3 POWERFUL WAYS TO REVOLUTIONIZE YOUR APPROACH TO CLOSED-LOOP QUALITY SYSTEM TRACEABILITY

Sponsored by **greenlight guru**

MEDICAL DEVICE QUALITY IS ALL WE DO, AND WE'RE ALWAYS AHEAD OF THE GAME.

75
years industry experience

275k
podcast listeners

#1
blog and podcast in the industry

90k
look to us for the latest in medical device quality

Customers by Device Class:
Blue = Class I Device
Green = Class II, IIa, IIb Devices
Purple = Class III Devices

G2 CROWD

LEADER

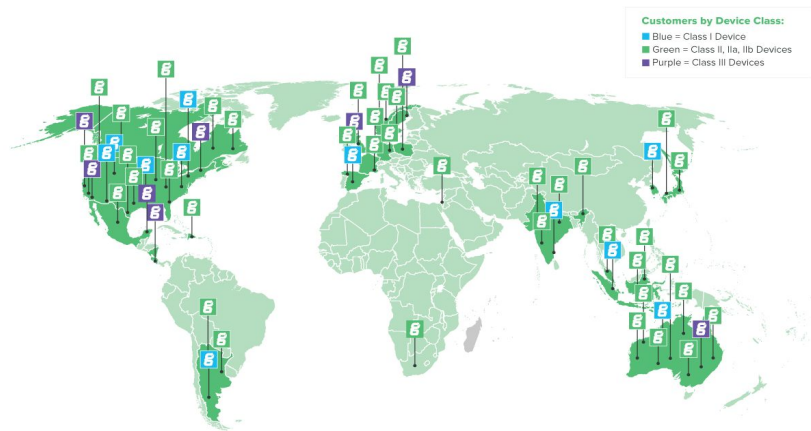QMS SOFTWARE

★★★★½
Since Winter 2019

"One stop shop for MDQMS"
★★★★★

"My QMS is world class"
★★★★★

"Greenlight Guru Software is the handrail for Medical Device Development and Documentation"
★★★★★

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COOK MEDICAL

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GCMI GLOBAL CENTER FOR MEDICAL INNOVATION

infinite biomedical technologies

RECOVERY FORCE

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3 POWERFUL STRATEGIES TO
MASTER CLOSED-LOOP TRACEABILITY

Today's Presenters:

Taylor Brown
Senior Medical Device
Guru at Greenlight Guru

Tom Rish
Senior Medical Device
Guru at Greenlight Guru

Jason McKibbin
COO at Greenlight Guru
Former COO & Owner at MEDISISS,
acquired by Medline

You will walk away knowing...

✓ **Industry challenges and barriers to demonstrating closed-loop traceability within your quality system**

✓ **How to overcome the common challenges**

✓ **Purpose-built tools with the latest technologies that enable your team to achieve closed-loop traceability**

✓ **3 powerful ways to advance your approach to closed-loop traceability**

✓ **How to optimize your QMS for traceability and maximize value from your quality data**

WHAT IS CLOSED-LOOP TRACEABILITY?

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Closed-Loop Traceability (CLT)

The ability to connect people, processes and data seamlessly across the value chain - closing the loop between pre- and post-market activities.

It is as much about tracing a problem as it is about preventing the issues in the first place.

Example: Product-related customer complaints or nonconformances can be traced back to specific design control elements, risk management, and change processes.

WHY CLT IS A MUST

1   **Simplifies** a complex quality system

2   **Improves the efficacy** of changes, investigations, root cause determinations
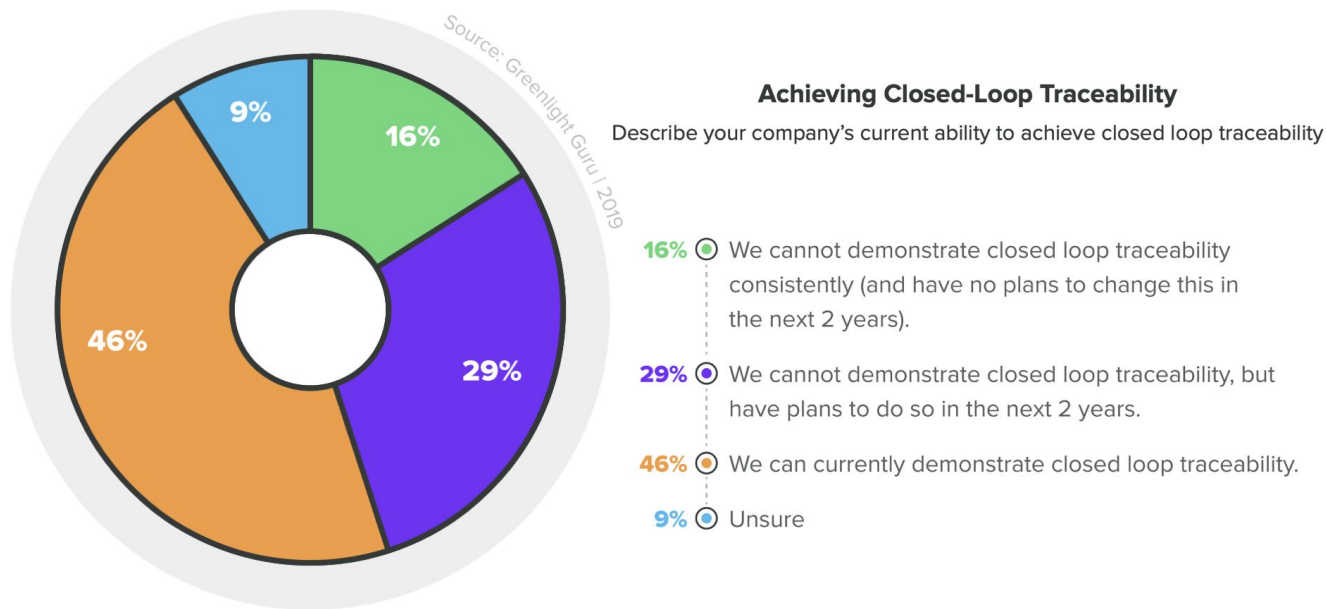
3   **Streamlines** audit and inspection prep time

WE SURVEYED 500+ MEDICAL DEVICE PROFESSIONALS

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When it comes to closed-loop traceability (CLT) throughout your quality system, **nearly half (45%) cannot demonstrate it today.**

Source: Greenlight Guru | 2019

Achieving Closed-Loop Traceability

Describe your company's current ability to achieve closed loop traceability

16% ⊙ We cannot demonstrate closed loop traceability consistently (and have no plans to change this in the next 2 years).

29% ⊙ We cannot demonstrate closed loop traceability, but have plans to do so in the next 2 years.

46% ⊙ We can currently demonstrate closed loop traceability.

9% ⊙ Unsure

Of those that can demonstrate CLT, **1 in 3 say it takes substantial effort to do so.**

INDUSTRY CHALLENGES AROUND CLOSED-LOOP TRACEABILITY

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JASON MCKIBBIN

COO at Greenlight Guru

Former COO & Owner at MEDISISS, acquired by Medline
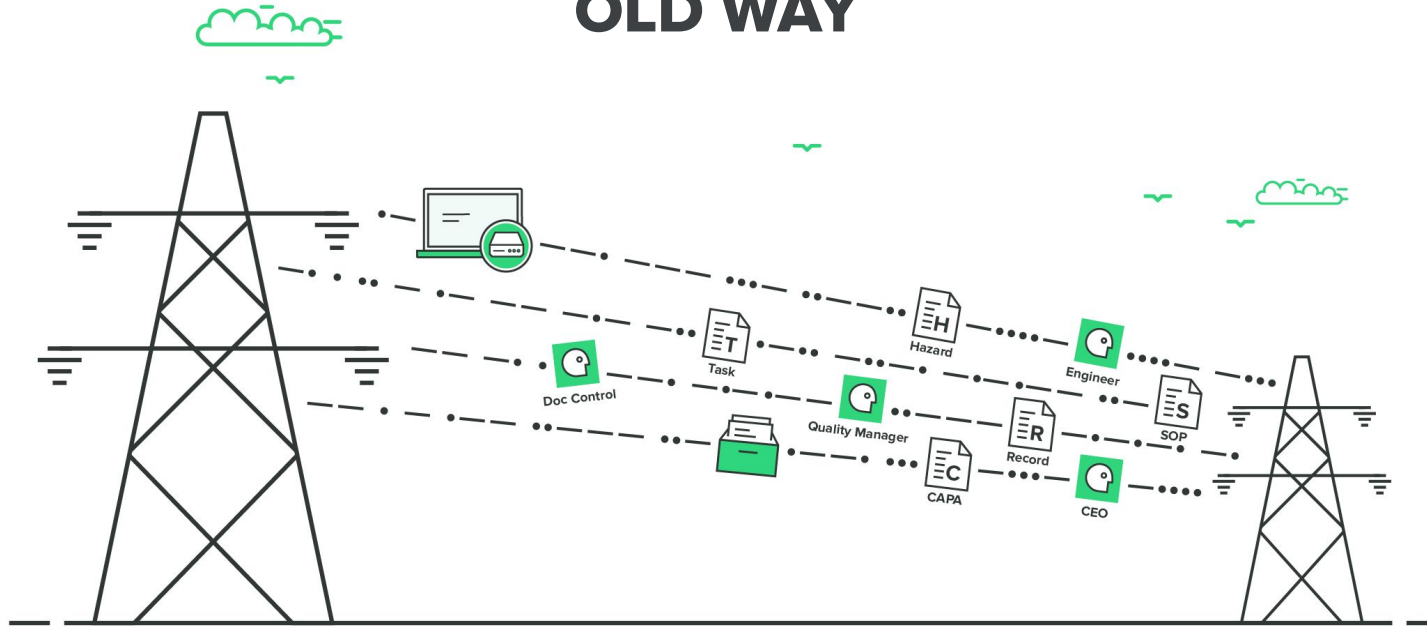
QUALITY ≠ "the quality departments responsibility"

THE OLD WAY
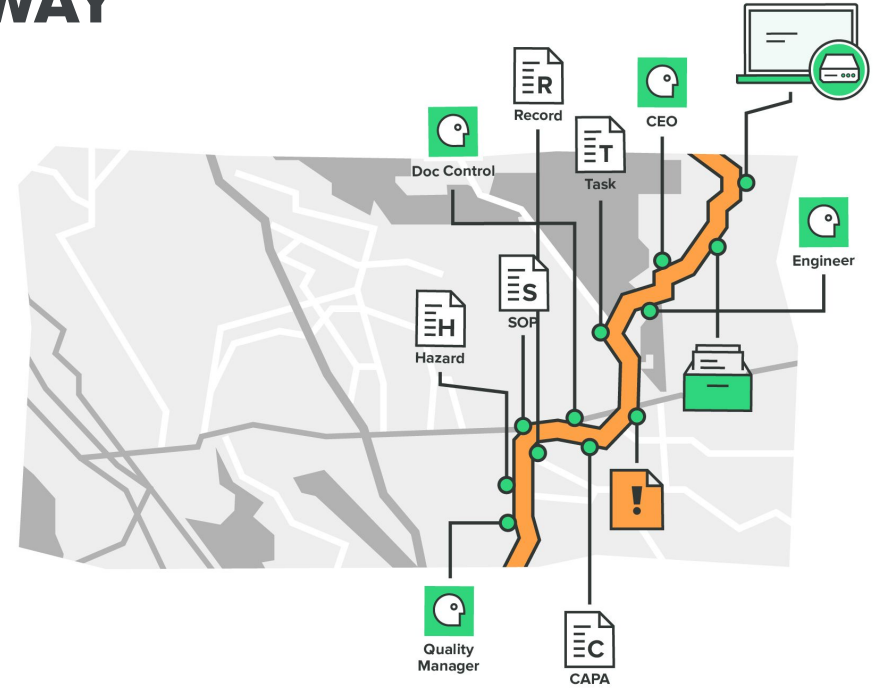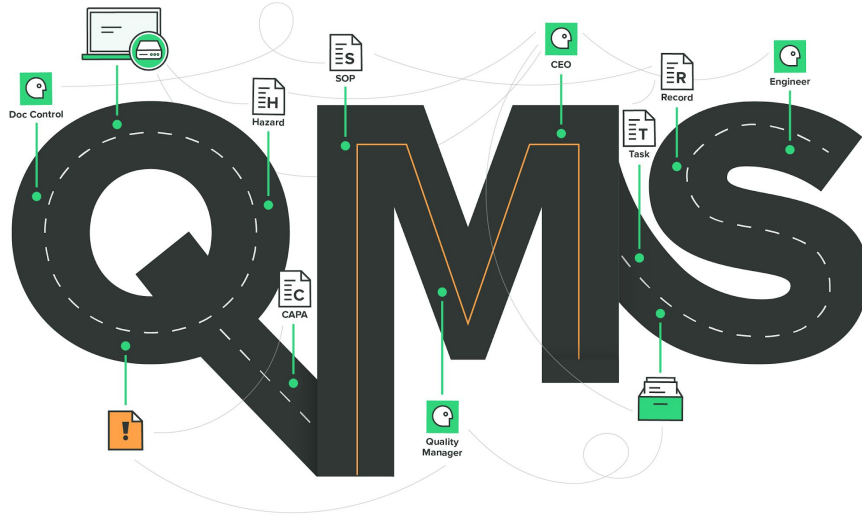
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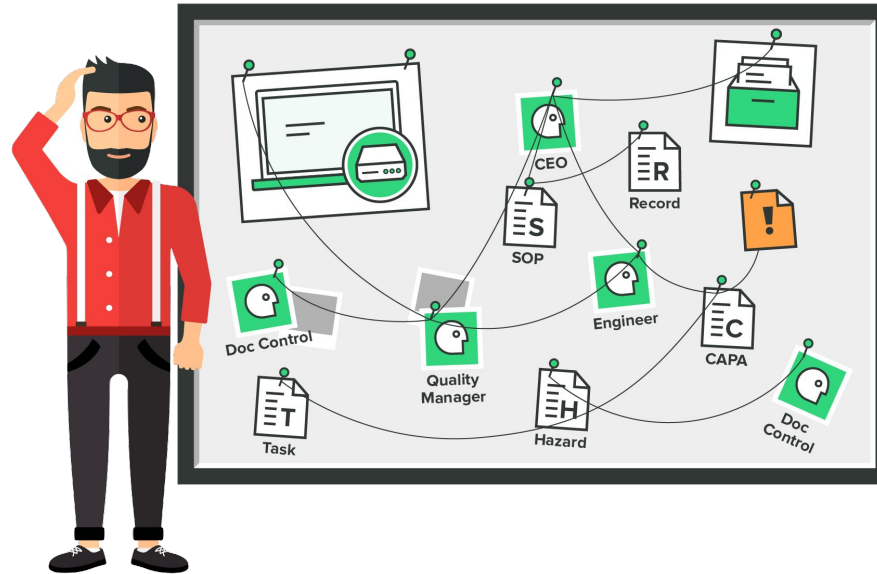
OLD WAY

Manual process, memory-driven, flying blind in your quality system

OLD WAY

Conversations were transmitted by morse code from point to point.

OLD WAY

Maps now tell you more about your road trip than just the route

THE NEW WAY

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OLD WAY

NEW WAY

OLD WAY	NEW WAY
Manual	**Automated**
Disconnected	**Connected**
Siloed	**Efficient**
Inefficient	**Intuitive**
Human Error	**Clear**
Risk-Ridden	**Data-driven**
Hidden Costs	**VISIBILE**

Manual process, memory-driven, flying blind in your quality system

A network **view** of your quality system

NEW WAY
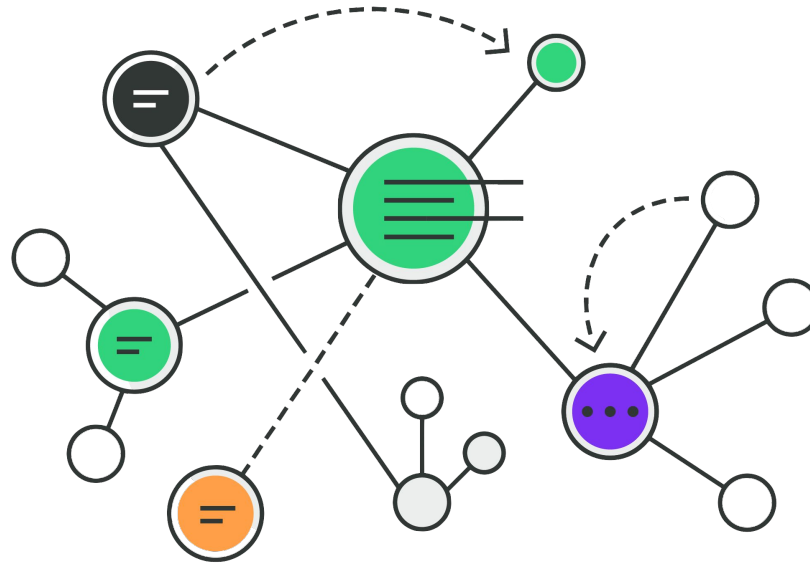
A network **view** of your quality system

GREENLIGHT GURU VISUALIZE
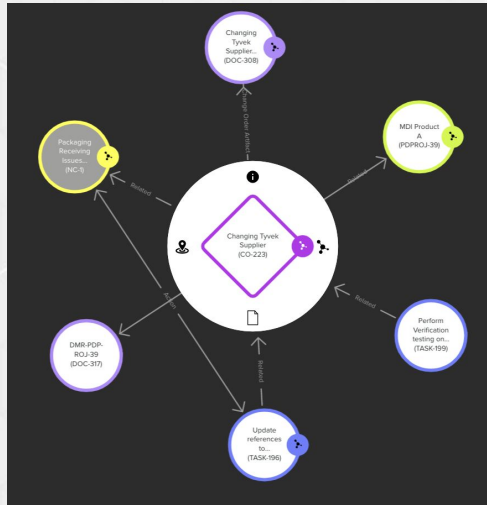
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GREENLIGHT GURU VISUALIZE

QUALITY AT A BIRD'S-EYE VIEW

✓ Relationship creation and virtual linking powered by **Machine Learning and Natural Language Processing**

✓ **Filter and layer** information to tailor your view of the QMS items and connections
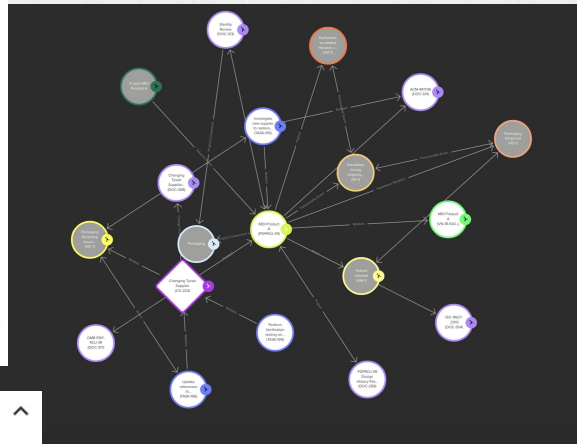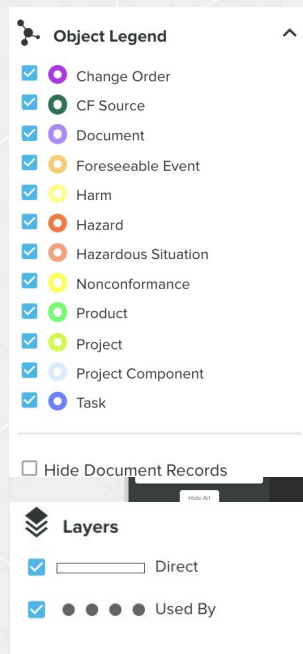
GREENLIGHT GURU VISUALIZE

QUALITY AT A BIRD'S-EYE VIEW

✓ **Directional mapping** of the relationships between items in your QMS

✓ Customizable anchor point for your **visual traceability map** to navigate through items in your QMS

"FYI as a **BSI auditor** I have come across people using your services and they do very well at audit.

This latest "invention" would save them time! I can't think of anything more valuable.

"I've always had to store all of this information **in my mind** and you guys have brought it to your software.

This is a really nice tool, **we need this!**"

"There are **so many** inputs, outputs, independent activities, that having a tool that can provide a picture of these relationships is i**nvaluable**!"

"Finding related documents in our QMS used to be a **very time-consuming exercise**.

With Greenlight Guru Visualize, I now have the visibility of all associated and related documents with **just a click.**"

3 POWERFUL WAYS TO ACHIEVE CLOSED-LOOP QUALITY SYSTEM TRACEABILITY

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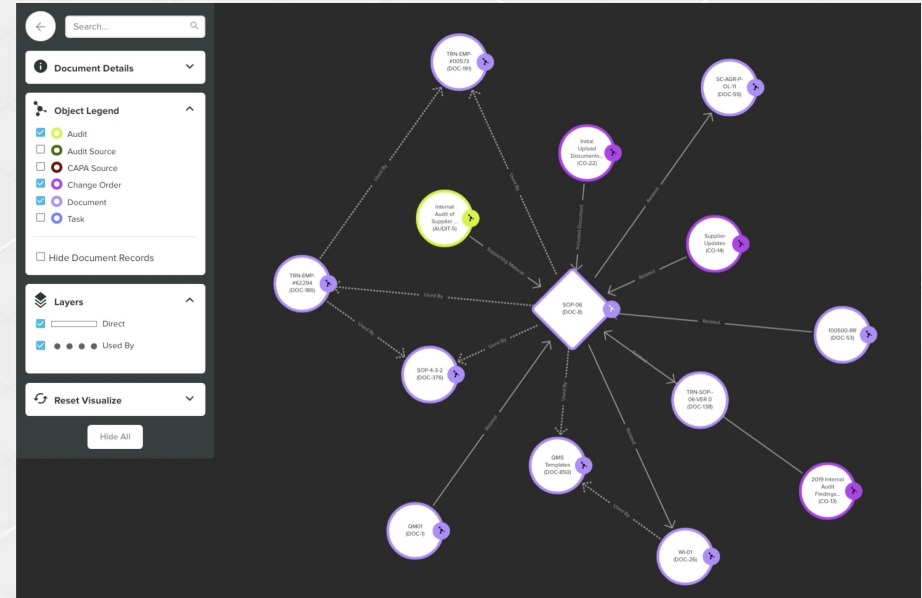**1** **Efficiently navigate** through the depths of your quality system

2

3

Referencing, remember, and digging

EFFICIENTLY
NAVIGATE

Find information faster

Audit preparation

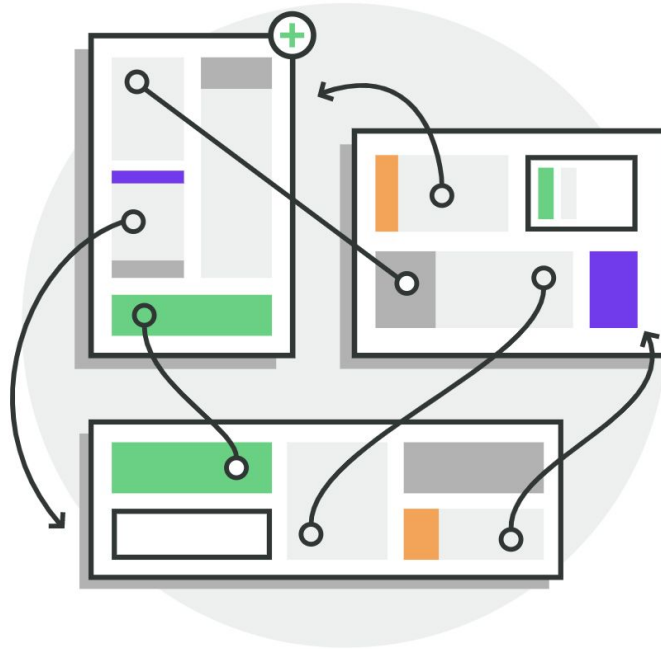**Document structure**

1   **Efficiently navigate** through the depths of your quality system

2   **Increase visibility** into relationships within your QMS

3

Missing the interconnectedness of your QMS

INCREASE
VISIBILITY

Clear, communicable connections

Comprehend relationships

Keep track of information

1 **Efficiently navigate** through the depths of your quality system

2 **Increase visibility** into relationships within your QMS

3 **Understand** the impact of any change

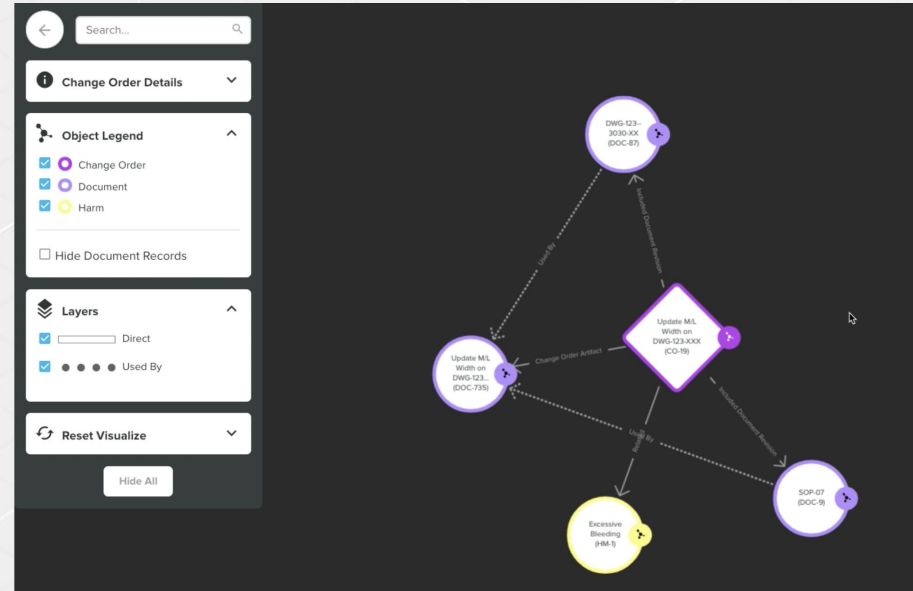Communicating changes; risk of error & re-work

UNDERSTAND
IMPACT OF CHANGE

Find documents that need updated

Reduce risk of human error

Avoid rework

REVOLUTIONIZE YOUR APPROACH TO TRACEABILITY

1 **Efficiently navigate** through the depths of your quality system

2 **Increase visibility** into relationships within your QMS

3 **Understand** the impact of any change

HOW TO OPTIMIZE TRACEABILITY TODAY

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3 THINGS YOU CAN DO TODAY:

1   **Understand why closed-loop traceability is a must for your business**

2   **Audit the current traceability of your QMS to ensure there is a closed-loop between all cross functional processes**
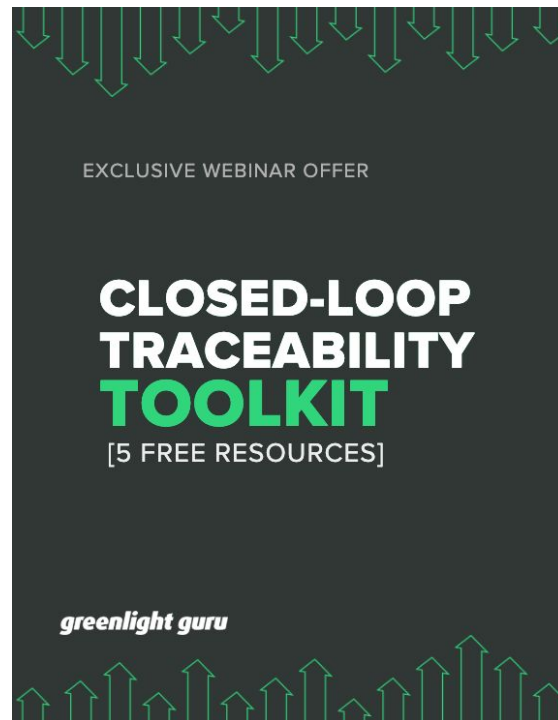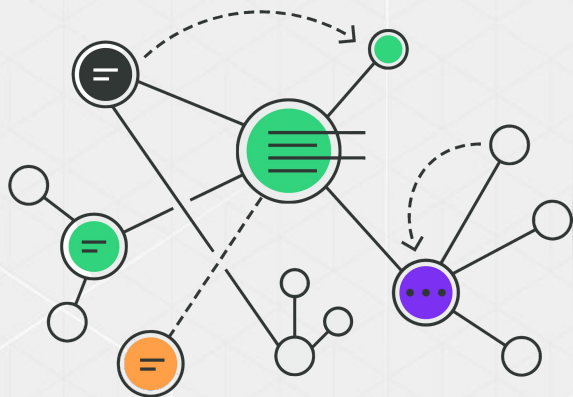
3   **Invest in purpose built tools to help you achieve closed-loop traceability**

EXCLUSIVE WEBINAR OFFER:

Free Toolkit to Help You Achieve
Closed-Loop Traceability
[5 Free Resources]

www.greenlight.guru/CLT-webinar-offer

EXCLUSIVE WEBINAR OFFER

CLOSED-LOOP
TRACEABILITY
TOOLKIT
[5 FREE RESOURCES]

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QUESTIONS?

DON'T FORGET!

Free Toolkit to Help You Achieve Closed-loop Traceability [5 Free Resources] ➜ https://www.greenlight.guru/clt-webinar-offer

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