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:

Laura Court
Solutions Engineer

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TRUSTED BY LEADING MEDTECH COMPANIES GLOBALLY

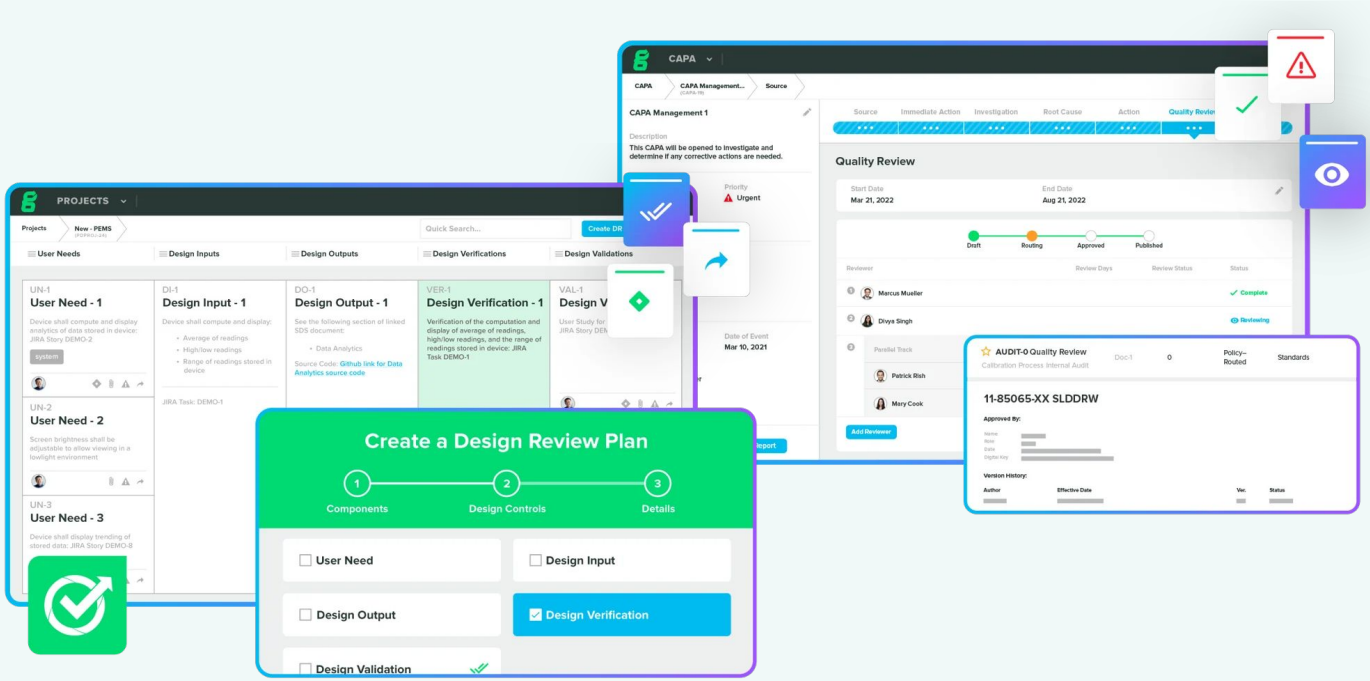
"Best QMS I have ever used..."

"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"

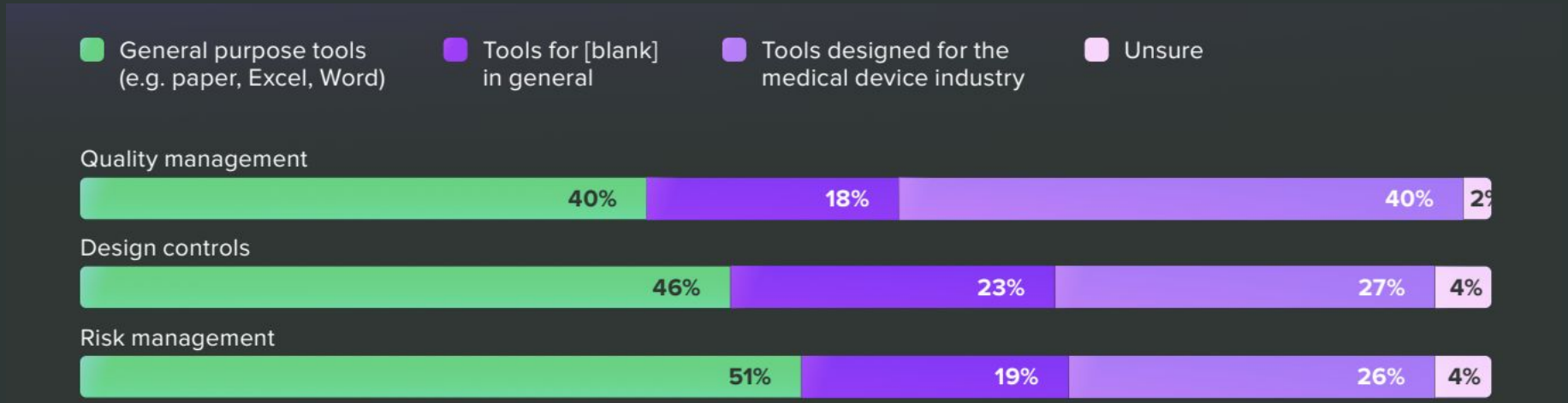


- Reduce Risk
- Spark Innovation
- Drive Collaboration
- Stay Compliant

Too many companies struggle through managing risk.

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

Risk 🤝 Spreadsheets



*2023 MedTech Industry Benchmark Report

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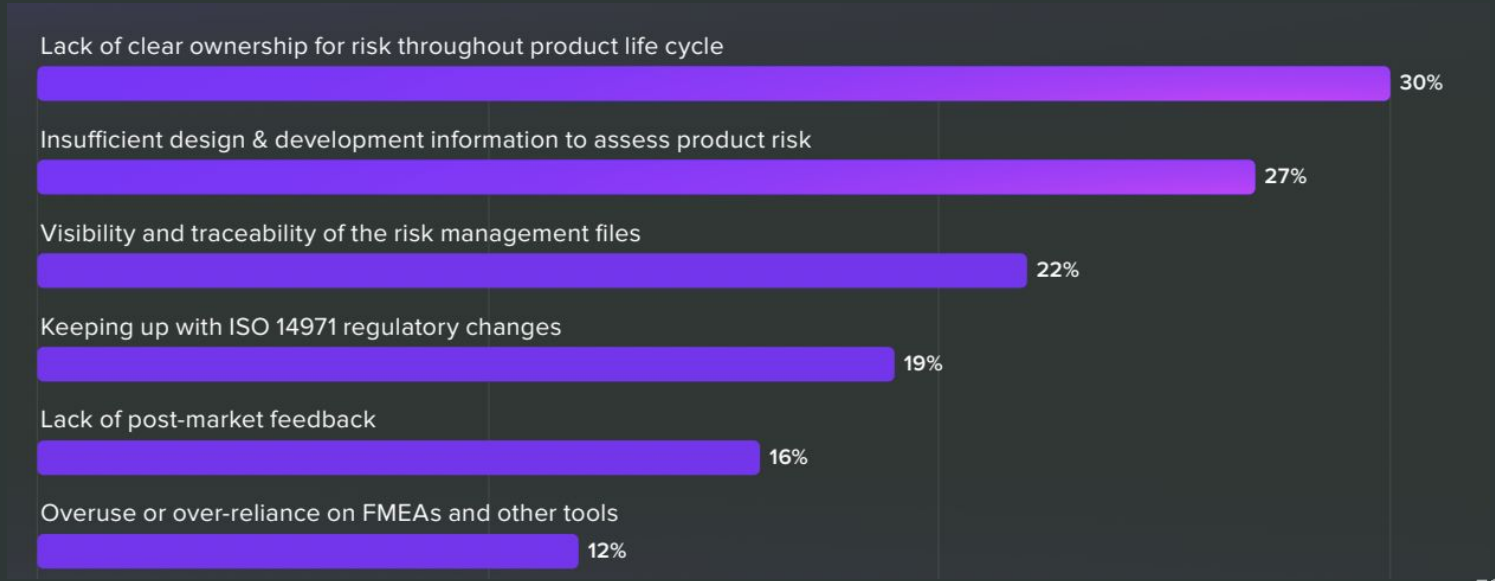
Biggest Challenges with Risk

Top challenges companies face when managing risk for their devices:



**2023 MedTech Industry Benchmark Report*

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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