



Integrating Risk Management Throughout the Entire Device Lifecycle with Greenlight Guru Quality

Greenlight Guru QMS Live Software Demo

February 8th, 2024

Documenting the design of a **safe product that meets user needs and requirements fuels the **performance and success** of your entire project.**

Deep-dive into Greenlight Guru's Risk Workspace

Today's Presenters:



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Solutions Engineer

greenlight guru



greenlight guru

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“Best QMS I have ever used...”

“User-friendly EDC and responsive 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”

Create a Design Review Plan

- 1 Components
- 2 Design Controls
- 3 Details

User Need Design Input
 Design Output Design Verification
 Design Validation

PROJECTS

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

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

User Need - 3
Device shall display rendering of stored data: JIRA Story DEMO-8

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

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

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

Design Validation - 1
User Study for JIRA Story DEMO-1

CAPA Management 1

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

Priority: Urgent

Quality Review

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

Drift Routing Approved Published

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

AUDIT-O Quality Review
Calibration Process Internal Audit

11-85065-XX SLDDRW

Approved By: [Redacted]

Version History: Author, Effective Date, Ver, Status

✓ Reduce Risk

✓ Spark Innovation

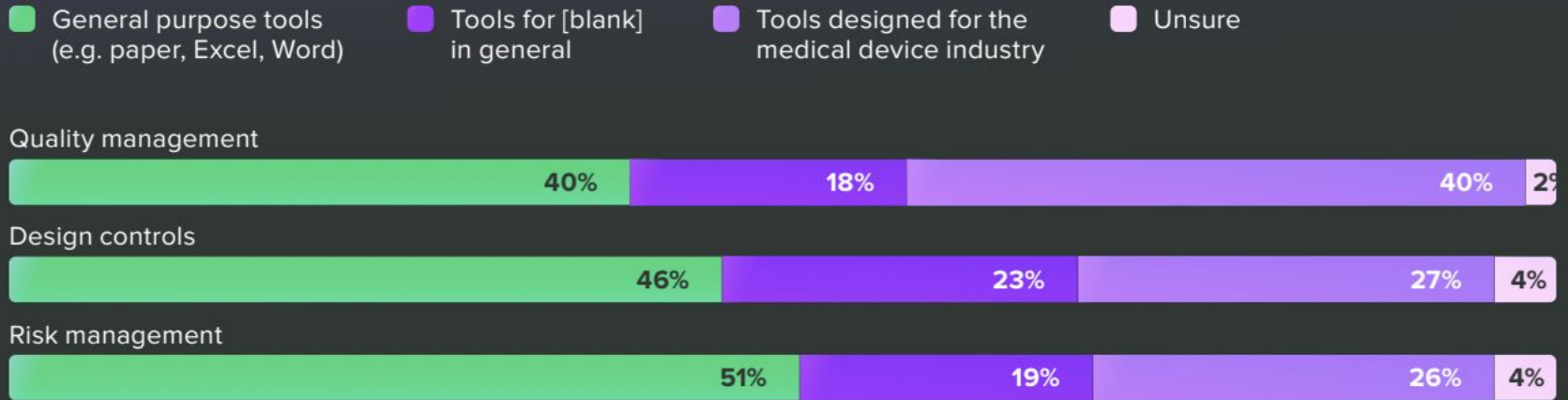
✓ Drive Collaboration

✓ Stay Compliant

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

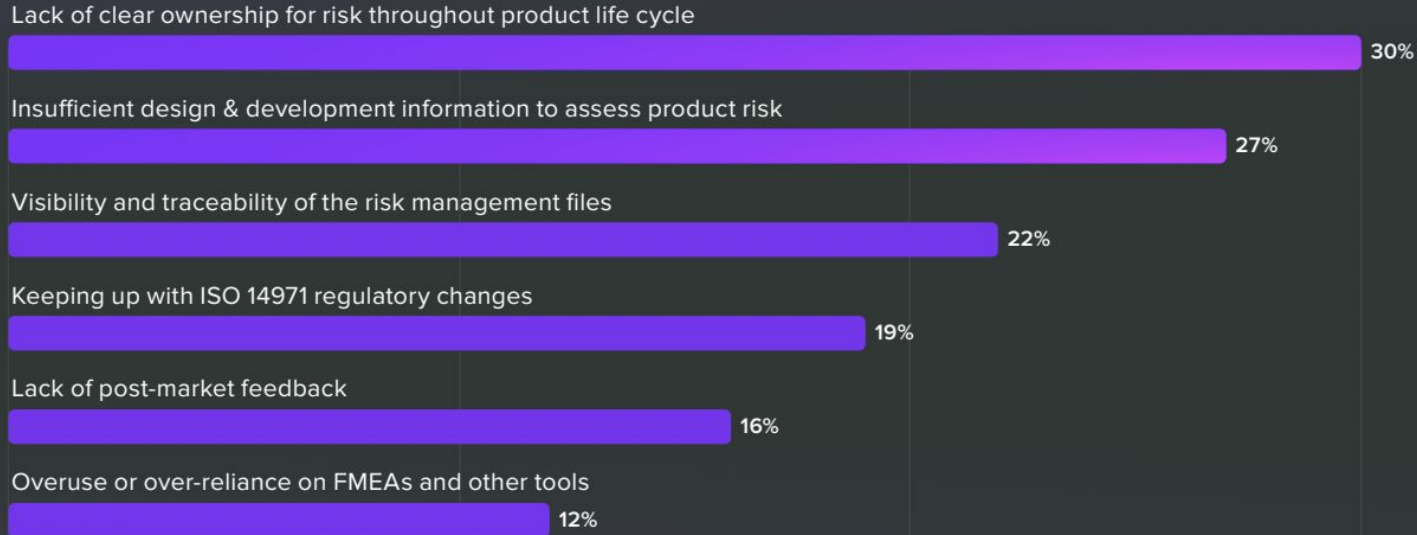
- ✘ Time**
- ✘ Resources**
- ✘ Money**
- ✘ Guesswork**
- ✘ Rework**
- ✘ Business Risk**
- ✘ Patient Risk**

Risk 🤝 Spreadsheets



Biggest Challenges with Risk

Top challenges companies face when managing risk for their devices:



Why A Risk-Based QMS

- ✓ Greater emphasis being put on Risk due to ISO 14971 and regulatory bodies
- ✓ Total product life cycle traceability - Easier to come back to and assess Risks.
- ✓ Tracing Risk throughout your quality ecosystem

Management Review – What is impact of failing to review critical items?

Training – What are consequences of ineffective training?

Calibration – What happens if done incorrectly?

Purchasing – What effect do purchased products have on safety and performance?

Supplier Monitoring – Are suppliers able to meet regulatory requirements?

See it in action

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