



CUSTOMER WEBINAR

# **HOW TO PREPARE FOR AND DRIVE SUCCESSFUL AUDITS WITH GREENLIGHT GURU**

THURSDAY, JUNE 17TH, 2021 @ 11:00 AM EST

# AGENDA

- How to start preparing for your next audit
- Using Greenlight Guru during an audit
- Best practices for on-site or virtual audits and inspections
- Audit success stories and lessons learned from Greenlight Guru users themselves
- Q&A

Prepare for your next audit and **ensure success** by hearing from other GG customers on how they leveraged the solution to **pass FDA, ISO, MDSAP, and other notified body audits.**

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TODAY'S PRESENTERS:

Quality Gurus:



**Taylor Brown**  
Senior Medical Device Guru



**Sara Adams**  
Medical Device Guru

Customer Panel:



# DAMINI AGARWAL

Director of Product Development,  
Infinite Biomedical Technologies



**infinite**  
biomedical technologies



# VEENA SOMAREDDY

Co-Founder, Neuro Rehab VR



## NEURO REHAB VR





# MORRIS SHERWOOD

Quality & Regulatory Expert,  
Zyris Dental



# GENNADY UTKIN

Quality Assurance Analyst,  
Zyris Dental

**ZYRIS**<sup>TM</sup>



# QUICK POLL

1. Have you already undergone an audit using Greenlight Guru?

2. What type of audit is next for your organization?

# 3 WAYS TO **PREPARE FOR AN AUDIT**



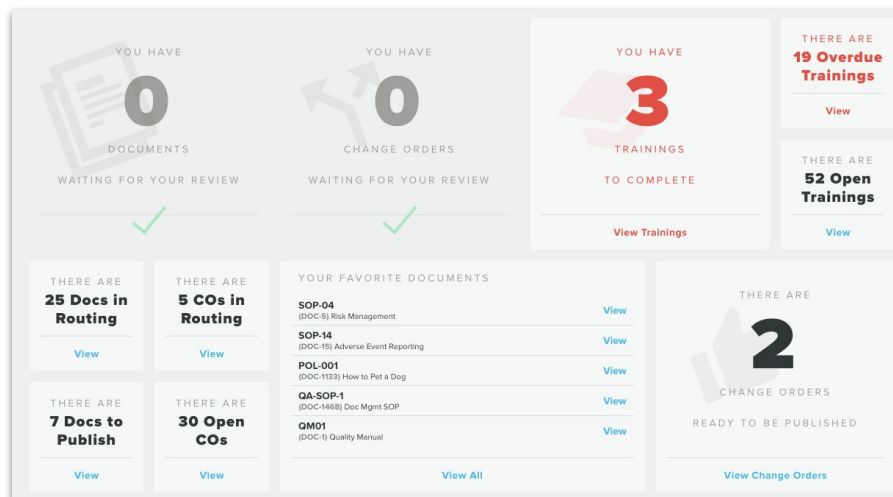
# GEMBA / PERFORM A DRY RUN

- Walk around the facility pretending to be the auditor.
- Identify changes that need to be made.



# GEMBA / PERFORM A DRY RUN

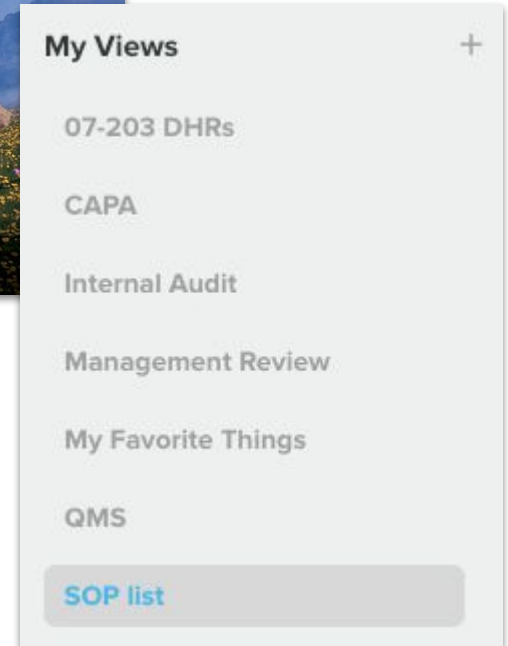
- Identify best people to be interviewed.
  - Be sure people know how to find procedures
- Make sure training is up to date



YOUR FAVORITE DOCUMENTS	
<b>SOP-04</b> (DOC-5) Risk Management	<a href="#">View</a>
<b>SOP-14</b> (DOC-15) Adverse Event Reporting	<a href="#">View</a>
<b>POL-001</b> (DOC-1133) How to Pet a Dog	<a href="#">View</a>
<b>QA-SOP-1</b> (DOC-1468) Doc Mgmt SOP	<a href="#">View</a>
<b>QM01</b> (DOC-1) Quality Manual	<a href="#">View</a>
<a href="#">View All</a>	

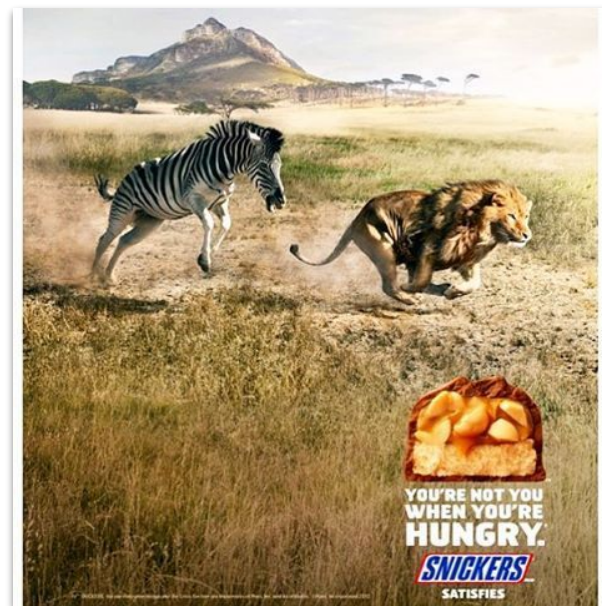
# GET ORGANIZED

- Read the audit plan & identify documents
- Find your Favorite things
  - Best CAPA, Training Event, Change Order, etc.
- Set up Document Views
  - Management Review, Internal Audit, Project Documents, etc.
- Planning prior to audit will let you be quick which helps establishes trust with your auditor



# ESTABLISH THE AUDIT SPACE

- Perform a tech check
  - Check Wifi
  - Check conferencing and screen sharing settings
- Set expectations for communicating with the auditor
  - How will you pass documents to the auditor?
- Set expectations for internal communication and scribes
- Audit etiquette reminders
- Make lunch plans



## DURING THE AUDIT

# ONLY PROVIDE WHAT IS REQUESTED

- Create an auditor-only group and share documents as requested

The screenshot displays the Greenlight Guru web application interface. At the top, a dark navigation bar includes the Greenlight Guru logo, a dropdown menu labeled 'MY COMPANY', and tabs for 'USERS' and 'GROUPS'. A search icon and a user profile for 'Taylor Brown, GG SME' are also present. Below the navigation bar, the 'Groups' section is active, showing a list of groups with 'Auditors (GROUP-5)' selected. The 'Auditors' group details are shown on the left, including a description 'To be shared with auditors', a status of 'Active', and an owner 'Taylor Brown'. The main content area shows the 'Users' tab for this group, with a table listing members. A 'Sharing' modal is open in the foreground, showing the document 'Auditors View PDF' being shared with the 'Auditors' group, specifically with 'Laura Court' (laura.court@greenlight.guru).

**MY COMPANY** ▾ | **USERS** | **GROUPS** | 🔍 | Taylor Brown GG SME

**Groups** ▾ **Auditors (GROUP-5)** + ⋮

**Auditors** ✎

Description  
To be shared with auditors

Status  
**Active**

Owner  
Taylor Brown

**Users** | Activity History

Name	Type
<b>Laura Court</b> laura.court@greenlight.guru	Internal

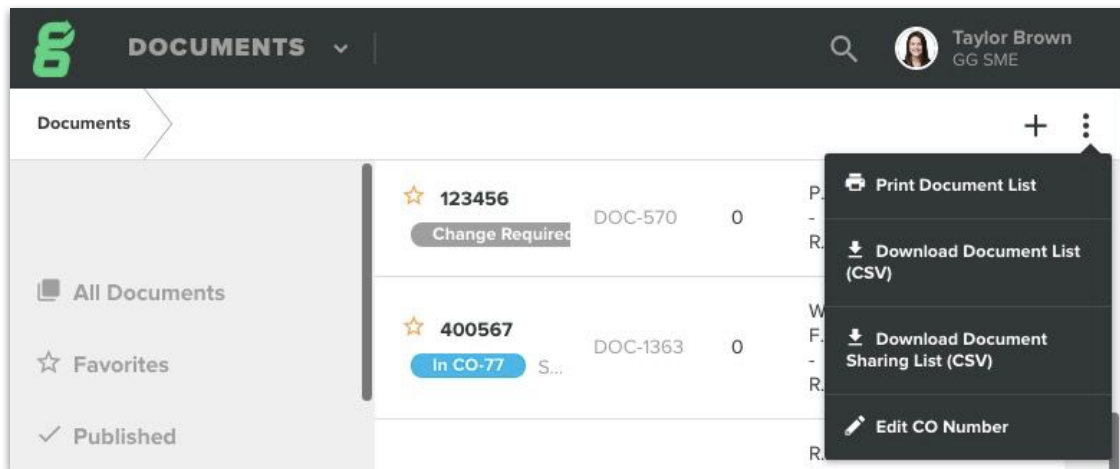
**Sharing** ✎

**Auditors**  
View PDF (1) ⬆

**Laura Court**  
laura.court@greenlight.guru

# ONLY PROVIDE WHAT IS REQUESTED

- Review document sharing settings within the Sharing List
- Do not forget to deactivate your auditors!





# READ MINDS

- Ask yourself “Where will the auditor go next?”
- Anticipate the question before asked
- Use Visualize to stay steps ahead





# READ MINDS

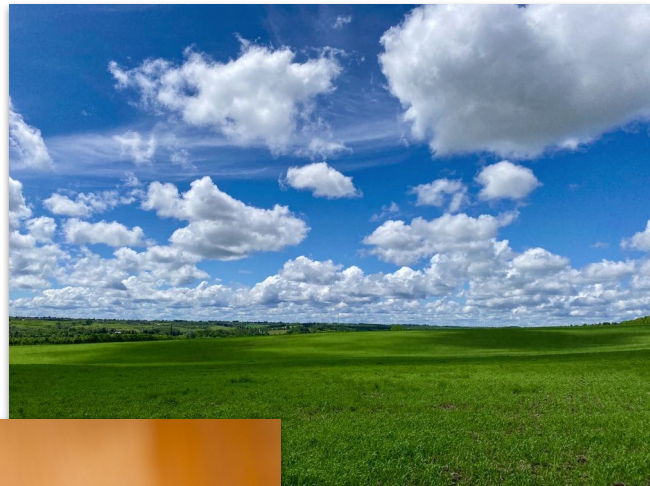
- Use Global Activity History to ~~stalk~~ locate your auditor

The screenshot displays the 'Global Activity History' page in the Greenlight Guru application. The interface includes a top navigation bar with the Greenlight Guru logo, a search icon, and a user profile for Taylor Brown (GG SME). Below the navigation bar, there are tabs for 'Administration' and 'Activity History', with 'Activity History' being the active tab. A sidebar on the left contains a 'CLEAR ALL FILTERS' button and filter sections for 'User' (set to Nathan Eckstein), 'Action', 'Workspace', 'Project', 'Start Date', and 'End Date'. The main content area shows a list of activity entries for Nathan Eckstein, including login attempts and document viewing actions. A right-hand sidebar contains links to 'HELP CENTER', 'MY ACCOUNT', 'MY SYSTEM', 'MY COMPANY', 'GLOBAL ACTIVITY HISTORY' (highlighted), and 'SIGN OUT'. A modal window titled 'Change Management' is open, showing details for a 'VIEWED' action on a 'Change Order Artifact'.

Global Activity History		
	Nathan Eckstein  LOGIN Successful Mon Jun 14 2021 13:57:39 GMT-0400 (Eastern Daylight Time)	
	Nathan Eckstein  LOGIN Successful Mon Jun 14 2021 13:41:46 GMT-0400 (Eastern Daylight Time)	
	Nathan Eckstein  VIEWED Change Order Artifact in CO-22 (Initial Upload Documents to GG) Mon Jun 14 2021 13:16:41 GMT-0400 (Eastern Daylight Time)	Change Management
	Nathan Eckstein  VIEWED Change Order Artifact in CO-22 (Initial Upload Documents to GG) Mon Jun 14 2021 13:11:35 GMT-0400 (Eastern Daylight Time)	Change Management
	Nathan Eckstein  VIEWED Change Order Artifact in CO-22 (Initial Upload Documents to GG) Mon Jun 14 2021 13:10:42 GMT-0400 (Eastern Daylight Time)	Change Management
	Nathan Eckstein  VIEWED (Signed) Document for Document SOP-01 (DOC-2) Ver. 1 Mon Jun 14 2021 13:10:30 GMT-0400 (Eastern Daylight Time)	Document Management
	Nathan Eckstein  VIEWED Printable Capa Artifact in CAPA-2 Mon Jun 14 2021 12:56:20 GMT-0400 (Eastern Daylight Time)	Capa
	Nathan Eckstein  VIEWED (Signed) Document for Document SOP-01 (DOC-2) Ver. 1 Mon Jun 14 2021 12:52:14 GMT-0400 (Eastern Daylight Time)	Document Management

# WORDS MATTER

- Keep the conversation positive
- Answer in absolutes
- Answer by pointing auditor to your procedure
- Pull up your procedures while the auditor is reviewing so you'll be ready to “read minds.”



# WORDS MATTER

- When all else fails, enjoy the silence.



## **CUSTOMER PANEL: ADVICE + SUCCESS STORIES**

# HEAR FROM OTHER GG USERS

Experienced in using GG for FDA, ISO, MDSAP, and other notified body audits.

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*Webinar recording will be sent via email and accessible via our Help Center.*