

WEBINAR

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



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Co-Founder & VP of QA/RA at 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.

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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



Forbes

QUALITYDIGEST



Inc.

MedTech
Intelligence



MedicalDesign
& OUTSOURCING



Entrepreneur



"One stop shop for MDQMS"



"My QMS is world class"



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



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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

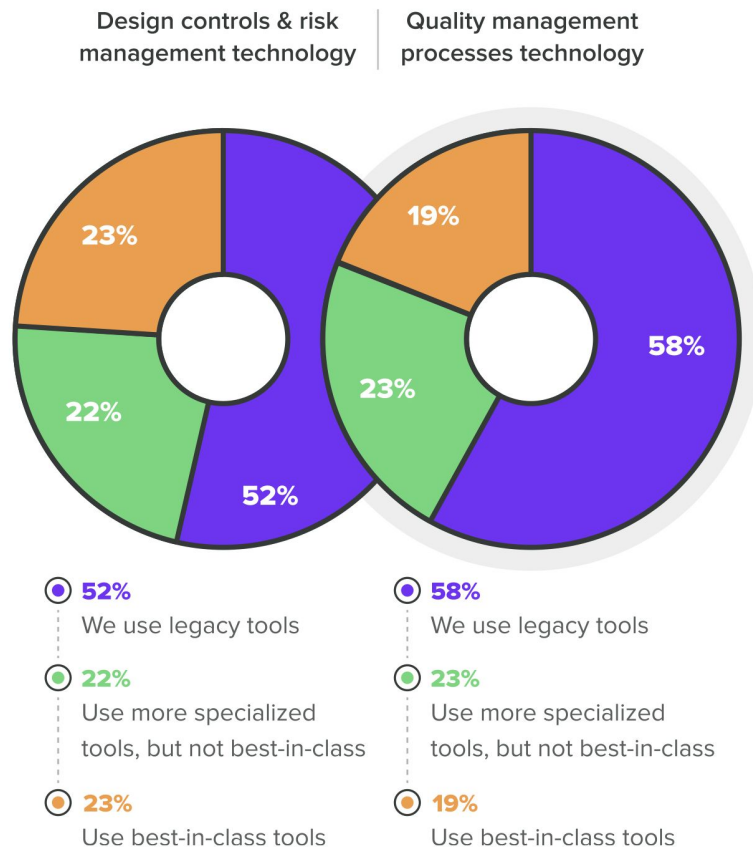
Top 5 Challenges in Managing Risk



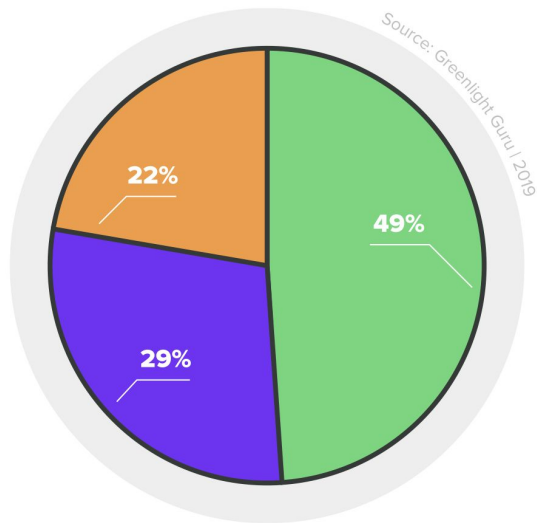
Source: Greenlight Guru | 2019

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**.



INTEGRATING RISK MANAGEMENT



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

● **49%**

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

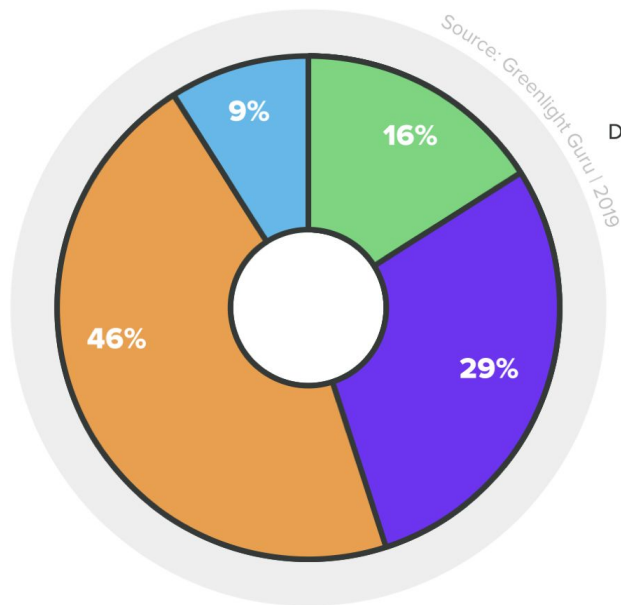
● **29%**

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.

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

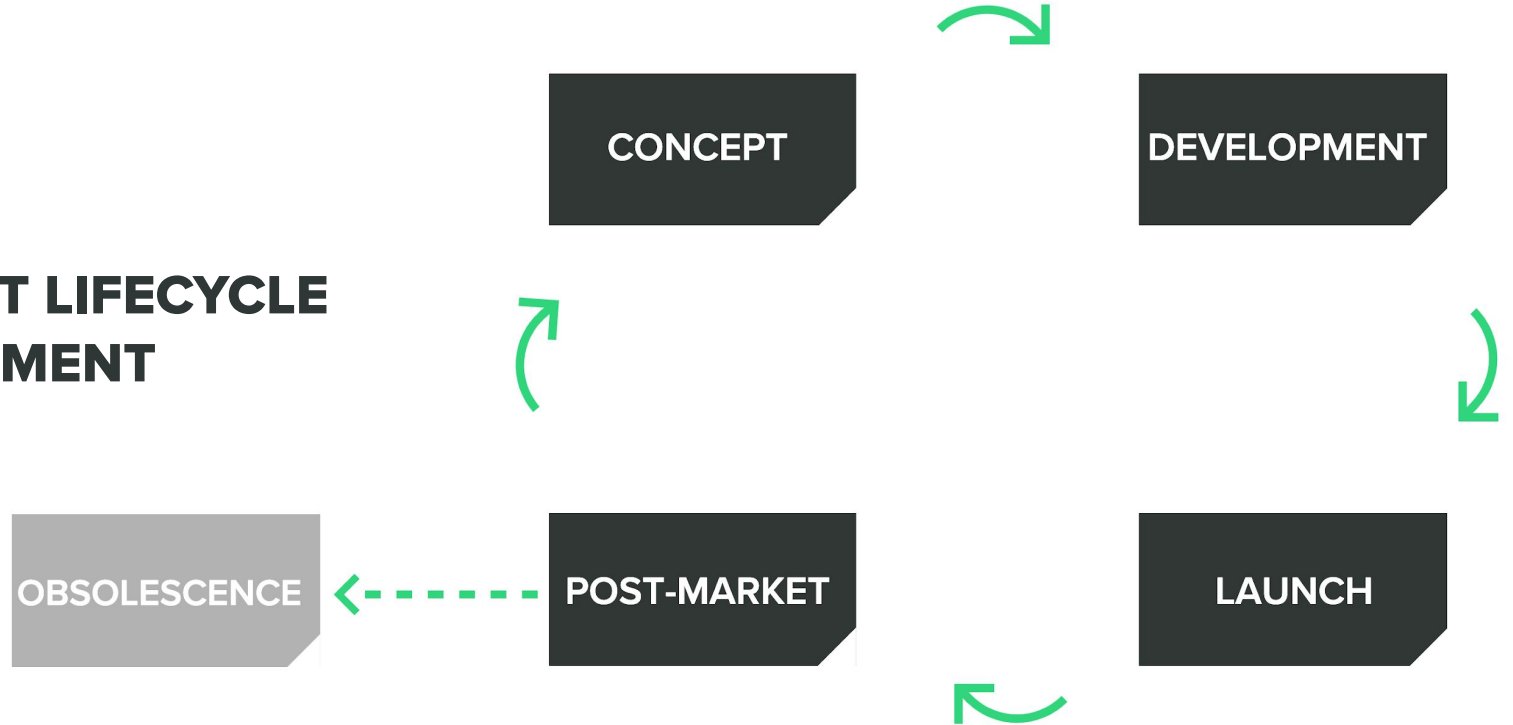
RISK MANAGEMENT FILE =

- 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

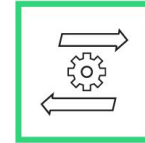
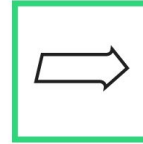
CONCEPT

DEVELOPMENT

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](http://www.greenlight.guru/risk-webinar-offer)



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

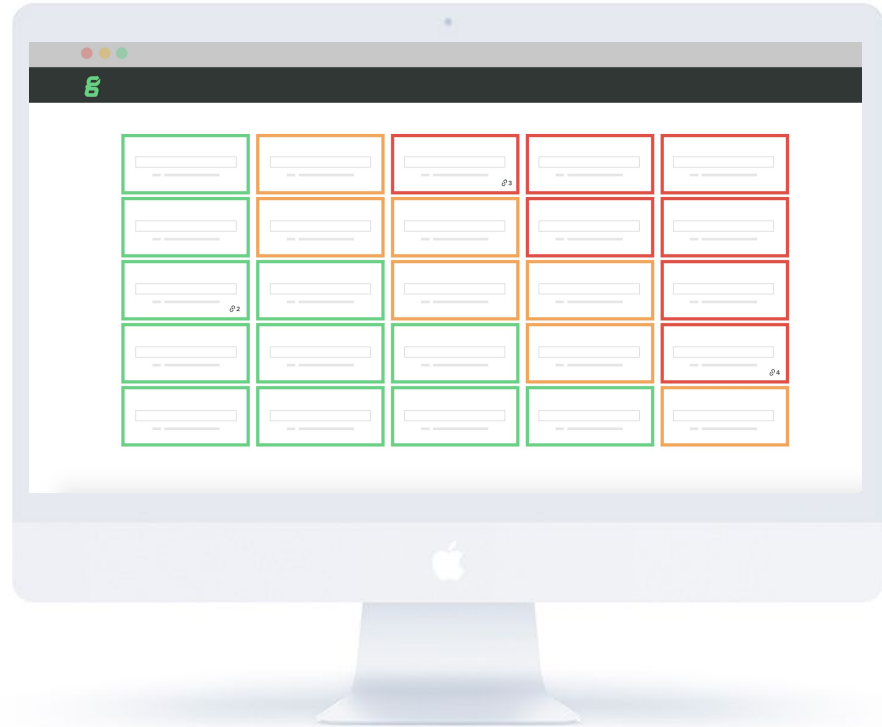
Project Phase	Risk Management Deliverables
Planning	<ul style="list-style-type: none">Risk Management Plan
Design and Development	<ul style="list-style-type: none">System Risk Analysis (hazard identification)System Risk EvaluationRisk Assessment (product & process)
Design Verification	<ul style="list-style-type: none">Risk ControlResidual Risk Acceptance
Design Validation	<ul style="list-style-type: none">Risk Management Report
Market Release	<ul style="list-style-type: none">Production & Post-Production Risk ManagementRevised 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.

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[SCHEDULE A FREE DEMO →](#)



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 occurring



RISK ASSESSMENT = RISK ANALYSIS + RISK EVALUATION

6 Evaluate the risks identified

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



Risk Acceptability Matrix

Probability	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
		Negligible No or negligible risk to patient	Minor Slight customer inconvenience; little to no effect on product performance, non-vital fault	Serious Short-term injury or impairment requiring additional medical intervention to correct (e.g. reoperation)	Major Severe, long-term injury; potential disability	Critical 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 interface showing a risk analysis workflow for a Total Knee Implant System.

Navigation: Projects > Total Knee Implant System > Risk

Sections: Hazards, Foreseeable Events, Hazardous Situations, Harms

Hazards:

- HZ-1: Chemical Hazards > Biocompatibility
- HZ-2: Operational Hazards > Use Error > Use by Unskilled/Untrained Personnel
- HZ-1: Chemical Hazards > Biocompatibility
- HZ-3: Biological Hazards > Bio-Contamination

Foreseeable Events:

- FE-1: Femoral Implant: Material corrodes in body - Cause: Incorrect material selection
- FE-2: Implant compatibility chart is not clear
- FE-3: Biocompatibility: Of is not

Hazardous Situations:

- HS-1: Patient exposed to corroded material.
- HS-2: Surgeon uses incorrect implant size

Harms:

- HM-1: Patient experiences infection leading to additional surgery
- HM-2: Patient experiences pain due to corrosion
- HM-3: Patient experiences pain due to surgeon using wrong size implant
- HM-4: Patient revised due to loosened implant

Risk Matrix

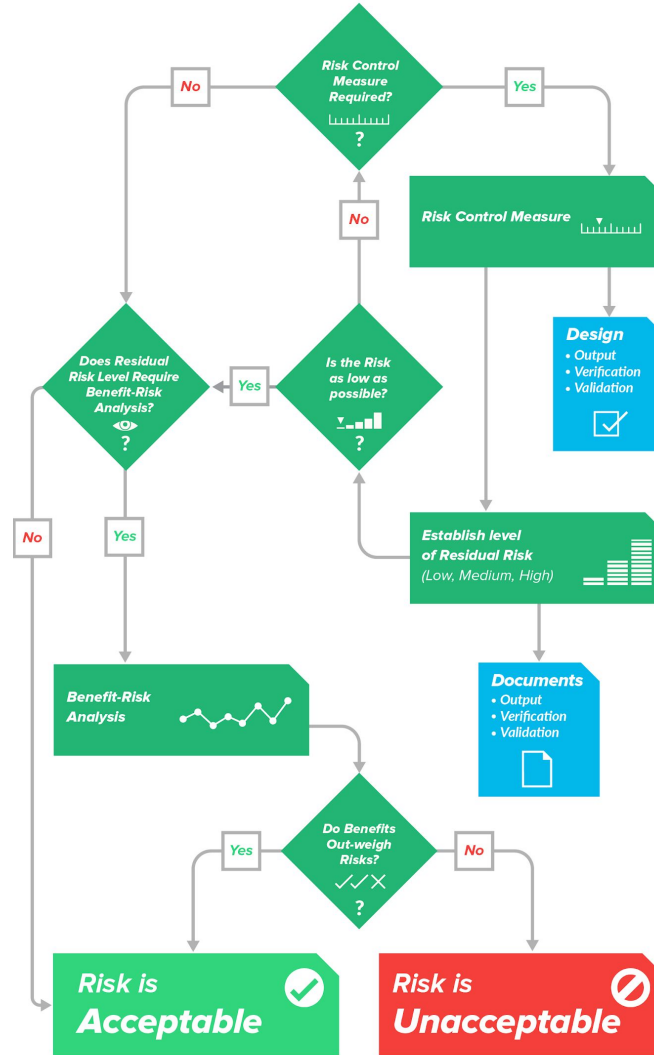
Project: PDPROJ-4 (Total Knee Implant System)
As Of: April 6, 2020 5:09 PM GMT

HAZARDS	FORESEEABLE EVENTS	HAZARDOUS SITUATIONS	HARMS	PROBABILITY	SEVERITY	RISK LEVEL	SOURCES	CONTROLS	INITIAL RISK	RESIDUAL RISK	RESIDUAL RISK LEVEL
HAZ-1: Biocompatibility	FE-1: Femoral Implant: Material corrodes in body - Cause: Incorrect material selection	HS-1: Patient exposed to corroded material	HM-1: Patient experiences infection leading to additional surgery	1 - Probable	4 - Major	High	HS-1: Biocompatibility - Implant material is made from incompatible material choice only HS-2: Biocompatibility - Implant material is made from incompatible material choice only HS-3: Biocompatibility - Implant material is made from incompatible material choice only HS-4: Biocompatibility - Implant material is made from incompatible material choice only	HS-1: Biocompatibility - Implant material is made from incompatible material choice only HS-2: Biocompatibility - Implant material is made from incompatible material choice only HS-3: Biocompatibility - Implant material is made from incompatible material choice only HS-4: Biocompatibility - Implant material is made from incompatible material choice only	1 - Probable	4 - Major	High
HAZ-2: Biocompatibility	FE-2: Implant compatibility chart is not clear	HS-2: Surgeon uses incorrect implant size	HM-2: Patient experiences pain due to surgeon using wrong size implant	1 - Occasional	3 - Serious	Medium	HS-1: Biocompatibility - Implant material is made from incompatible material choice only HS-2: Biocompatibility - Implant material is made from incompatible material choice only HS-3: Biocompatibility - Implant material is made from incompatible material choice only HS-4: Biocompatibility - Implant material is made from incompatible material choice only	HS-1: Biocompatibility - Implant material is made from incompatible material choice only HS-2: Biocompatibility - Implant material is made from incompatible material choice only HS-3: Biocompatibility - Implant material is made from incompatible material choice only HS-4: Biocompatibility - Implant material is made from incompatible material choice only	1 - Probable	3 - Serious	Medium
HAZ-3: Biocompatibility	FE-3: Biocompatibility: Of is not	HS-3: Patient experiences pain due to surgeon using wrong size implant	HM-3: Patient experiences pain due to surgeon using wrong size implant	1 - Occasional	4 - Major	Medium	HS-1: Biocompatibility - Implant material is made from incompatible material choice only HS-2: Biocompatibility - Implant material is made from incompatible material choice only HS-3: Biocompatibility - Implant material is made from incompatible material choice only HS-4: Biocompatibility - Implant material is made from incompatible material choice only	HS-1: Biocompatibility - Implant material is made from incompatible material choice only HS-2: Biocompatibility - Implant material is made from incompatible material choice only HS-3: Biocompatibility - Implant material is made from incompatible material choice only HS-4: Biocompatibility - Implant material is made from incompatible material choice only	1 - Probable	4 - Major	Medium

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

DEVELOPMENT

LAUNCH

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.

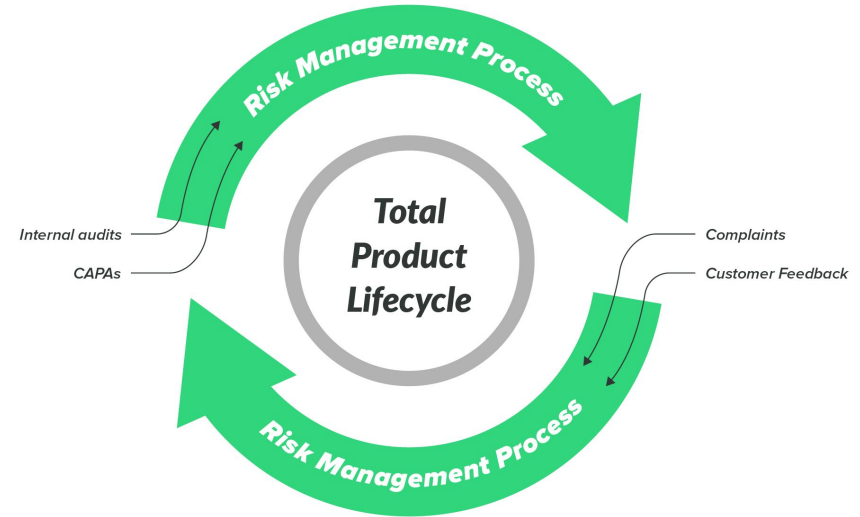


PRODUCTION INFORMATION

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 \neq

- **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

High Scrap Rate of Femoral Components

Description
An increasing trend of non-conformances was identified. The non-conformances occur during final inspection for femoral components. The ML width is undersized so all components are scrapped. A CAPA is being opened to investigate the situation and determine a root cause.

Due Date: Oct 31, 2018
Priority: High
CAPA Type: Corrective

Assigned To: Tom Rish
Reported To: Taylor Brown

Reported On: Sep 26, 2018
Date of Event: Sep 26, 2018
Initiated By: Tom Rish
External ID: Customer A

Supporting Materials
SOP-11 (Ver 6) (CAPA)

Investigation

Required Risk Assessment
Rationale
An investigation is required to determine the cause of an increasing number of non-conformances related to the ML width of femoral components being out of specification. A risk assessment is not required because no non-conforming parts have been released to the field. All non-conformances are identified during final production and the items are scrapped.

Problem Statement
The scrap rate is increasing for all sizes of femoral component implants. Items are being scrapped due to the ML width being undersized.

Tasks:

- TASK-176** Analyze Inspection Data (Complete)
- TASK-177** Inspect Tooling (Complete)
- TASK-178** Review Process Validation Documents (Open)
- TASK-179** Review Calibration Records (Open)
- TASK-180** Review Manufacturing Work Instructions (Complete)
- TASK-670** Assess Risk (Open)

CAPA Report Draft

CAPA Title: High Scrap Rate of Femoral Components
Description: An increasing trend of non-conformances was identified. The non-conformances occur during final inspection for femoral components. The ML width is undersized so all components are scrapped. A CAPA is being opened to investigate the situation and determine a root cause.

Due Date: Oct 31, 2018
Assigned To: Tom Rish
Reported On: Sep 26, 2018
Initiated By: Tom Rish
Priority: High
External ID: Customer A

Team:

- James Lyons** (Document Control)
- Tom Rish** (CAPA Manager)
- Taylor Brown** (Product Development Manager)
- Chris Alexander** (Designer)
- Mike Gaskin** (Product Development)
- Jon Sygar** (Quality Manager)
- Barnet Mueller** (Equipment Manager)
- Jason McMillan** (CAPA Manager)
- Greg Oppman** (Designer)

Supporting Materials:
SOP-11 (Ver 6) (CAPA)

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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



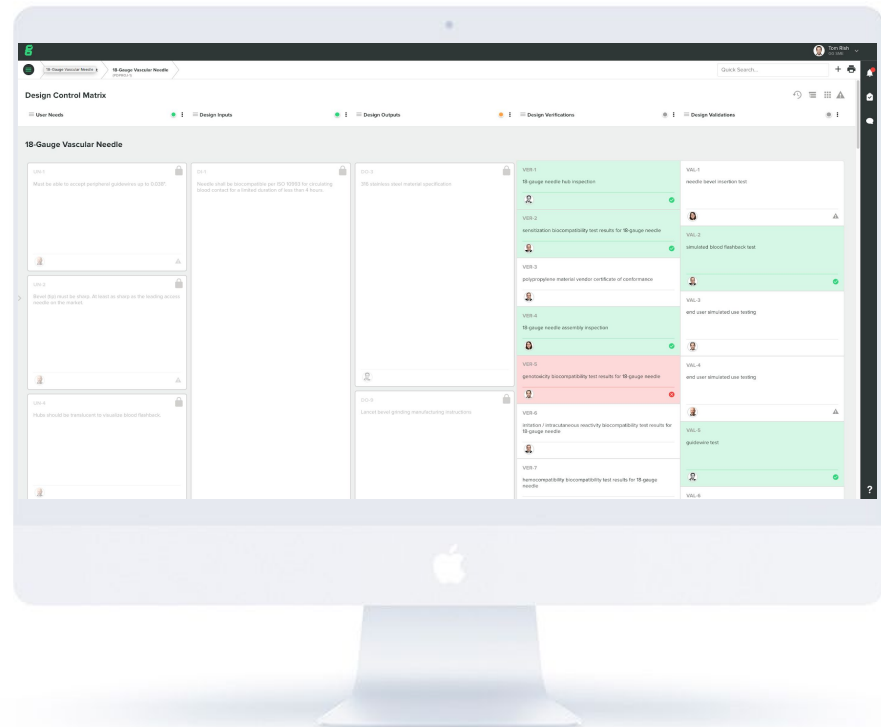
LinkAnything drives full lifecycle traceability



Zero effort system validation



Drive collaboration with task management, comments, and notifications



QUESTIONS?



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