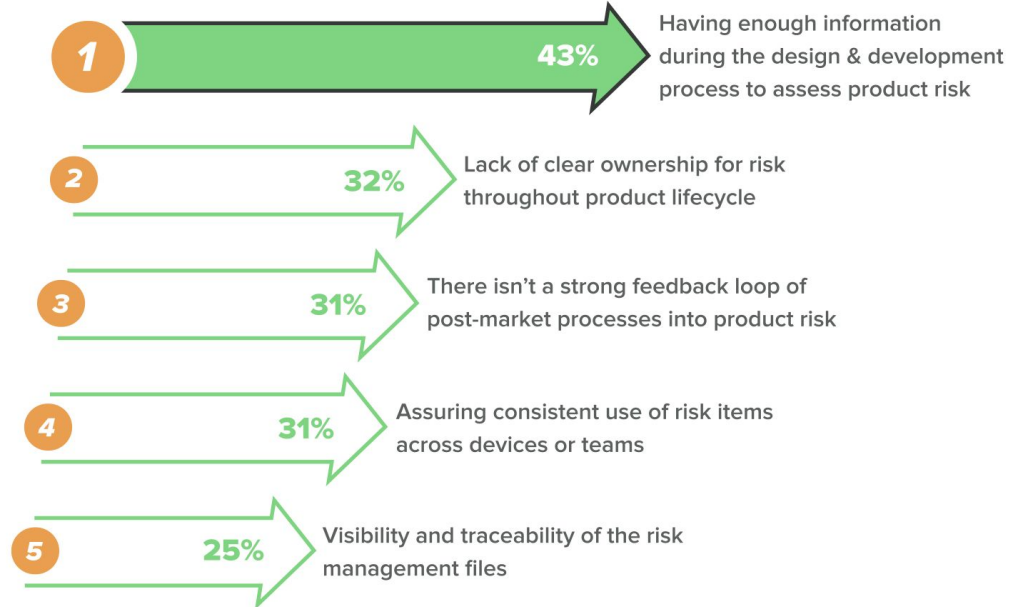


Source: Greenlight Guru | 2019

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.”

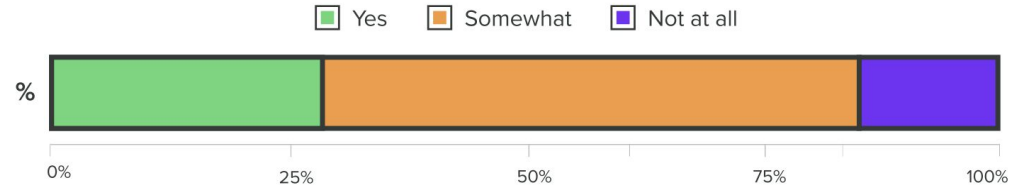
Top 5 Challenges in Managing Risk



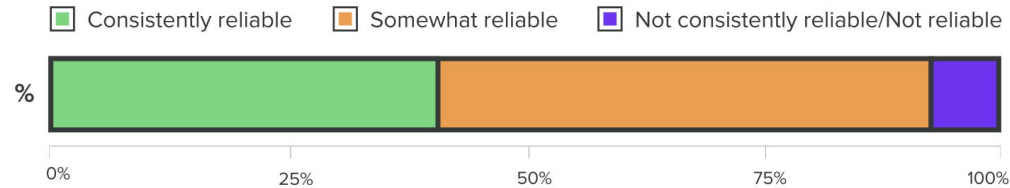
Source: Greenlight Guru | 2019

Data Access & Reliability

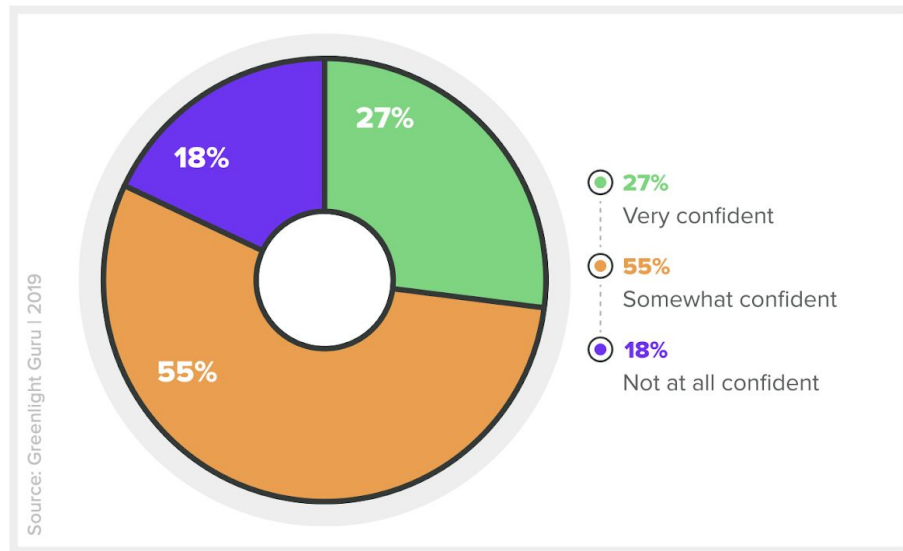
Is the data collected from your company's Quality System considered easily accessible in real time?



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



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.**



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

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

[illegible]

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

6

Projects

Total Knee Implant System (PDPROJ-4)

Risk

Hazards

1

Foreseeable Events

Hazardous Situations

Harms

1

HZ-1
Chemical Hazards » Biocompatibility

HZ-2
Operational Hazards » Use Error » Use by Unskilled/Untrained Personnel

HZ-3
Biological Hazards » Bio-Contamination

FE-1
Femoral Implant: Material corrodes in body - Cause: Incorrect material selection

FE-2
Implant compatibility chart is not clear

FE-3
Biocompatibility: CE is not

Risk Matrix

Project: PDPROJ-4 (Total Knee Implant System)

As Of: April 6, 2020 5:09 PM GMT

| Hazard | Foreseeable Events | Hazardous Situations | Harms | Probability | Severity | Risk Level | Sources | Controls | Residual Probability | Residual Severity | Residual Risk Level |
|---|---|---|---|--------------|-----------|------------|---|--|----------------------|-------------------|---------------------|
| HZ-1 Biocompatibility | HZ-1 Femoral Implant Material corrodes in body - Cause: Incorrect material selection (ISO-10) | HS-1 Patient exposed to corroded material | HS-1 Patient experiences infection leading to additional surgery | 1 - Probable | 3 - Major | High | SD-1 Incompatibility - Implant must be made from incompatible material (ISO-10) | SD-1 C-10: Specification - Corrosion Resistance: Report (ISO-10:10) | 1 - Inoperable | 3 - Major | Low |
| | | | | | | | SD-2 Corrosion - Cathodic, non report (ISO-10:10) | SD-2 C-10: Specification - Cathodic Corrosion Resistance: Report (ISO-10:10) | | | |
| | | | | | | | SD-3 Corrosion - Cathodic, non report (ISO-10:10) | SD-3 C-10: Specification - Cathodic Corrosion Resistance: Report (ISO-10:10) | | | |
| | | | | | | | SD-4 Corrosion - Cathodic, non report (ISO-10:10) | SD-4 C-10: Specification - Cathodic Corrosion Resistance: Report (ISO-10:10) | | | |
| HZ-2 Operational Hazards » Use Error » Use by Unskilled/Untrained Personnel | FE-2 Implant compatibility chart is not clear | HS-2 Surgeon uses incorrect implant size | HS-2 Patient experiences pain due to corrosion | 1 - Probable | 3 - Major | High | SD-1 Incompatibility - Implant must be made from incompatible material (ISO-10) | SD-1 C-10: Specification - Corrosion Resistance: Report (ISO-10:10) | 1 - Inoperable | 3 - Major | Low |
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| | | | | | | | SD-3 Corrosion - Cathodic, non report (ISO-10:10) | SD-3 C-10: Specification - Cathodic Corrosion Resistance: Report (ISO-10:10) | | | |
| | | | | | | | SD-4 Corrosion - Cathodic, non report (ISO-10:10) | SD-4 C-10: Specification - Cathodic Corrosion Resistance: Report (ISO-10:10) | | | |
| HZ-3 Biological Hazards » Bio-Contamination | FE-3 Biocompatibility: CE is not | HS-3 Surgeon uses incorrect implant size | HS-3 Patient experiences pain due to surgeon using wrong size implant | 1 - Probable | 3 - Major | High | SD-1 Incompatibility - Implant must be made from incompatible material (ISO-10) | SD-1 C-10: Specification - Corrosion Resistance: Report (ISO-10:10) | 1 - Inoperable | 3 - Major | Low |
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| | | | | | | | SD-4 Corrosion - Cathodic, non report (ISO-10:10) | SD-4 C-10: Specification - Cathodic Corrosion Resistance: Report (ISO-10:10) | | | |

From anywhere.

This document contains proprietary and confidential information - Page 4 of 24

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***



**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.

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.**



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

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

High Scrap Rate of Femoral Components

Description: An increasing trend of non-conformances was identified. The non-conformances occur during final inspection for femoral components. The ML width is undersized so all components are scrapped. A CAPA is being opened to investigate the situation and determine a root cause.

Due Date: **Oct 31, 2018** | Priority: **High**

CAPA Type: **Corrective**

Assigned To: **Tom Rish**

Reported To: **Taylor Brown**

Reported On: **Sep 26, 2018** | Date of Event: **Sep 26, 2018**

Initiated By: **Tom Rish**

External ID: **Customer A**

Supporting Materials: [SOP-11 \(Ver 8\) \(CAPA\)](#)

Investigation

Source: Immediate Action: Investigation: Root Cause: Action: Quality Review: Verification:

Investigation

Investigation Required: Risk Assessment Required: Start Date: **Sep 28, 2018** | End Date: **Oct 12, 2018**

Rationale: An investigation is required to determine the cause of an increasing number of non-conformances related to the ML width of femoral components being out of specification. A risk assessment is not required because no non-conforming parts have been released to the field. All non-conformances are identified during final production and the items are scrapped.

Problem Statement: The scrap rate is increasing for all sizes of femoral component implants. Items are being scrapped due to the ML width being undersized.

TASK-176 Analyze Inspection Data (Completed) | **TASK-177** Inspect Tooling (Completed) | **TASK-178** Review Process Validation Documents (Open) | **TASK-179** Review Calibration Records (Open)

TASK-180 Review Manufacturing Work Instructions (Completed) | **TASK-670** Assess Risk (Open)

CAPA Report Draft

CAPA Title: High Scrap Rate of Femoral Components

An increasing trend of non-conformances was identified. The non-conformances occur during final inspection for femoral components. The ML width is undersized so all components are scrapped. A CAPA is being opened to investigate the situation and determine a root cause.

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Team

James Lyons (Document Control) | **Jon Sygar** (Quality Manager)

Tom Rish (CAPA Manager) | **Barnet Mueller** (Equipment Manager)

Taylor Brown (Product Development Manager) | **Jason McMillan** (CAPA Manager)

Chris Alexander (Designer) | **Greg Oppman** (Designer)

Mike Gaskin (Product Development)

Supporting Materials: [SOP-11 \(Ver 8\) \(CAPA\)](#)

Table of Contents

SOURCES

IMMEDIATE ACTIONS

INVESTIGATION

ROOT CAUSE

ACTIONS

VERIFICATIONS

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

The screenshot displays the Greenlight Guru interface, divided into two main sections. The left section, titled 'Change > CO-1', provides details for a specific change. It includes a description, justification, classification (Record - Routed), category (Change Management), due date (Oct 28, 2019), priority (Medium), impact (Major), assigned to (GG Tester), and invited by (GG Tester). Below this, there are tags (business, electrical, lab) and a team section with an 'Add Team Members' button. The right section, titled 'Documents', shows a list of documents associated with the change. The list includes 'SOP-2 Verification Process', 'SOP-1 Quality Process', and 'SOP-10 Procedures'. Each document entry shows its ID, version, and a 'Check Out' or 'Add to Routing' button. A search bar and tabs for 'All', 'Not Updated', and 'Updated' are at the top of the document list. An 'Edit Document Order' button is located at the bottom right of the document list.

Change > CO-1

Edit Change Documents

CO-1 Change Case Material

Description
Praesent in felis eleifend, hendrerit felis ullamcorper, maximus libero. Aenean ut blandit diam, nec laoreet justo.

Justification
Need to change the case material to resin to aid better sanitation.

Classification
Record - Routed

Category
Change Management

Due Date
Oct 28, 2019

Priority
Medium

Impact
Major

Assigned To
GG Tester

Invited By
GG Tester

Tags
business electrical lab

Team
+
Add Team Members

Related Items
Document CAPA-7 Quality Review Ver. 0 in CAPA-7 (Testing Full CAPA Completion)
CAPA-29 (Testing Caps Stage Locking)
CAPA-29 (Testing Caps Stage Locking)

View Documents Routing Activity History

All Not Updated Updated

Name ID Ver Actions

SOP-2 Verification Process Doc-12 0 Check Out

SOP-1 Quality Process Curabitur hendrerit consequat erat et cursus Doc-1 0 Check Out

SOP-10 Procedures Morbi posuere posuere nisl et amet gravida Doc-2456 3 Add to Routing

Edit Document Order

Add New Document

Any routed documents need to go through change. Would you like to add this document to an existing Change Order or create a new one?

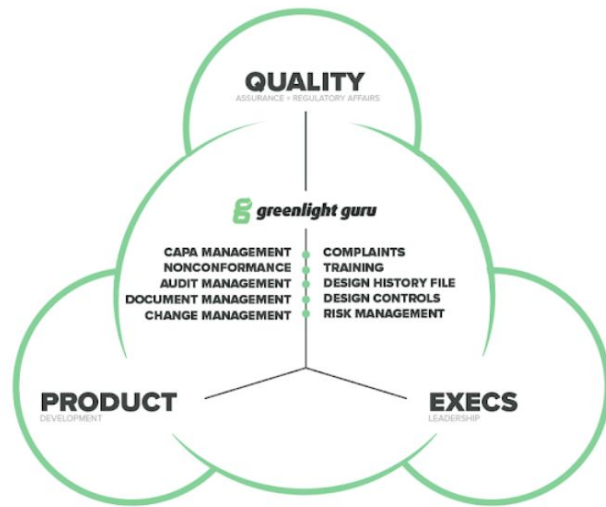
☒ Add to Existing Change ☐ Add New Change

☐ Do not add to change

* Select Change Order
CO-1 Change Case Material

☐ Add another after submitting Cancel **Add Document to Change**

**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?

**THEY
ARE**

- **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



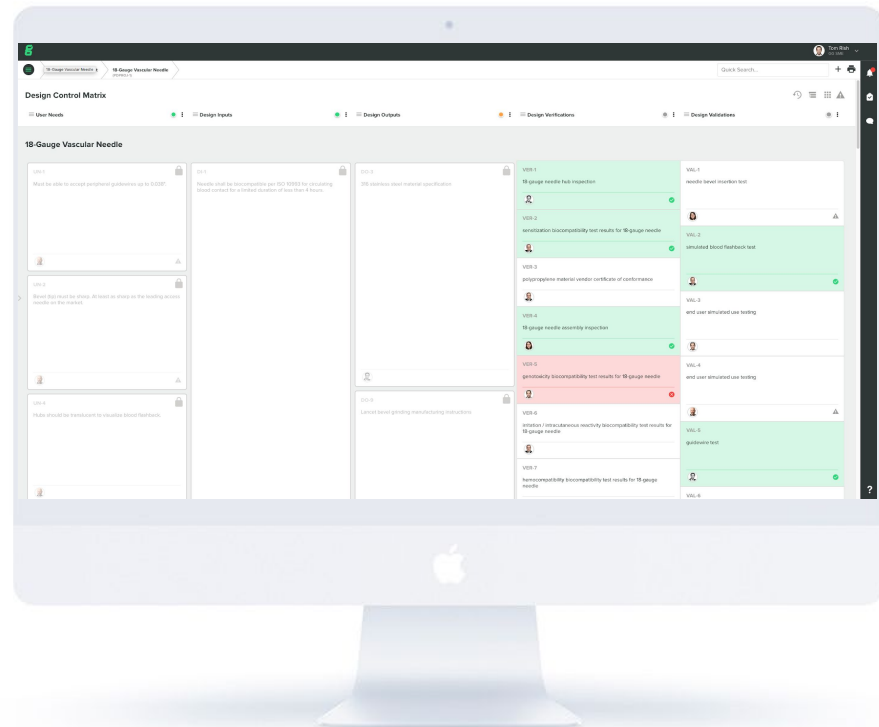
LinkAnything drives full lifecycle traceability



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