



# Risk Solutions

## Sneak Peek Partner Webinar

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May | 2023

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# Today's Speakers



**Pete Plotas**  
VP, Global Alliances



**Radhika Pandya**  
Assoc. Product  
Marketing Manager



**Rob Granger**  
Product Manager  
Risk Mgmt



**Tyler Foxworthy**  
Chief Data Scientist



# The Problem with Risk in MedTech

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- ✘ Time
- ✘ Resources
- ✘ Money
- ✘ Guesswork

# Biggest Challenges with Risk

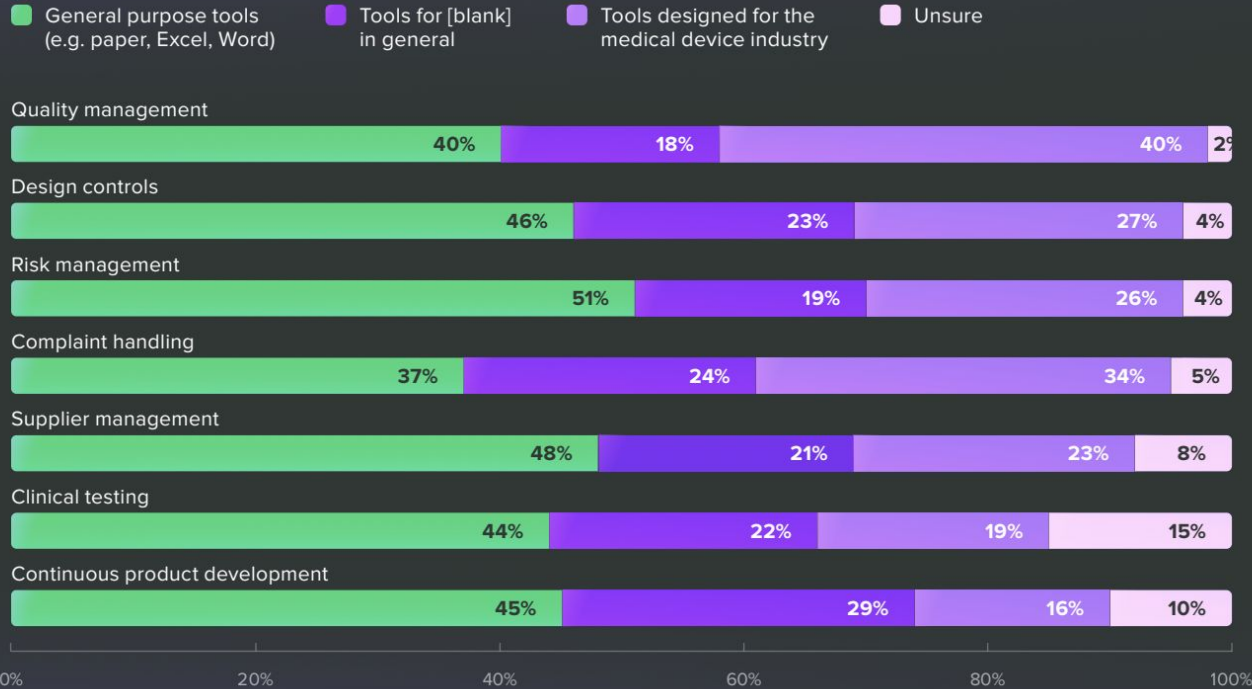
Top challenges companies face when managing risk for their devices:



\*2023 MedTech Industry Benchmark Report

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# Risk & Spreadsheets



\*2023 MedTech Industry Benchmark Report

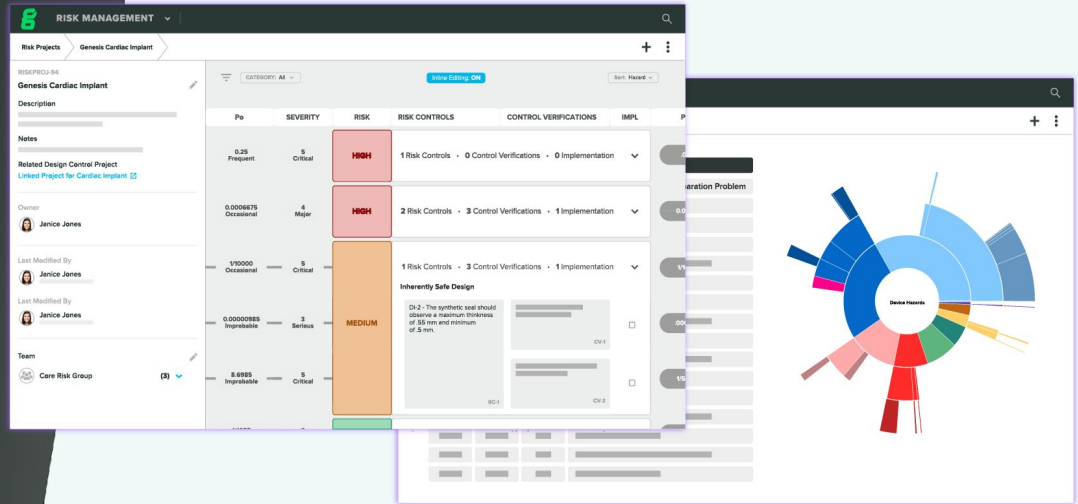
# The Problem with Risk in MedTech

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Teams need **better software**  
and **better data** that help  
them assess & document  
risk with traceability across  
the device lifecycle.

# Introducing... Risk Solutions

A New Era of Risk  
Management for  
MedTech.



Risk Management = better software

Risk Intelligence = better data

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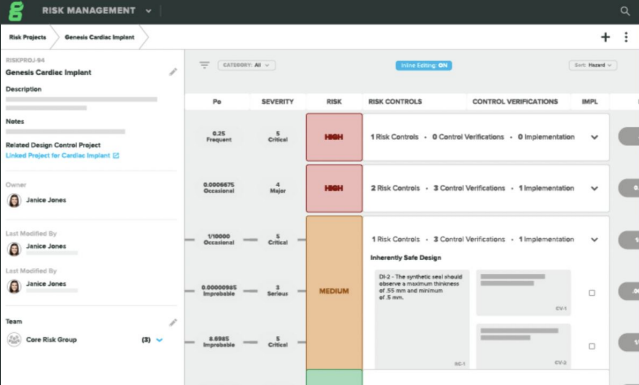


# Risk Management

Risk Management aligns with ISO 14971:2019 and provides intuitive, collaborative workflows for creating risk matrices and documenting risk while providing complete traceability throughout the entire device life cycle.

- New, standalone workspace
- In-line editing
- IMDRF codes for Harms and Hazards
- Po, P1/P2 probability modes
- & more

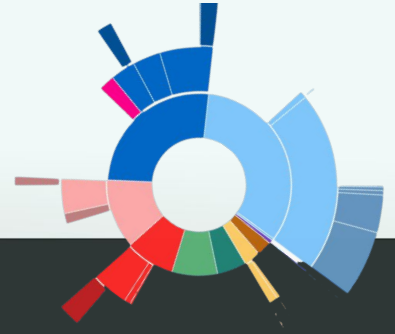
*Let's see a demo →*



The screenshot displays the Risk Management interface for a project named 'Genetic Cardiac Implant'. The interface includes a sidebar with project details and a main table for risk assessment. The table has columns for Probability (Po), Severity, Risk, Risk Controls, Control Verifications, and Implementation (IMPL). The risks are color-coded: High (red), Major (orange), and Medium (yellow).

Po	SEVERITY	RISK	RISK CONTROLS	CONTROL VERIFICATIONS	IMPL
0.25 Frequent	5 Critical	HIGH	1 Risk Controls	0 Control Verifications	0 Implementation
0.000005 Occasional	4 Major	HIGH	2 Risk Controls	3 Control Verifications	1 Implementation
1/1000 Occasional	5 Critical	HIGH	1 Risk Controls	3 Control Verifications	1 Implementation
0.000005 Improbable	3 Serious	MEDIUM	Inherently Safe Design		
0.0005 Improbable	5 Critical	HIGH			

# Risk Intelligence



**Coming Soon!** Our in-house data science team is working on a new technology that will transform the way you approach risk by enabling you with insights.

**What is it?** AI coupled with advanced statistical modeling provide you with risk data for your device in seconds

**What data will it provide?** Hazards, harms, probabilities of occurrence - with confidence intervals for devices based on product codes and device keywords

[Let's take a quick look →](#)

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# What's Next?

Risk Management is slated for June 21 release

Additional information sessions to come on Risk Solutions

Share your feedback / reactions with us

Contact your Partner Account Manager to discuss these solutions

# Resources For You

[Walkthrough](#) of key features in new Risk Management

[1-Pager](#) about Risk Management

[Upcoming webinar](#) - Implementing Risk Throughout the Entire Product Lifecycle

*More to come in Help Center and GGA as we approach the release*

# Poll & Q/A