WEBINAR

HOW TO INTEGRATE RISK MANAGEMENT THROUGHOUT THE LIFECYCLE OF A MEDICAL DEVICE IN THE COMING DECADE

Jon Speer
Co-Founder & VP of QA/RA at Greenlight Guru

greenlight guru

ABOUT THE PRESENTER

Jon D. Speer

Co-founder and VP of QA/RA of Greenlight Guru

- **22+** years in medical device industry
- Product development engineer, quality manager, regulatory specialist
- **40+** products to market
- Expert at QMS implementations
- Dozens of ISO audits & FDA inspections

Greenlight Guru produces beautifully simple quality, design control and risk management software exclusively for medical device manufacturers.

jon.speer@greenlight.guru
+1 317 960 4280

greenlight guru

MEDICAL DEVICE QUALITY IS ALL WE DO, AND WE'RE ALWAYS AHEAD OF THE GAME

75
years industry experience

275k
podcast listeners

#1
blog and podcast in the industry

90k
look to us for the latest in medical device quality

FEATURED IN

THE VERGE · TechCrunch · Forbes · QUALITYDIGEST · MDDI · Inc. · MedTech Intelligence · MED DEVICE ONLINE · Medical Design & OUTSOURCING · TNW THE NEXT WEB · Entrepreneur · MPO

G2 CROWD

"One stop shop for MDQMS"

"My QMS is world class"

"Greenlight Guru Software is the handrail for Medical Device Development and Documentation"

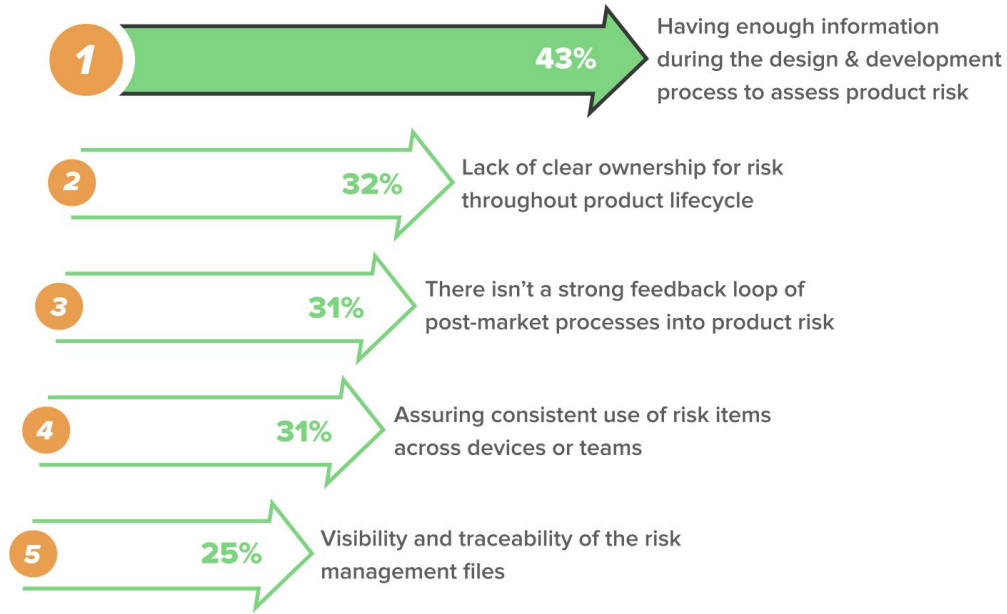
greenlight guru

Topics We'll Cover Today

- Current challenges with Risk Management for medical device companies
- Understanding of Risk Management as defined by ISO 14971:2019
- Incorporating risk management throughout the design control process
- Using risk management as a tool during design & development
- Applying a "risk-based approach" to all your QMS processes
- Q&A

CURRENT CHALLENGES IN RISK MANAGEMENT

Top 5 Challenges in Managing Risk

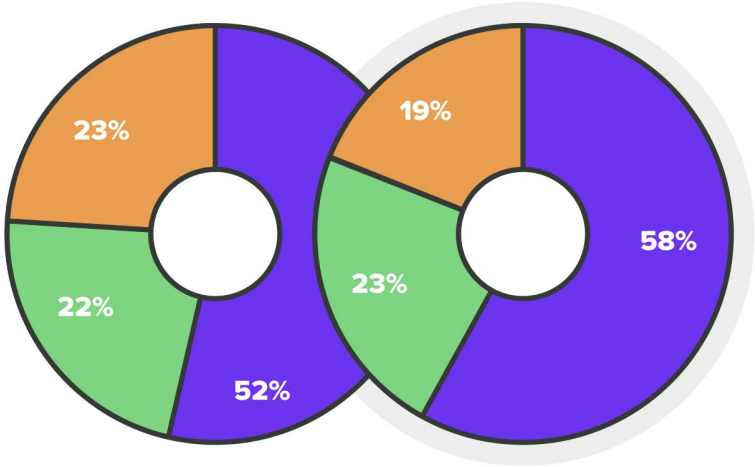


Source: Greenlight Guru | 2019

CURRENT TOOLS & TECHNOLOGY

Over half of medical device companies are leveraging legacy and ad-hoc tools creating tremendous **(and costly) inefficiencies**, as well as introducing both **patient and business risk.**

Design controls & risk management technology | Quality management processes technology

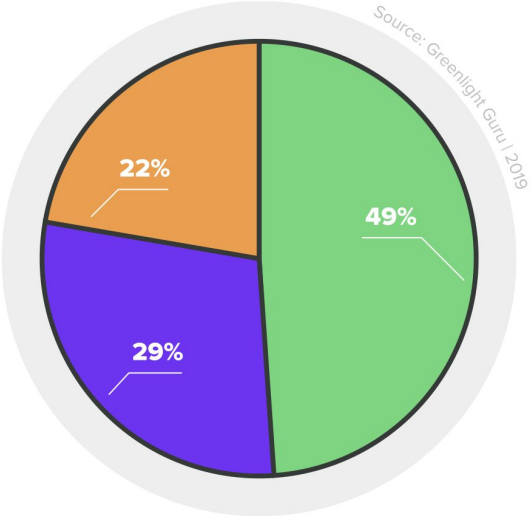


- **52%** We use legacy tools
- **22%** Use more specialized tools, but not best-in-class
- **23%** Use best-in-class tools

- **58%** We use legacy tools
- **23%** Use more specialized tools, but not best-in-class
- **19%** Use best-in-class tools

Source: Greenlight Guru | 2019

INTEGRATING RISK MANAGEMENT



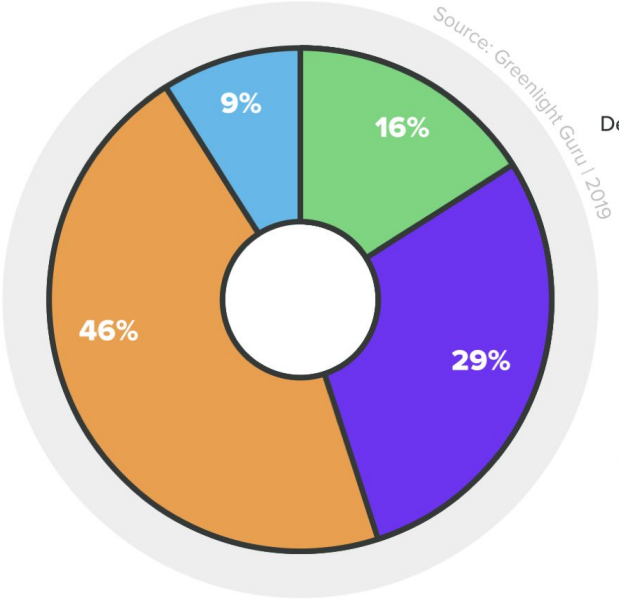
49%
We fully integrate risk management into our quality management system throughout the product lifecycle.

29%
We do not fully integrate risk management into our quality management system, and documenting risk takes modest effort.

22%
We do not fully integrate risk management into our quality management system, and documenting risk takes substantial effort.

1 in 3 say product level risk management is minimally or not at all integrated with post-market quality processes.

BENEFITS OF INTEGRATED RISK



Achieving Closed-Loop Traceability

Describe your company's current ability to achieve closed loop traceability

- 16% We cannot demonstrate closed loop traceability consistently (and have no plans to change this in the next 2 years).
- 29% We cannot demonstrate closed loop traceability, but have plans to do so in the next 2 years.
- 46% We can currently demonstrate closed loop traceability.
- 9% Unsure

> Of those that can demonstrate CLT, **1 in 3** say it takes substantial effort to do so.
>
> Part of achieving CLT, requires reaching fully integrated risk management.

UPDATES TO ISO 14971:2019

REVISIONS TO ISO 14971

- Normative references
- Updates terms & definitions
- Clarify risk analysis
    - Benefit-Risk Analysis
- Production & post-production activities
    - Alignment with ISO 13485

Guidance:

- Annex A: Rationale for requirements
- Annex B: Risk Management for medical devices
- Annex C: Fundamental risk concepts

UPDATES TO ISO 24971

All information in ISO TR 24971:2019 is guidance and is NOT REQUIREMENTS

- **Annex D - Risk concepts**
- **[NEW] Annex F - Risk management for cybersecurity**
- **[NEW] Annex G - Risk management file**
- **Annex H - In vitro diagnostic (IDV) devices**

IMPACT IN EU

- EN ISO 14971:2019
- Additional annexes
    - Z Annexes - address issues in RM process with Medical Device, Active Implantable, and IVD Directives
- ~~MDD~~ → EU MDR

UNDERSTANDING RISK MANAGEMENT

KEY TERMS:

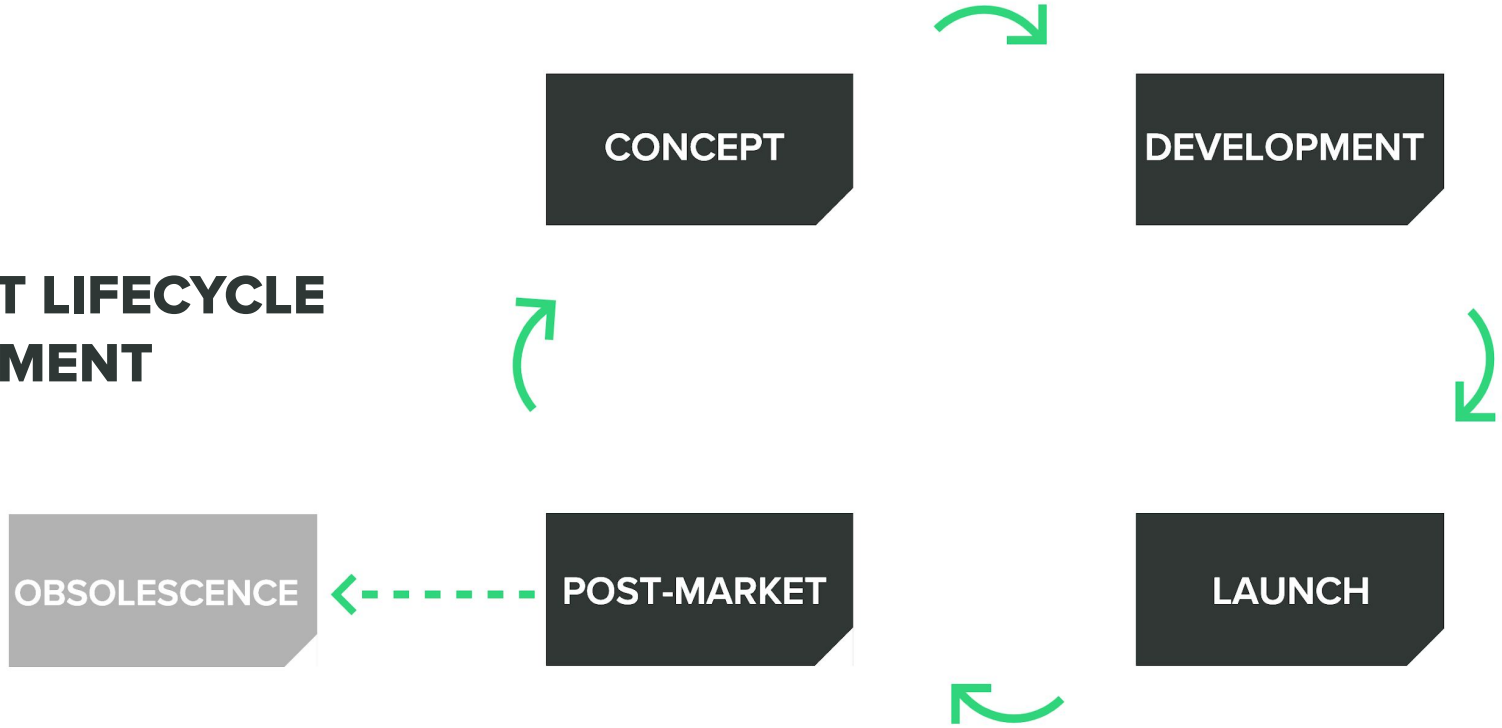
- **Risk Analysis** - systematic use of available information to identify hazards and to estimate the risk
- **Risk Estimation** - a process used to assign values to the probability of occurrence of harm and the severity of that harm
- **Risk Evaluation** - a process of comparing the estimated risk against given risk criteria to determine the acceptability of the risk
- **Risk Assessment** - overall process comprising a risk analysis and a risk evaluation
- **Risk Control** - process in which decisions are made and measures implemented by which risks are reduced to, or maintained within, specified levels
- **Residual Risk** - risk remaining after risk control measures have been taken

RISK MANAGEMENT FILE =

- Risk Management Plan
- Risk Analysis
- Risk Evaluation
- Risk Controls
- Evaluation of Overall Risk Acceptability
- Risk Management Review
- Production & Post- Production Risks

RISK MANAGEMENT PROCESS OVERVIEW

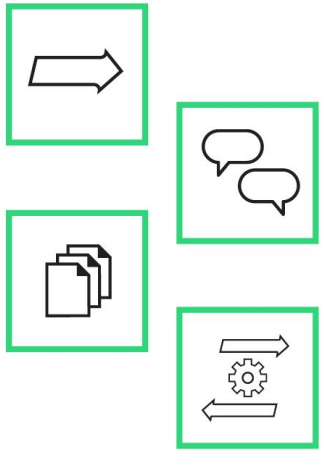
PRODUCT LIFECYCLE MANAGEMENT



RISK MANAGEMENT PLAN

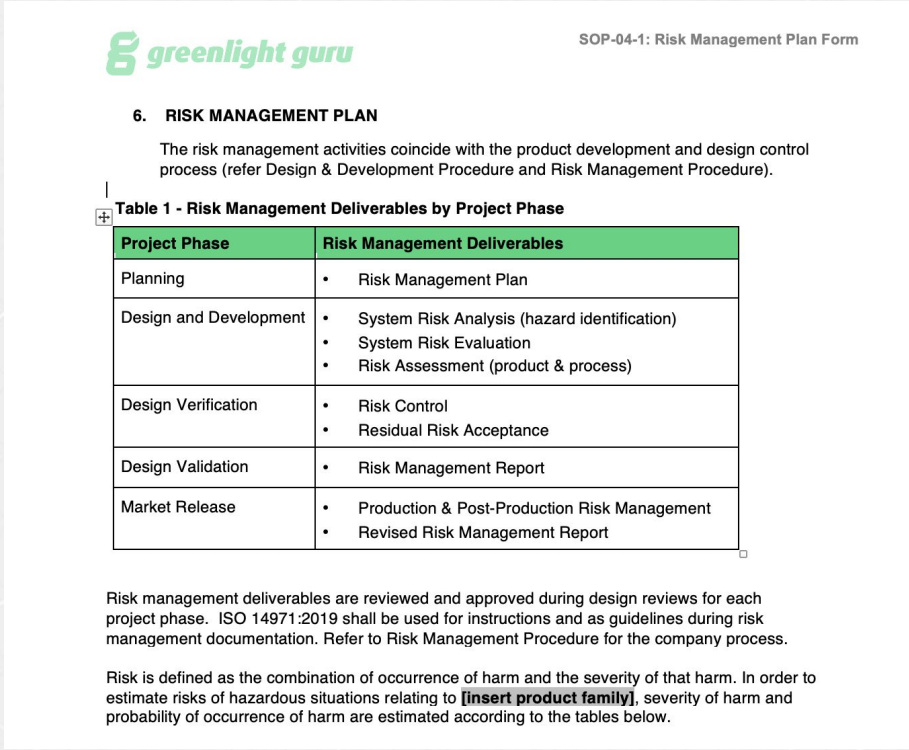
1 *Establish a risk management framework*

- ☐ Define your risk management process
- ☐ Establish management roles and responsibilities
- ☐ Document your risk management plan
- ☐ Establish a living risk management file



FREE RISK MANAGEMENT PLAN TEMPLATE + EXCLUSIVE WEBINAR OFFER:

http://www.greenlight.guru/risk-webinar-offer



greenlight guru

SOP-04-1: Risk Management Plan Form

6. RISK MANAGEMENT PLAN

The risk management activities coincide with the product development and design control process (refer Design & Development Procedure and Risk Management Procedure).

Table 1 - Risk Management Deliverables by Project Phase

Project Phase	Risk Management Deliverables
Planning	• Risk Management Plan
Design and Development	• System Risk Analysis (hazard identification) • System Risk Evaluation • Risk Assessment (product & process)
Design Verification	• Risk Control • Residual Risk Acceptance
Design Validation	• Risk Management Report
Market Release	• Production & Post-Production Risk Management • Revised Risk Management Report

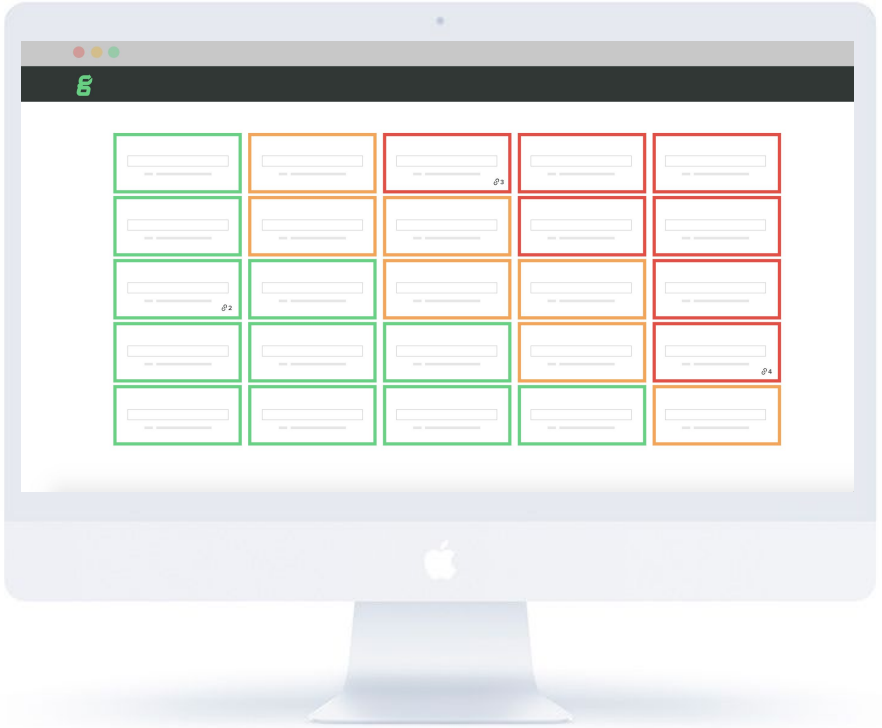
Risk management deliverables are reviewed and approved during design reviews for each project phase. ISO 14971:2019 shall be used for instructions and as guidelines during risk management documentation. Refer to Risk Management Procedure for the company process.

Risk is defined as the combination of occurrence of harm and the severity of that harm. In order to estimate risks of hazardous situations relating to **[insert product family]**, severity of harm and probability of occurrence of harm are estimated according to the tables below.

greenlight guru

INTERESTED IN GREENLIGHT GURU'S RISK MANAGEMENT SOFTWARE?

[SCHEDULE A FREE DEMO →]



greenlight guru

RISK ASSESSMENT = RISK ANALYSIS + RISK EVALUATION

2 Specify intended use

Understand and define the scope of your device and document its intended use

3 Identify hazards

Identify the potential sources of harm associated with your product.
These are known as hazards

4 Define hazardous situations and foreseeable sequences of events

Estimate risk of each hazardous situation

5 Estimate risk

Risk is the combination of severity of potential harm and probability of that harm occuring

RISK ASSESSMENT = RISK ANALYSIS + RISK EVALUATION

6 *Evaluate the risks identified*

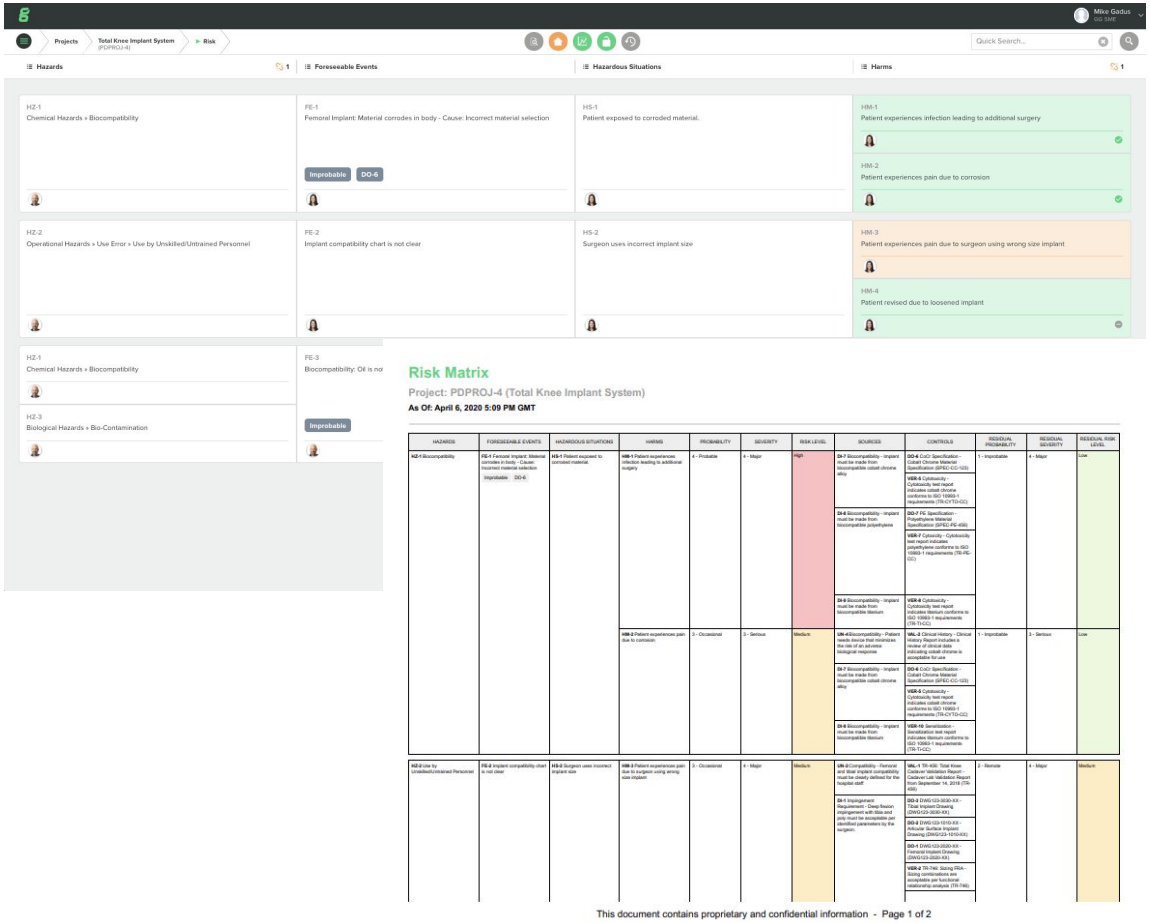
- Are these risk levels acceptable?
- Is risk reduction required?

Risk Acceptability Matrix

Probability	Negligible	Minor	Serious	Major	Critical
Frequent 1 in 100		Requires Benefit-Risk Analysis	Requires Benefit-Risk Analysis	Requires Benefit-Risk Analysis	Requires Benefit-Risk Analysis
Probable 1 in 1,000		Requires Benefit-Risk Analysis	Requires Benefit-Risk Analysis	Requires Benefit-Risk Analysis	Requires Benefit-Risk Analysis
Occasional 1 in 10,000			Requires Benefit-Risk Analysis	Requires Benefit-Risk Analysis	Requires Benefit-Risk Analysis
Remote 1 in 100,000				Requires Benefit-Risk Analysis	Requires Benefit-Risk Analysis
Improbable 1 in 1,000,000					Requires Benefit-Risk Analysis
	No or negligible risk to patient	Slight customer inconvenience; little to no effect on product performance, non-vital fault	Short-term injury or impairment requiring additional medical intervention to correct (e.g. reoperation)	Severe, long-term injury; potential disability	Loss of limb; life-threatening injury

Severity

Simplify risk analysis by linking to Design Controls in a traceable system with a paperless, living risk management file

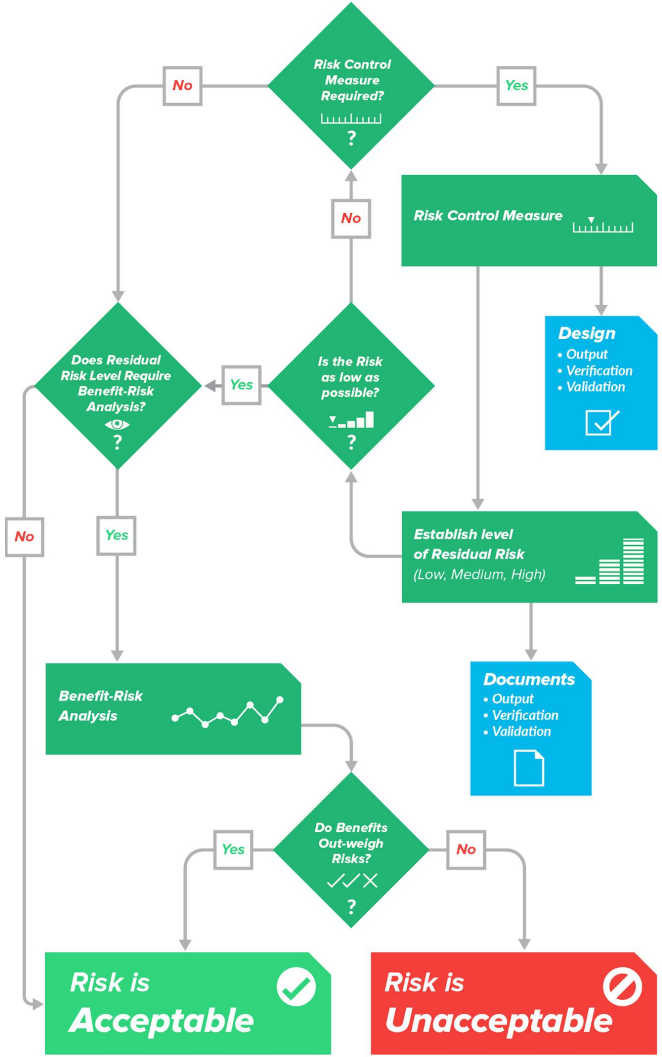


greenlight guru

RISK MANAGEMENT + DESIGN CONTROLS

1. Understand the importance of Intended Use
2. Product Risk Management is a cycle—even during product development
3. Risk Management & Design Controls have the same purpose

RISK CONTROL



BENEFIT / RISK ANALYSIS (BRA)

- After you identify Risk Controls and evaluate residual risks, it is still possible that you will have some risks that are still in the unacceptable level. In these cases, it might make sense to conduct and document a benefit / risk analysis (BRA).

- The BRA must be documented and provided objective evidence and rationale for why the medical benefits outweigh the unacceptable risks. If you are able to do so, the BRA is a special provision for moving forward with unacceptable risks.

RISK ACCEPTABILITY // REVIEW & REPORT

8 Evaluation Of Overall Risk Acceptability

Evaluate risk of the product in its entirety.

- Is the risk level acceptable?
- Do the benefits outweigh the potential risks?

9 Risk Management Review

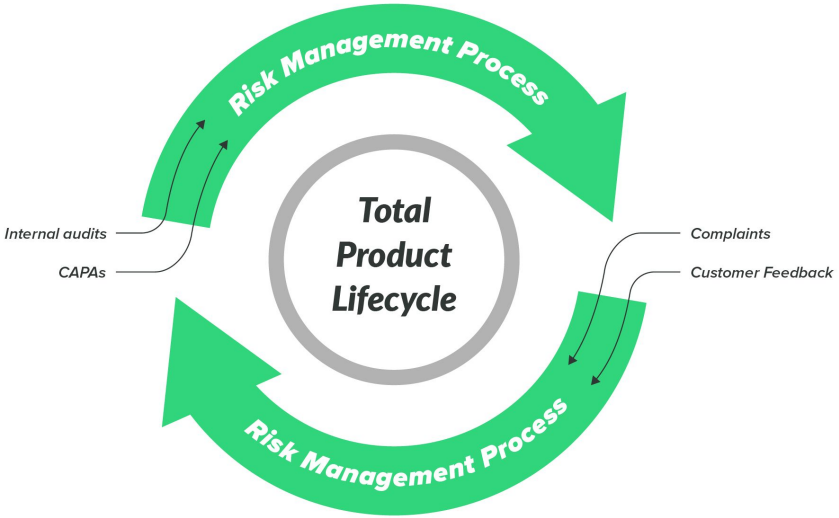
Carry out a risk management review and prepare a risk management report before sending your device to commercial production.

PRODUCTION INFORMATION

10 Production And Post-production Information

Internal audits, CAPAs, complaints, customer feedback and non-conforming material all ‘feed’ into the risk management process.

Risk management is a total product lifecycle process.



RISK MANAGEMENT AS A COMPETITIVE ADVANTAGE

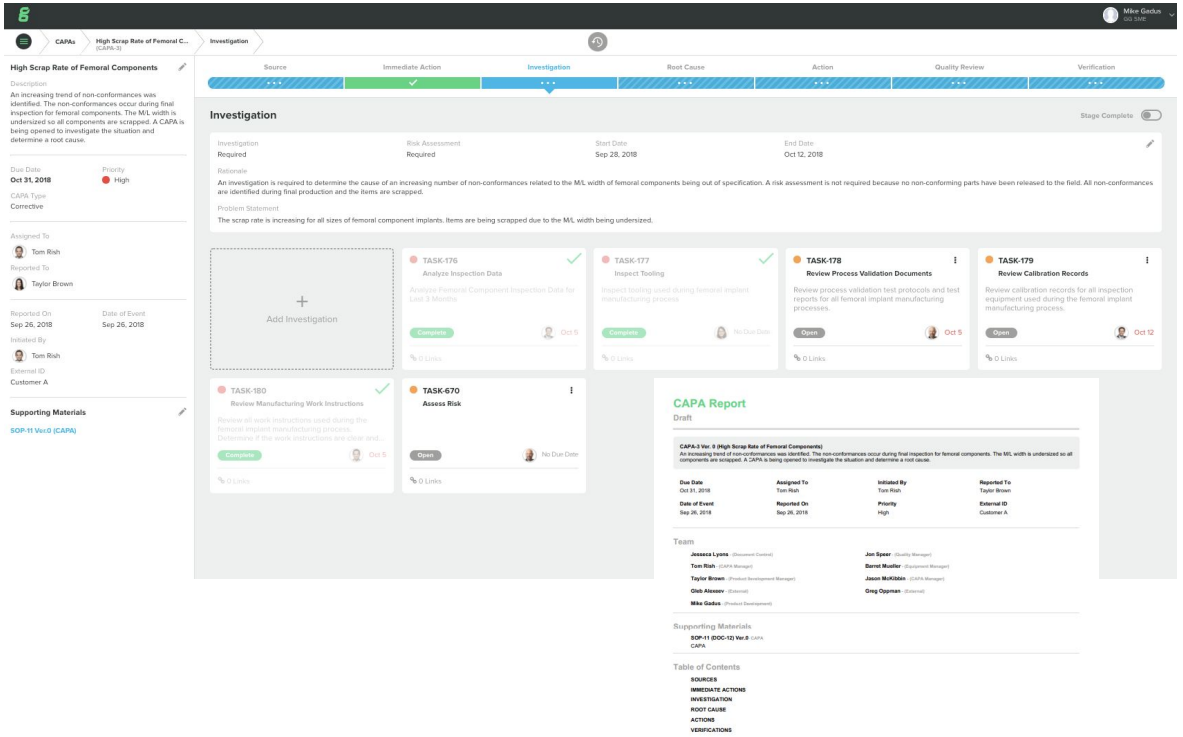
RISK MANAGEMENT ≠ 

- **The Longer You Wait, The Tougher It Gets** – delaying design controls and risk management documentation actually caused lengthy delays in projects
- **Understanding The Purpose** – design, develop, manufacture, and sell medical devices that are as safe as possible for their intended uses
- **Value Of Documentation** – FDA inspectors, ISO auditors, and other regulatory bodies and business associates are likely to review your design controls and risk management

RISK BASED QMS

- Greater emphasis on Risk due to ISO 14971 and regulatory bodies
- Manage risks throughout QMS
    - **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?
- Manage risks through entire product lifecycle (like ISO 14971)

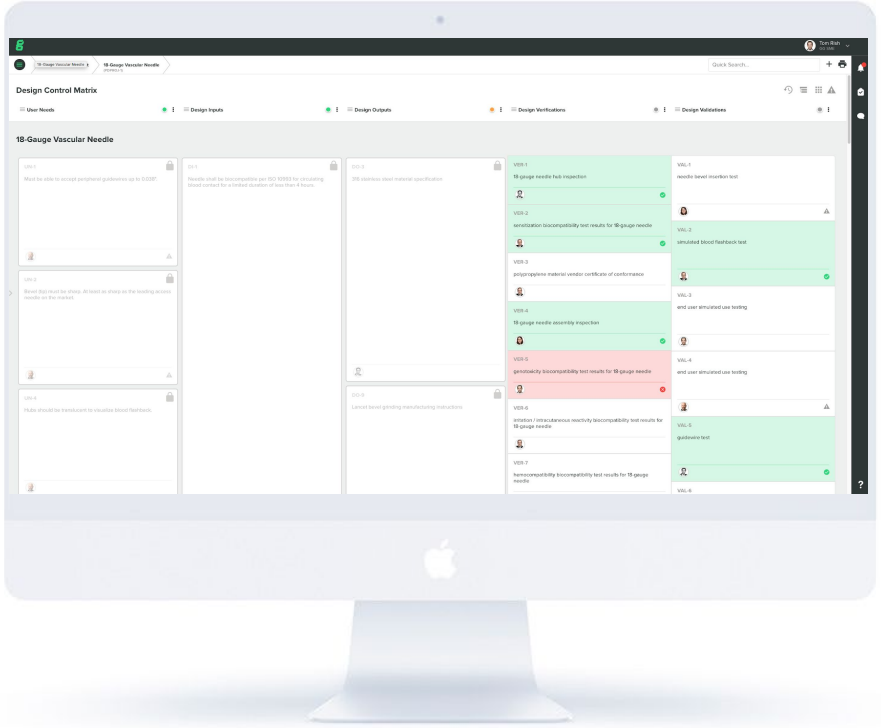
Manage risk-based quality processes in a connected ecosystem that unites internal and external stakeholders



greenlight guru

GREENLIGHT GURU'S MDQMS PLATFORM CAPABILITIES

- **Built-in controls** that align with 21 CFR Part 820 and ISO 13485:2016
- **Flexible review & approval workflows** with Part 11 compliant e-Signatures
- **Fully integrated risk** aligned to ISO 14971
- **LinkAnything** drives full lifecycle traceability
- **Zero effort** system validation
- **Drive collaboration** with task management, comments, and notifications



greenlight guru

QUESTIONS?

Jon Speer
jon.speer@greenlight.guru

DON'T FORGET!
Free Risk Management Plan Template + Exclusive Webinar Offer → http://www.greenlight.guru/risk-webinar-offer