



# 2024 Revealed: What's New and What's Next for Greenlight Guru

Thursday, January 25th, 2024

# Latest Advancements, Future Updates, and a Look into our Product Roadmap

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## Today's Presenters:



**Etienne Nichols**  
Medical Device Guru



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Sr Mgr, Product Marketing



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Senior Product Manager



**Chris Hicks**  
Product Manager



**Stanley Finkelshteyn**  
Vice President, Product



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# MedTechSuite

# Moving MedTech Forward

**100+** years of industry experience

**522k** podcast listeners

**200k+** look to us for the latest in MedTech

**#1** blog & podcast in the industry

## TRUSTED BY LEADING MEDTECH COMPANIES GLOBALLY

**1700+**

510(k) clearances & CE marked devices

**2000+**

ISO 13485 certifications

**1100+**

I-III/SaMD/IVD

MedTech companies worldwide in all device classes and types

**500+**

clinical trials



*"Best QMS I have ever used..."*

*"User-friendly EDC and esponsive support team"*

*"This is the easiest eQMS I have used in the 20 years I have been in the Medical Device Industry."*

*"The whole experience of using Greenlight Guru Clinical is accessible and user-friendly"*

*"Makes your QMS Simple and Effective"*

# For Today

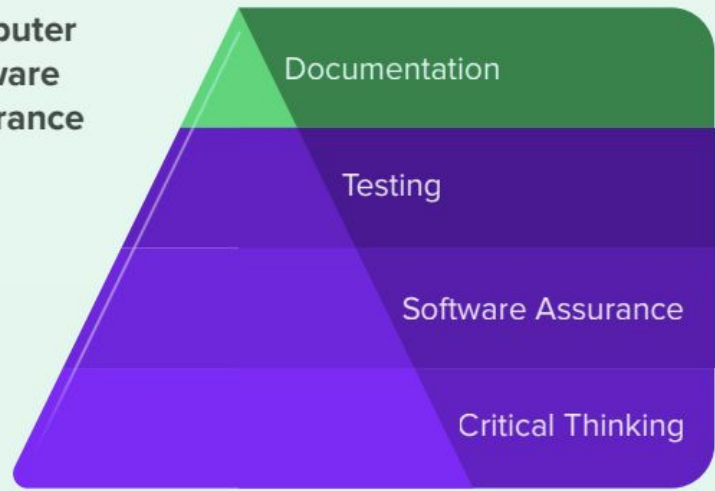


# What's New

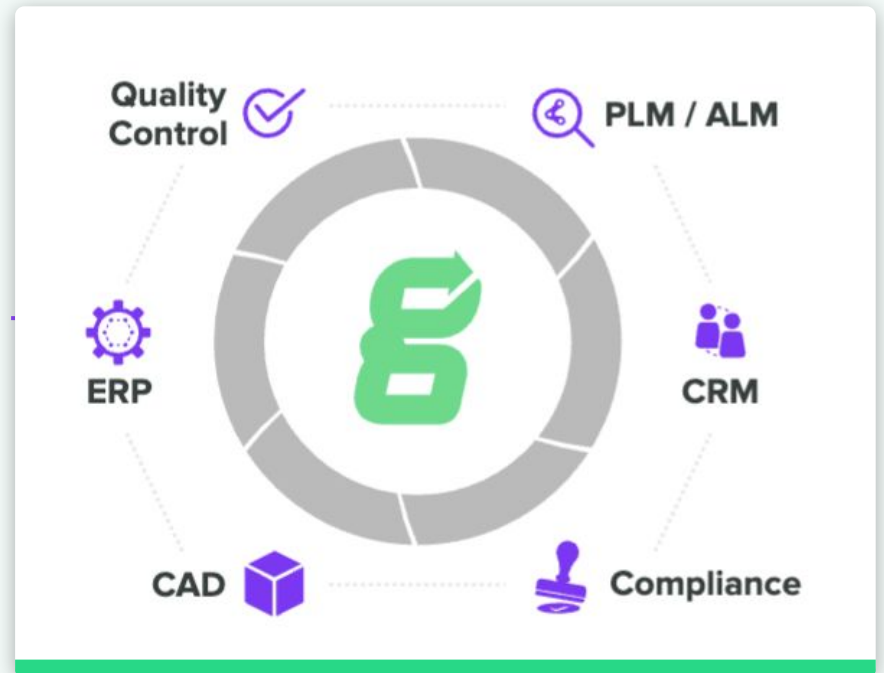
*A look back at 2023 and recent updates*

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# Computer Software Assurance



Po	SEVERITY	RISK	RISK CONTROLS	CONTROL VERIFICATIONS	IMPL
0.25	Frequent	Critical	HIGH	1 Risk Controls · 0 Control Verifications · 0 Implementation	
0.0009675	Occasional	Major	HIGH	2 Risk Controls · 3 Control Verifications · 1 Implementation	
1.0000	Occasional	Critical	MEDIUM	1 Risk Controls · 3 Control Verifications · 1 Implementation	
0.000000000	Insignificant	Minor	MEDIUM		
8.68E5	Insignificant	Critical			



Training Events (9)	Users (623)
77.8% COMPLIANCE	96.7% COMPLIANCE

Requirements (19)	ID	Trainer	Status
Sample Training	REQ-01	Chris Hicks	Active
Expense Training	REQ-02	Amanda Garcia	Cancelled
510 Policy Training	REQ-03	Noelani Buonomo	Plan
Emergency Action Plan	REQ-04	Jimmy Valner	Active



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# Clinical

The screenshot shows the Greenlight Guru Clinical interface. At the top, there is a navigation bar with the Greenlight Guru logo, the text "Official Demo 2.0 - eCRF > Reports", and a sidebar on the left with various icons. Below the navigation bar, there are tabs for "Data Points", "Forms", and "Data Events". A "Quick filter" dropdown and a "FILTERS" button are visible. The main content area displays a table with the following data:

Subject Id	Site	Enrollment Status	Data Event	Form	Form Updated	Question
002	Normal Study Site	Excluded	Adverse Event	AE form	2021-01-07 05:20	Please elaborate on location if other
002	Normal Study Site	Excluded	Adverse Event	AE form	2021-01-07 05:20	What is the current location of the device
002	Normal Study Site	Excluded	Adverse Event	AE form	2021-01-07 05:20	Event Categorisation
002	Normal Study Site	Excluded	Adverse Event	AE form	2021-01-07 05:20	Anticipated?
002	Normal Study Site	Excluded	Adverse Event	AE form	2021-01-07 05:20	Relationship to device

# What's Coming

*What we have in store for upcoming releases*

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**Too many  
companies struggle  
through managing risk.**

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**53%** are still using general purpose tools for risk management

- ✘ Time
- ✘ Resources
- ✘ Money
- ✘ Guesswork
- ✘ Rework
- ✘ Business Risk
- ✘ Patient Risk

# Biggest challenge?

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It's a tie between

1. lack of **visibility/traceability of risk management files** and
2. lack of **clear ownership** of risk throughout the product life cycle.

**PROJECTS**

Projects: New - PEMS

Quick Search...

Create DR

User Needs | Design Inputs | Design Outputs | Design Verifications | Design Validations

UN-1 **User Need - 1**  
Device shall compute and display analytics of data stored in device. JIRA Story DEMO-2

UN-2 **User Need - 2**  
Screen brightness shall be adjustable to allow viewing in a lowlight environment

UN-3 **User Need - 3**  
Device shall display trending of stored data. JIRA Story DEMO-8

DI-1 **Design Input - 1**  
Device shall compute and display:  
• Average of readings  
• High/low readings  
• Range of readings stored in device  
JIRA Task: DEMO-1

DO-1 **Design Output - 1**  
See the following section of linked SDS document:  
• Data Analytics  
Source Code: [Github link for Data Analytics source code](#)

VER-1 **Design Verification - 1**  
Verification of the computation and display of average of readings, high/low readings, and the range of readings stored in device. JIRA Task DEMO-1

VAL-1 **Design V**  
User Study for JIRA Story DEMO

**CAPA**

CAPA Management... Source

**CAPA Management 1**

Description  
This CAPA will be opened to investigate and determine if any corrective actions are needed.

Priority **Urgent**

Date of Event **Mar 10, 2021**

**Quality Review**

Start Date: Mar 21, 2022 | End Date: Aug 21, 2022

Draft | Routing | Approved | Published

Reviewer: Marcus Mueller (Complete), Divya Singh (Reviewing)

Parallel Track: Patrick Rish, Mary Cook

**AUDIT-O Quality Review**  
Calibration Process Internal Audit | Doc-1 | 0 | Policy-Routed | Standards

**11-85065-XX SLDDRW**

Approved By: [Name], [Date], [Digital Key]

Version History: Author, Effective Date, Ver., Status

**Create a Design Review Plan**

1 Components | 2 Design Controls | 3 Details

User Need |  Design Input

Design Output |  Design Verification

Design Validation |

✓ Reduce Risk

✓ Spark Innovation

✓ Drive Collaboration

✓ Stay Compliant

# Conduct Efficient, Compliant Risk Reviews

The screenshot displays the 'RISK MANAGEMENT' interface for a project named 'Genesis Cardiac Implant'. The current view is 'Initial risk review', which is in an 'In Review' state. The workflow consists of four stages: 1. Draft, 2. Routing, 3. Approved, and 4. Published. The 'Draft' stage is currently active. A table lists the reviewers and their status:

Reviewer	Reason	Status
1. Makenna Bator (Owner)		Approve
2. Parallel Track		
Allison Wilson (Reviewer)		Waiting
Alex Aminoff (Reviewer)		Waiting
Ashlynn Baptista (Reviewer)		Waiting
Maria Levin (Reviewer)		Waiting
Marvin Dokidis (Reviewer)		Waiting

- ✓ Drive Collaboration & Accountability
- ✓ Build Risk Management File
- ✓ Simplify Compliance & Audit Readiness

***See it in action***

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**Maintaining training compliance is still a burdensome activity.**

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**39%** say the biggest training challenge is ensuring training is completed

**40%** are still using general purpose tools for training management

# It's often...

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- ✘ Too Manual
- ✘ Too Much of a Time & Resource Drain
- ✘ Too Challenging to Maintain
- ✘ Not Always Audit Ready

# Manage & Automate Required Training

The screenshot displays the 'TRAINING' section of the Greenlight Guru software. The interface includes a navigation bar with 'TRAINING', 'ACTIVITIES', 'PEOPLE', and 'MY TRAINING'. Below this, there are tabs for 'Events (67)', 'Requirements', and 'Documents'. A sidebar on the left offers filters for 'Open', 'Complete', and 'Canceled'. The main area shows a table of training events with columns for Title, ID, Due Date, Trainer, Percent Reviewed, and Status. Each row includes a progress bar and a status indicator (Active, Plan, or Overdue).

Title	ID	Due Date	Trainer	Percent Reviewed	Status
A New Test Procedure Training Desc...	TRN-48		Barret Mueller	57%	Active
Audit Training (Copy of TRN-510) IA-2023-001 training...descr.	TRN-518		Sara Adams	0% 100%	Active
Eng Group n/a	TRN-507	26 AUG 2023 9:42am (EDT)	Craig Moore	0%	Plan
Essential Medical Training desc	TRN-506	31 AUG 2023 11:47am (EDT)	Nathan Eckstein	0%	Plan
example example	TRN-504	17 AUG 2023 2:27pm (EDT)	Taylor Holcomb	0%	Plan
Example Example	TRN-533	27 OCT 2023 10:09am (EDT)	Taylor Holcomb	0%	Overdue

- ✓ Automatically Re-Assign Training
- ✓ Eliminate Training Gaps & Errors
- ✓ Simplify Compliance & Audit Readiness



***See it in action***

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# What's Next

*Where do we have our focus set for 2024*

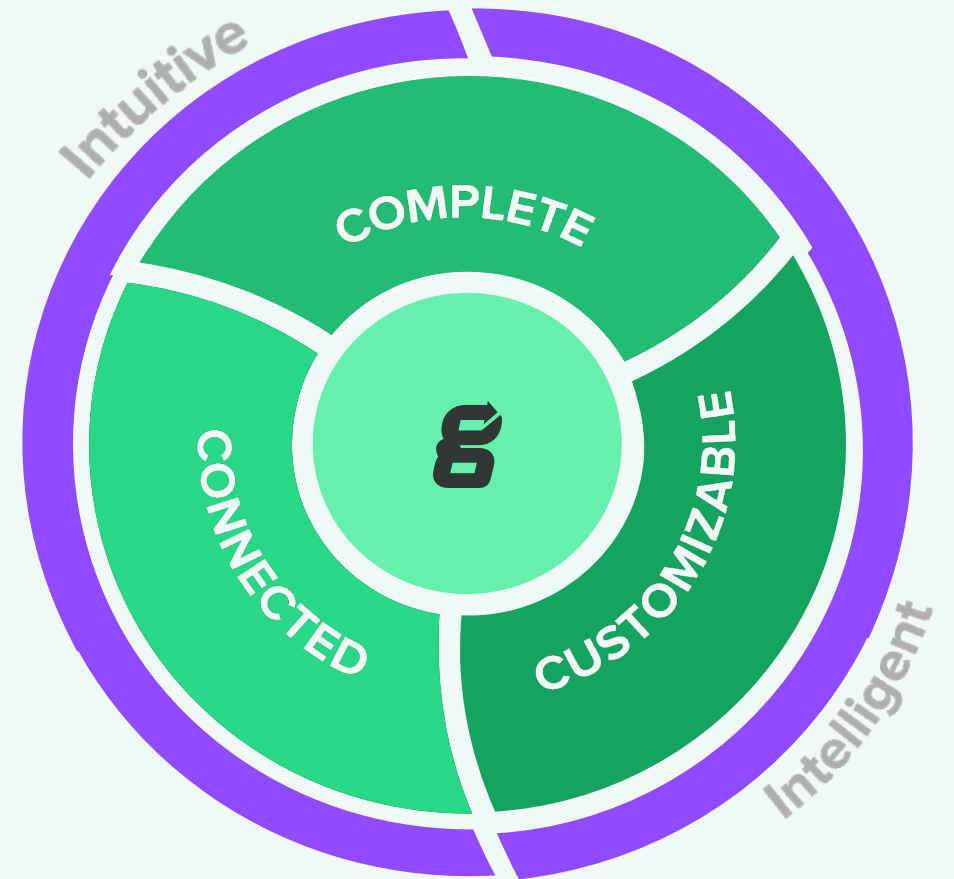


**Stanley Finkelshteyn**  
Vice President, Product

# 2024 Product Priorities

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**Improve the quality of life** by providing cloud-based solutions for MedTech companies to bring life-changing products to people faster, and with less risk.



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# Complete

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A platform that profoundly understands MedTech and surfaces insights to customers that help drive action, where the action leads to efficiency, quality, and improved time to market.

**Training Visibility:** Continue to drive efficient and compliant training

**Now**

**Quizzing:** Validate that users understand training.

**R&D**

**Robust Supplier Management:** Information object and lifecycle management capabilities for suppliers.

***Under Consideration***

# Connected Ecosystem

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Fit and connect into our customer's broader tech stacks making it simple to get data in and out of the platform for further analysis or to support internal workflow(s).

**API (Import & Export):** Allow external systems to retrieve and load data into Greenlight Guru

*Ongoing*

**Quality Data Syncs:** Real-time updates for events in your quality process lifecycle

*Under Consideration*

# Customizable

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Build for added flexibility, allowing for personalized adaptations in workflows and data management to meet specific customer needs.

**Bulk Actions:** Efficiently find, manipulate and transport information in a flexible way

*R&D*

**Notification Management:** Manage notification preferences for organization and users.

*R&D*

**Quality Process:** Introduce flexibility and configuration to meet different needs

*Under Consideration*

# Intuitive

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Ensure our platform is designed for simplicity and efficiency, offering an accessible, user-friendly experience for all customer throughout their journey.

**Advanced UX:** Enhance the experience to support common actions and accessibility

*R&D*

**Simplified Onboarding:** Adopt quickly and spend less time learning how to use the app

*Under Consideration*

# Intelligent

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Infusing AI and data insights into our platform to empower MedTech professionals with smarter decision-making tools for better outcomes.

**Digital Guru:** Conversational search with regulatory-domain knowledge

*R&D*

**Risk Intelligence:** Recommend Hazards and Harms

*Under Consideration*

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**Wait there's more...**

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**Clinical**

2024

### **Continued Compliance**

eConsent for additional markets and use-cases

IMDRF AE report coding

R&D

### **Advancing MedTech Studies**

Enhancing study configuration, rules, and notifications

### **Empowering Users**

Site status reports

Audit log exports

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# Our Journey Involves **You**

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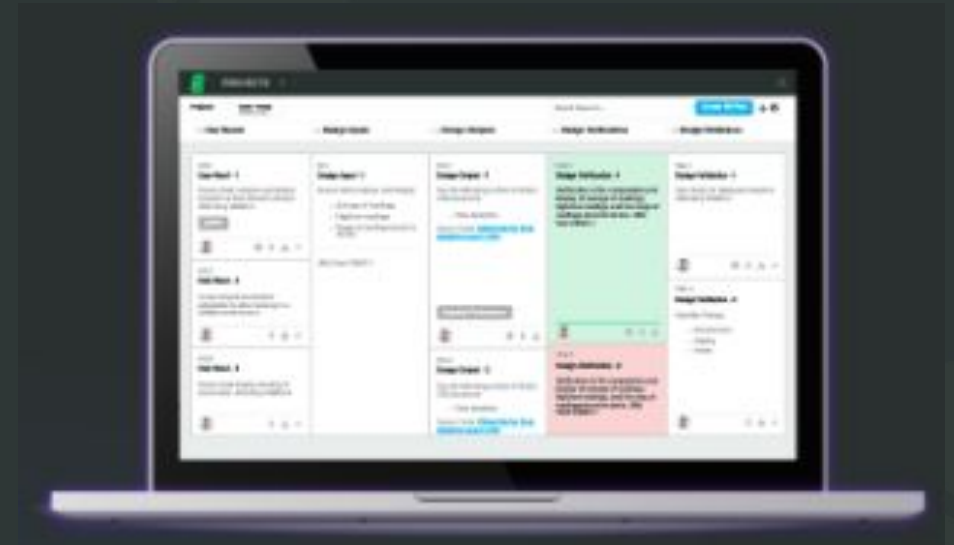
Providing and pursuing opportunities of discovery, collaboration, and feedback with our partners to build great products and services for the MedTech industry.

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# Join our community

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Not a customer? [Get a personalized demo today](#) of our complete offering and stay in the know for upcoming product advancements slated for 2024.



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**Thank you!**

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**Q&A**