



# 3 WAYS TO TRANSFORM YOUR CHANGE PROCESS THROUGH **AI-POWERED PREDICTIVE QUALITY**

February 11th at 1:00 PM (ET) / 10:00 AM (PT)

# 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

114k

look to us for the  
latest in quality

## FEATURED IN



G<sup>2</sup> | CROWD

LEADER

QMS  
SOFTWARE



Since Winter 2019

“Great eQMS Software...”

“The software is easy to use with little to no customization needed. It has been a great tool for developing our device through design control. The post-market additions have been amazing as well as tasks. **After using multiple types of eQMS software over the years, this is the best by far!**”

“My QMS is world class”



“One-stop shop”



“Design controls lifesaver”



“Fantastic product, even better team”



# 3 Impactful Ways to Transform the Change Management Process

Today's Presenters:



**Jon Speer**

Founder of Greenlight Guru



**Tom Rish**

Senior Medical Device Guru

# You will walk away knowing...

- Current industry challenges around reactive change management
- How purpose-built tools streamline and control the change management process
- Future of AI and machine learning in your quality system
- 3 proactive ways to transform your change management process
- How to understanding the downstream impact of a change and reducing the number of missed documents

What is **Change Management**?

# CHANGE MANAGEMENT

Managing modifications and implementing changes to products and processes.

Triggers:

- Product/design changes
- Processes updates
- Document modifications
- New/updated regulations

# CHANGE CONTROL

Reviewing proposed changes and determining to implement the change or denying the change request entirely.

Change Order includes:

- Describe the change
- Identify what else is impacted
- Identify relevant stakeholders involved
- Justify the reason for the change

# Common Challenges with Change Management

**1**

**Lack of visibility into quality system and information**

**2**

**Waiting and working reactively for errors to present themselves**

**3**

**Increased risk of inconsistent, incomplete changes**

# POLL:

1. How much time does it take you to **compile a change order?**
2. How many change orders do you complete **in a year?**
3. On average, how many reviewers are included **per change order?**





***What is keeping you from getting a change right the first time?***

***How many of those are the result of missing something in the initial change order?***

***Do you have the necessary visibility into your quality information when making a change?***

# What we know...

**20%**

say it takes a week or longer to run a change impact analysis.

**60%**

leverage traceability with change management.

# Reactive.



Reactive inefficiencies and increased risk of inconsistent, incomplete, and need for multiple changes orders.



Stacks of papers, gather signatures, rinse, and repeat

Shift to **Predictive Quality**

## OLD WAY

Manual  
User-Driven  
Disconnected  
Inefficient  
Human Error  
Risk-Ridden  
Hidden Costs

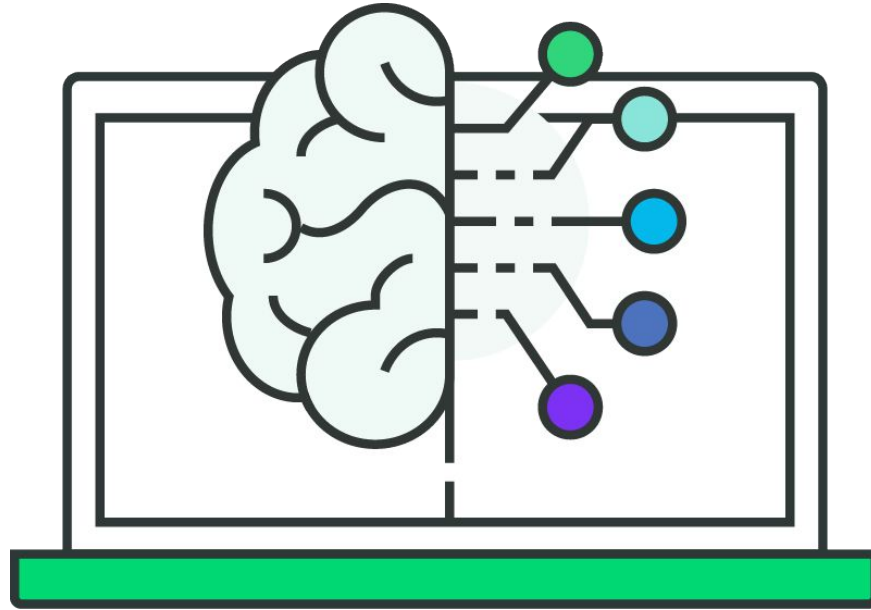
Wait for changes and mistakes to happen,  
then react.

## NEW WAY

AI-Powered  
Machine Learning  
Automated  
Streamlined  
Cross-functional  
Connected  
PROACTIVE

Predict the **impact** of change.

# Predictive.



*Real-time visibility into your change process and AI-powered recommendations that support you in making proactive quality decisions around a change.*

# BIGGEST PRODUCT RELEASE







**The world's first AI and machine learning  
recommendation engine for medical device quality.**

# HALO<sup>SM</sup> FOR CHANGE MANAGEMENT

Predict the impact of change.



AI-powered recommendations that reduce risk and improve quality.

- ✓ Know where to focus first
- ✓ Eliminate wasteful spend
- ✓ Embrace cross-functionality
- ✓ Reduce risk of human error

Change > CO-6 (Updates to drawings for Product A) > DOC-17

**SOP-05 (DOC-17) Ver. 0**

Status: **Draft**

Description: Supplier Evaluation

Classification: Procedure - Routed

Category: Supplier

Tags: **SOP**

Effective Date: Not available.

Owner: Tom Rish

**greenlight guru**

| STANDARD OPERATING PROCEDURE |                      |             |
|------------------------------|----------------------|-------------|
| Document Title               | Document Description | Version No. |
| SOP-05                       | SUPPLIER EVALUATION  | 0           |

**1. PURPOSE**  
To define the criteria and methods for selecting, evaluating, and monitoring suppliers for addition to or disqualification from the Approved Supplier List (ASL).

**2. SCOPE**  
This procedure applies to all suppliers of products, materials, goods, and services impacting product quality.

**3. RESPONSIBILITIES**

| Function    | Responsibilities  |
|-------------|---|
| Engineering | <ul style="list-style-type: none"><li>Identify potential supplier and collect business information related to the supplier.</li><li>Maintain supplier performance data for ongoing supplier monitoring.</li></ul> |
| Purchasing  | <ul style="list-style-type: none"><li>Purchase goods / services from supplier on Approved Supplier List</li></ul>   |

Recommendations

| Title                 | ID     | Why is this being recommended |
|-----------------------|--------|-------------------------------|
| SOP-25 PMCF           | DOC-29 | Change order details analysis |
| SOP-345-USF Usability | DOC-28 | Change order details analysis |







# HALO<sup>SM</sup> FOR CHANGE MANAGEMENT

## Predict the impact of change.



## Real-time visibility into the impact of a change.

- ✓ See downstream impact in minutes
- ✓ Eliminate time spent chasing people or information
- ✓ Filter away from the noise

| View  | Evaluation  | Documents | Recommendations      | Routing  | Activity History |
|---|-------------|-----------|----------------------|--|------------------|
| All   | Not Updated | Updated   | <input type="text"/> |  |                  |
| Name  | ID          | Ver.      | Author               | Actions  |                  |
|  <b>SOP-345-USF</b><br>Usability            | DOC-28      | 1         | Taylor Brown         | <a href="#">Add to Routing</a>   |                  |
|  <b>SOP-115</b><br>Handling External Audits | DOC-27      | 0         | Taylor Brown         | <a href="#">Add to Routing</a>   |                  |
|  <b>2020.6.2</b><br>Validation Memo         | DOC-        |           |                      | <div> <div>View</div> <div>Evaluation</div> <div>Documents</div> <div>Recommendations</div> <div>Routing</div> <div>Activity History</div> </div> <div> <input checked="" type="checkbox"/> Perform Evaluation within Greenlight Guru           <input type="checkbox"/> Upload Evaluation Form         </div> |                  |
|  <b>SOP-25</b><br>PMCF                      | DOC-        |           |                      | <div> <div>Is the product impacted?</div> <div>           NO           <div>             RATIONALE<br/>             This is the initial release of the QMS. No product documentation has been generated yet. All work on the product will be sub procedures.           </div> </div> </div>                    |                  |

View

Evaluation

Documents

Recommendations

Routing

Activity History

☒ Perform Evaluation within Greenlight Guru

☐ Upload Evaluation Form

Is the product impacted?

NO

RATIONALE  
This is the initial release of the QMS. No product documentation has been generated yet. All work on the product will be subject to these procedures.

Are processes impacted?

NO

RATIONALE  
This is the initial release of the QMS. No process documentation has been generated yet. All work on processes will be subject to these procedures.

Is risk affected?

NO

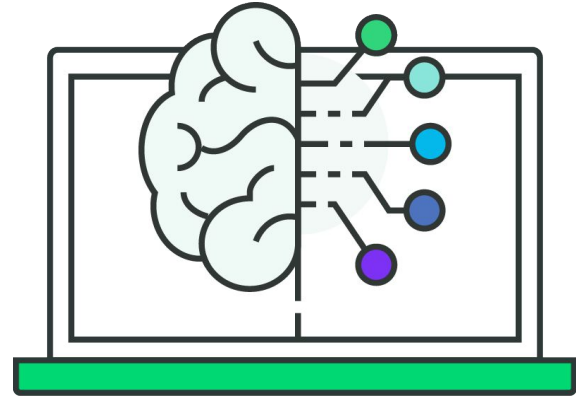
RATIONALE  
This is the initial release of the QMS. No product documentation, including a risk management file, has been generated yet. All work on the

# Stop reacting.



Reactive inefficiencies and increased risk.

# Start predicting.



AI-powered, streamlined, proactive quality.

## **3 Powerful Strategies to Transform Your Change Management Process**

**1**

**Leverage AI to identify documents for your change order**

**2**

**3**







*"I don't want to spend the time documenting, linking, and reviewing documents. I need to know if something has already been done."*

# Leverage AI to identify documents for your change order

List of recommendations

Confidence in connection

Know where to focus

| View   | Evaluation  | Documents | Recommendations | Routing                        | Activity History |
|--|-------------|-----------|-----------------|--------------------------------|------------------|
| All  | Not Updated | Updated   |                 |                                |                  |
|  |             |           |                 |                                |                  |
| Name   | ID          | Ver.      | Author          | Actions                        |                  |
|  <b>SOP-345-USF</b><br>Usability            | DOC-28      | 1         | Taylor Brown    | <a href="#">Add to Routing</a> | ⋮                |
|  <b>SOP-115</b><br>Handling External Audits | DOC-27      | 0         | Taylor Brown    | <a href="#">Add to Routing</a> | ⋮                |
|  <b>2020.6.2</b><br>Validation Memo         | DOC-26      | 0         | Taylor Brown    | <a href="#">Add to Routing</a> | ⋮                |
|  <b>SOP-25</b><br>PMCF                      | DOC-29      | 1         | Taylor Brown    | <a href="#">Add to Routing</a> | ⋮                |
| <a href="#">Edit Document Order</a>  |             |           |                 |                                |                  |



1

Leverage ai to identify documents for your change order

2

Perform an efficient change impact analysis

3



*"I need an easy way to find all the information that may be impacted by a change, so I don't miss anything"*

# Perform an efficient change impact analysis

Identify missed documents

Assess & review items

Change evaluation form

Change > CO-6 (Updates to drawings for Product A) > DOC-17

**SOP-05 (DOC-17) Ver. 0**

Status  
**Draft**

Description  
Supplier Evaluation

Classification  
Procedure - Routed

Category  
Supplier

Tags  
**SOP**

Effective Date  
Not available.

Owner  
Tom Rish

Download PDF Download Editable 100%

**greenlight guru**

| STANDARD OPERATING PROCEDURE |                      |             |
|------------------------------|----------------------|-------------|
| Document Title               | Document Description | Version No. |
| SOP-05                       | SUPPLIER EVALUATION  | 0           |

**1. PURPOSE**  
To define the criteria and methods for selecting, evaluating, and monitoring suppliers for addition to or disqualification from the Approved Supplier List (ASL).

**2. SCOPE**  
This procedure applies to all suppliers.

**3. RESPONSIBILITIES**  
Engineer  
Purchasing  
Regulatory Quality Assurance

View **Evaluation** Documents Recommendations Routing Activity History

☒ Perform Evaluation within Greenlight Guru ☐ Upload Evaluation Form

Is the product impacted?

**NO** RATIONALE  
This is the initial release of the QMS. No product documentation has been generated yet. All work on the product will be subject to these procedures.

Are processes impacted?

**NO** RATIONALE  
This is the initial release of the QMS. No process documentation has been generated yet. All work on processes will be subject to these procedures.

Is risk affected?

**NO** RATIONALE  
This is the initial release of the QMS. No product documentation, including a risk management file, has been generated yet. All work on the b70-300d8675839c/evaluation object to these procedures. SOP-04 Risk Management covers the risk process.

**1**

**Leverage AI to identify documents for your change order**

**2**

**Perform an efficient change impact analysis**

**3**

**Improve the quality of your change orders**



*“Feels like we are starting over every time. We can’t do paperwork for its own sake or risk the safety of our products because something in the change process was missed.”*

# Improve the quality of your change orders

Save reviewer's time

Audit perception

Reduce number of change orders

Open COs (2)

| FILTER BY IMPACT |   | FILTER BY PRIORITY |                |              |           |        |        |
|------------------|---|--------------------|----------------|--------------|-----------|--------|--------|
| Priority         | Title   | ID                 | Assign...      | Due D...     | Days O... | Impact | Status |
| ●                | <b>Creation of QMS</b><br>The purpose of this change order is to relea...                   | CO-5               | Tom Rish       | Dec 30, 2020 | 34        | Major  | Draft  |
| ●                | <b>Updates to drawings for Product A</b><br>The tooling for the Accelerator on Product A... | CO-6               | Wade Schroeder |              | 4         | Major  | Draft  |

# TRANSFORM YOUR CHANGE MANAGEMENT PROCESS

**1**

**LEVERAGE AI TO IDENTIFY DOCUMENTS FOR YOUR CHANGE ORDER**

**2**

**PERFORM AN EFFICIENT CHANGE IMPACT ANALYSIS**

**3**

**IMPROVE THE QUALITY OF YOUR CHANGE ORDERS**

# **HALO<sup>SM</sup>** FOR CHANGE MANAGEMENT

Predict the impact of change.



AI-powered  
recommendations that  
reduce risk and improve  
quality.



Real-time visibility into  
the impact of a change.



# HOW TO STREAMLINE CHANGE TODAY

## 3 THINGS YOU CAN DO TODAY:

1

Audit your current change control process to review the efficiency and effectiveness of building a change order.

2

Implement document control best practices that make finding, accessing, and analyzing changing documents for your change order easier.

3

Invest in purpose built tools to integrate AI into your change management process

# EXCLUSIVE WEBINAR OFFER:

## Change Control Starter Kit

### [2-for-1]

#### Includes:

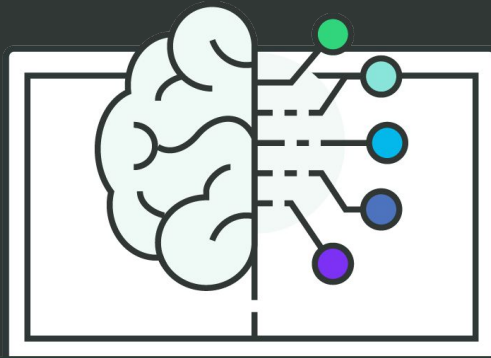
- Change order template
- Change impact analysis checklist

[www.greenlight.guru/change-impact-webinar-offer](http://www.greenlight.guru/change-impact-webinar-offer)



Thank **you!**





# Q&A

## DON'T FORGET!

Exclusive Webinar Offer: Free Change Control Starter Kit → [www.greenlight.guru/change-impact-webinar-offer](https://www.greenlight.guru/change-impact-webinar-offer)