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How to Simplify Compliance with the New ISO 13485:2016

Presented by:

Jon D. Speer

Founder & VP QA/RA

Today's Agenda

ISO 13485 Overview

What has changed in the new ISO 13485:2016

Why putting off compliance until later could cost you

How eQMS software can help simplify compliance

5 Steps to take now to make for a smooth transition

Questions

Who is Jon Speer

- 18+ years in the medical device industry
- 40+ products to market
- Speaker
- Thought leader and regular contributor at Med Device Online, MedCity News, QMed, Quality Digest and other leading industry publications
- Expert in implementing quality systems
- Run one of the most popular blogs & the #1 podcast in the medical device industry
- Founder and VP QA/RA greenlight.guru

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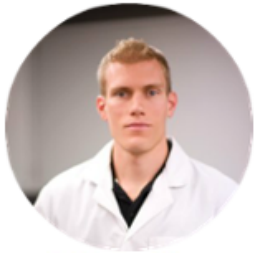
greenlight.guru – Quality Management Software

- The **only** eQMS solution designed exclusively for the unique needs of the medical device industry
- Designed by medical device professionals with decades of experience for medical device professionals
- Offer software + services to enable you to comply with regulations and standards like FDA 21 CFR Part 820 and ISO 13485:2016
- Customers & partners all over the globe on five continents



Nanofiber SOLUTIONS

Jed Johnson PhD, CTO

"greenlight.guru has been instrumental for us moving so quickly through the ISO certification and I would highly recommend it."

My Free Gift For You At The End – QMS Audit Checklist

My Goals For You Today

1. You understand the major changes that are part of this revision of ISO 13485.

2. You understand the benefit of not putting off compliance until the last minute.

3. You understand how leveraging market leading technology can help simplify your compliance.

4. You have an actionable set of steps you can begin taking today at your company to comply with the updated standard.

ISO 13485:2016

A brief overview

What is ISO 13485?

- The world-wide sector Quality Management System (QMS) standard for medical device organizations

- Takes general quality system requirements for all organizations intending to provide products or services to customers and modifies it for application within the highly regulated medical device industry

- An internationally agreed way to implement common regulatory concepts (presumption of conformity) that support maximizing the potential benefits of making the strategic decision to implement a quality management system

Potential Benefits of ISO 13485

- Enhances the ability of the organization to meet customer and regulatory requirements.
- Helps the organization's capability to address product safety and effectiveness.
- Allows the organization to obtain external recognition of conformity of the quality management system to accepted requirements (certification).

What ISO 13485 is NOT

- It is not a required structure for your Quality Management System.
- It is not regulation—not the law.
- It does not define requirements for the products and services provided by the organization.
- It does not define other business requirements or initiatives (e.g. financial or environmental requirements).

Why did ISO 13485 need to change?

- The standard was due for revision based on the regular 5-year cycle (second edition released in 2003)

- First review (2008) determined no change needed.

- This review (2012/13) there were a couple of drivers.
  - Requests from GHTF and AHWP
  - User survey—generally pointed out the need for clarifications (implicit requirements)
  - European Union lost faith in ISO 13485 as a way to obtain **presumption of conformity** with the EU Medical Device Directive (issuance of EN ISO 13485:2012)

User Input—Clarity

- Enhance Clarity for Users – **Manufacturer's voice**
  - Survey of users found a desire for the standard to provide more clarity (implicit requirement)
  - Guidance exists in ISO TR 14969 but few individuals know this document exists (auditor interpretation)

- Auditing (ambiguity) **– Certification body's voice**
  - Some clauses difficult to audit against
  - Nonconformities could be written against different clauses
  - MDSAP—Medical Device Single Audit Program

User Input—Global Harmonization

- Further Harmonization – **Global voice**
  - GHTF Study Group 3 had published several guidance documents with additional concepts--can these be incorporated and used with changes to the standard?
  - More countries developing medical device regulations did not believe ISO 13485 could meet their needs
  - Prevalence of importers & distributors in a few geographies
  - Outsourcing of both manufacturing (contract manufacturing) and design (contract design)
  - Organizations that only do part of the overall process
- Enhance compatibility with latest regulations and expectations

User Input—EU Challenges

- Standard not Robust Enough – **EU Regulator Voice**
  - Due to scandals in EU with breast and hip implants the entire regulatory framework was being challenged
  - Determined that ISO 13485 alone and as written could NOT assure presumption of conformity to the MDD's "appropriate quality system" requirement
  - More prescriptive requirements need to be included in the standard

Current ISO Timeline

- ISO 13485:2016 is published.
- WG1 has started work on a guidance handbook (approx. 1 year)
- The recommended 3 year transition accepted by TC 210 and IAF—no new certifications/re-certifications after year 2
- Periodic review has been accelerated to March 2019

What has changed in the new ISO 13485:2016

Overview

- Integrates risk throughout the QMS and product life-cycle—risk-based decision-making
- Move toward harmonization with US CFR, Brazilian law (ANVISA), CMDR (Canada), and other law (MDD, JPAL, TGA)—MDSAP
- Additional linkage to documentation required for regulatory purposes
- Integration of QMS software

Overview (cont.)

- Emphasis on appropriate infrastructure
- New references to other standards (usability, sterile barrier, etc.)
- New sections on complaint handling and reporting to regulatory authorities
- Clarity for auditing
- Planning and documenting corrective action (without undue delay) and preventive action

Annexes & Bibliography

- **Annex A**—comparison between 2003 & 2016 versions
- **Annex B**—correspondence of sections between ISO 9001:2015 and ISO 13485:2016
- **Bibliography**—the information provided helps locate documents referenced in the definitions and in the informational notes

List of Clauses Impacted

- ***1 Scope***
- ***3 Terms and definitions***
- ***4 Quality management system***
- ***4.1 General requirements***
- 4.2 Documentation requirements
- 5.6 Management review
- 6.2 Human resources
- 6.3 Infrastructure
- 6.4 Work environment and contamination control
- 7.1 Planning of product realization
- 7.2 Customer-related processes
- ***7.3.2 Design and development planning***
- ***7.3.3 Design and development inputs***
- 7.3.5 Design and development review
- ***7.3.6 Design and development verification***
- ***7.3.7 Design and development validation***
- ***7.3.8 Design and development transfer***
- ***7.3.9 Control of design and development changes***
- ***7.3.10 Design and development files***
- ***7.4.1 Purchasing process***
- ***7.4.2 Purchasing information***
- ***7.4.3 Verification of purchased product***
- 7.5.1 Control of production and service provision
- 7.5.2 Cleanliness of product
- 7.5.4 Servicing activities
- 7.5.6 Validation of processes for production and service provision
- 7.5.7 Particular requirements for validation of processes for sterilization and sterile barrier systems
- 7.5.8 Identification
- 7.5.11 Preservation of product
- 8.2.1 Feedback
- 8.2.2 Complaint handling
- 8.2.3 Reporting to regulatory authorities
- 8.2.6 Monitoring and measurement of product
- 8.3 Control of nonconforming product
- 8.4 Analysis of data
- 8.5.2 Corrective action
- 8.5.3 Preventive action

1 Scope

- Scope includes organizations that have a role in one or more stages of the 'life-cycle'
- Identification of 'outsourced' processes
- Maintain exclusion for design control if permitted by regulatory requirements with new option to "not apply" requirements of clauses 6, 7, and 8 (with justification) depending on organization's role

3 Terms and Definitions

- **Removed:** Supply Chain explanation, Active Implantable Medical Device, Active Medical Device

- **Modified:** Complaint, Labeling, Implantable Medical Device, Medical Device and Sterile Medical Device

- **Added:** Authorized Representative, Clinical Evaluation, Distributor, Importer, Life-cycle, Manufacturer, Medical Device Family, Performance Evaluation, Post Market Surveillance, Product (from 9000:2005), Purchased Product, Risk, Risk Management, Sterile Barrier System and Sterile Medical Device

4 Quality Management System & 4.1 General Requirements

- Re-organized this entire clause
- Redefined ‘document’ to mean: Establish, implement and maintain (as well as documenting)
- Must document organization’s role
- Establish risk-based approach within processes—proportionate to the risk
- Maintain control of outsourced processes
- QMS software validation

7.3.2 Design and Development Planning

- Maintain (update) planning documents
- Reviews separated from verification/validation
- Add method to assure traceability (inputs/outputs) and resource planning (including competencies)

7.3.3 Design and Development Inputs

- Add usability (ref. to IEC 62366)
- Add ‘standards’ as an input
- Risk management moved up in list
- Added processes to other requirements
- Added ‘able to be verified or validated’

7.3.4 Design and Development Outputs

- In a form suitable for verification against design & development input
- Approved prior to product release

7.3.6 Design and Development Verification

- Planned & documented arrangements
- Plan includes: Method, acceptance criteria and statistical technique with rationale for sample size
- Connection to other devices
- Report includes: Results (same) and conclusions (new)

7.3.7 Design and Development Validation

- Planned & documented arrangements
- Plan includes: Method, acceptance criteria and statistical technique with rationale for sample size
- Connection to other devices
- Report includes: Results (same) and conclusions (new)
- Clinical/performance evaluation not released for use (from notes in the 2003 version).
- Use of production units (representative product)/document equivalency (rationale for choice of product)
- Clinical evaluation or performance evaluation in accordance with regulatory requirements.

7.3.8 Design and Development Transfer

- NEW SECTION
- Document procedures
- Verify design outputs are suitable for manufacturing
- Verify production specifications can meet product requirements

7.3.9 Control of Design and Development Changes

- Document procedures

- Determine significance of change to function, performance, usability, safety & regulatory requirements

7.3.10 Design and Development File

- NEW SECTION

7.4.1 Purchasing Process, 7.4.2 Purchasing Information, & 7.4.3 Verification of Purchased Product

- Purchasing process controls—risk based
  - Supplier evaluation & selection
  - Supplier monitoring & re-evaluation
  - Supplier documentation
  - Communication
- Purchasing information
  - Addition of “requirements for qualification of supplier personnel”
  - Notification of changes (written agreement)
- Verification of purchased product—risk based

Why Putting Off Compliance Until Later Could Cost You

ISO 13485:2016

Risk-Based QMS

- ISO 14971 risk management approach serving as a foundation for QMS
- ALL QMS processes utilize risk-based approach
- ALL QMS processes “feeding” into product risk management
- Risk-Based QMS is about managing your business

Better Processes

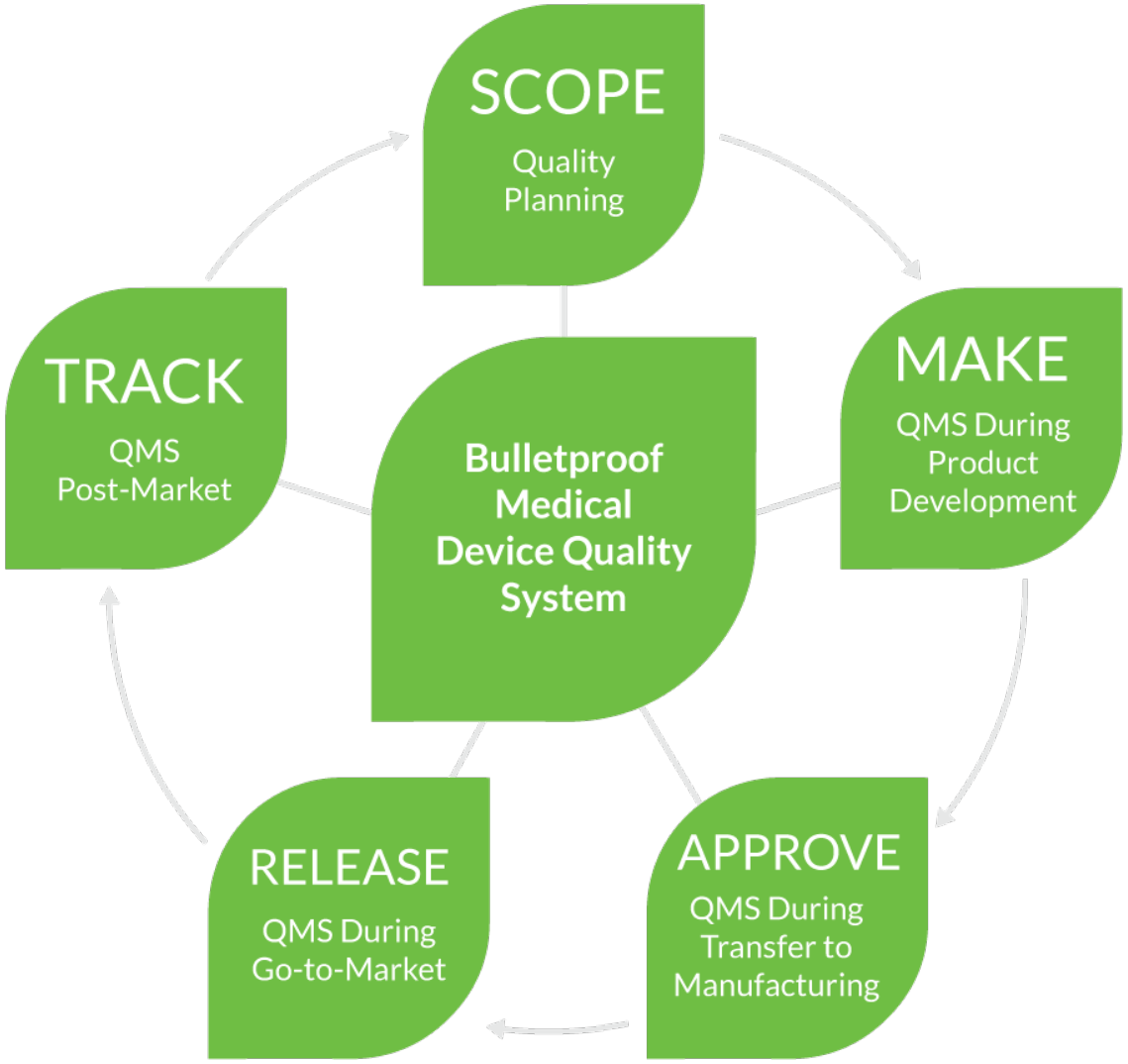
- Opportunity for better integration across entire QMS
- Improved efficiency
- Better alignment with global regulatory bodies
- Medical devices that are safer and more effective

The Costs

- Do you want to wait until implementing ISO 13485:2016 becomes mandatory from your registrar?
- Not integrating risk-based approaches into your QMS
- QMS wrong-size & complicated
- Out of sync with regulatory expectations and best practices
- Lack of competitive advantage

How eQMS Software Can Help Simplify Compliance

ISO 13485:2016


SCOPE
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Bulletproof Medical Device Quality System

A Bulletproof Medical Device Quality Management System Must...

And my system works so well because it does leverage the best...

People <-This is you and your amazing team

Processes <- This is my S.M.A.R.T. 5 Phase QMS System

Technology <- This is what we're about to talk about

WHY Implementing a Bulletproof Quality System Is So Important...

1. It's the law.
2. It will get you to market faster and with less risk.
3. It protects the patients.
4. An audit will happen. Will you be ready?
5. It allows you to focus on doing your actual job.
6. You're not worrying about the potential costs of non-compliance.

Traceability + objective evidence

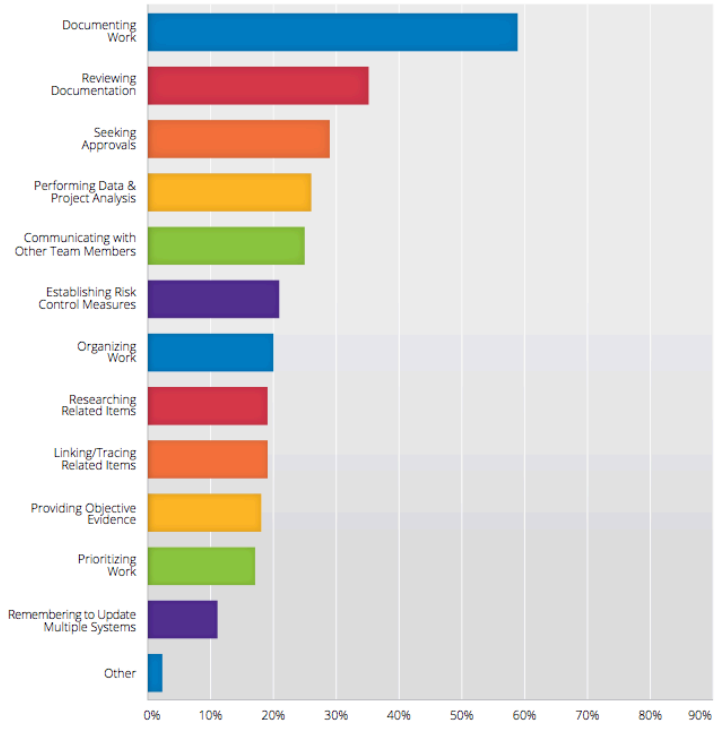
= everything

“If it wasn’t documented, it didn’t happen.”

But traceability and documentation take soo long.

Given the continued majority of companies using document-driven processes, it should be no surprise that respondents again said documenting work and reviewing documents are two of their three most time-consuming tasks. One big change: 29% said seeking approvals was one of their top three, compared to 18% in 2014.

What are your most time-consuming tasks?



And you're not a high paid secretary.
You need to focus on designing innovative devices…

…not updating spreadsheets.

Realize this…

Paper-based quality systems are not the cheapest and easiest type of QMS to implement…

…even if you're an early stage company, with little to no funding, and a product still in R&D.

And the best, market leading companies understand this…

Here's what going with a paper-based system will mean for your company...

You will...

- Have missing documents and records
- Documents and records will be out of sync
- Must have review and approval signature will be missing during an audit

What you will experience using greenlight.guru…

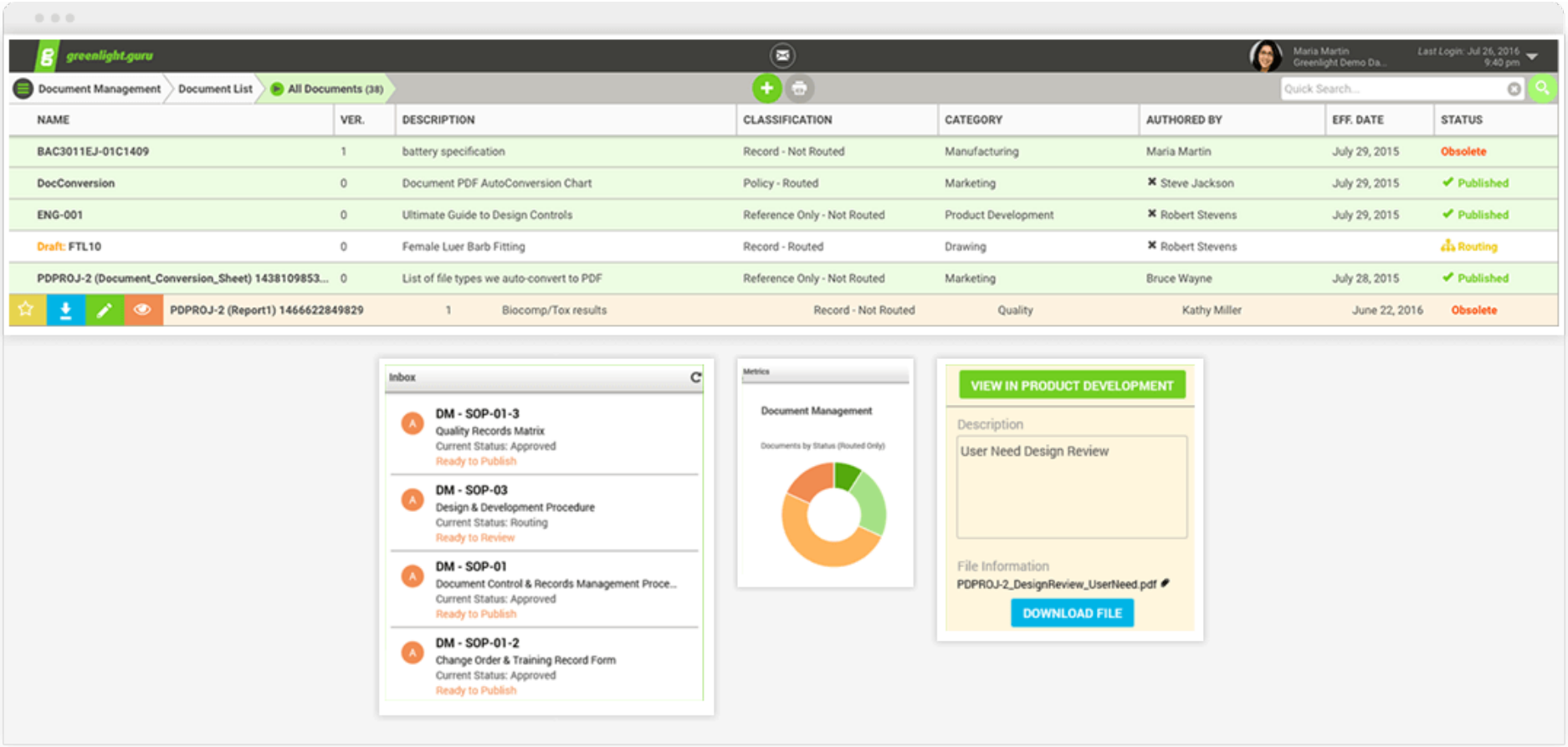
- Comply with all the latest regulations by leveraging technology with the latest best practices built in
- Easily manage and mitigate risk
- Improve your time to market by increasing efficiency and effectiveness of processes
- Empower stakeholders with real time access to complete and accurate data
- Single Source of Truth

greenlight.guru vs. a paper-based quality system…

Top 10 ways to save time using greenlight.guru vs. a paper-based a approach…

1. Documenting work
2. Reviewing documentation
3. Communicating with other team members
4. Performing data/project analysis
5. Organizing work
6. Prioritizing work
7. Linking / tracing related items
8. Seeking approvals
9. Providing objective evidence
10. Establishing risk control measures

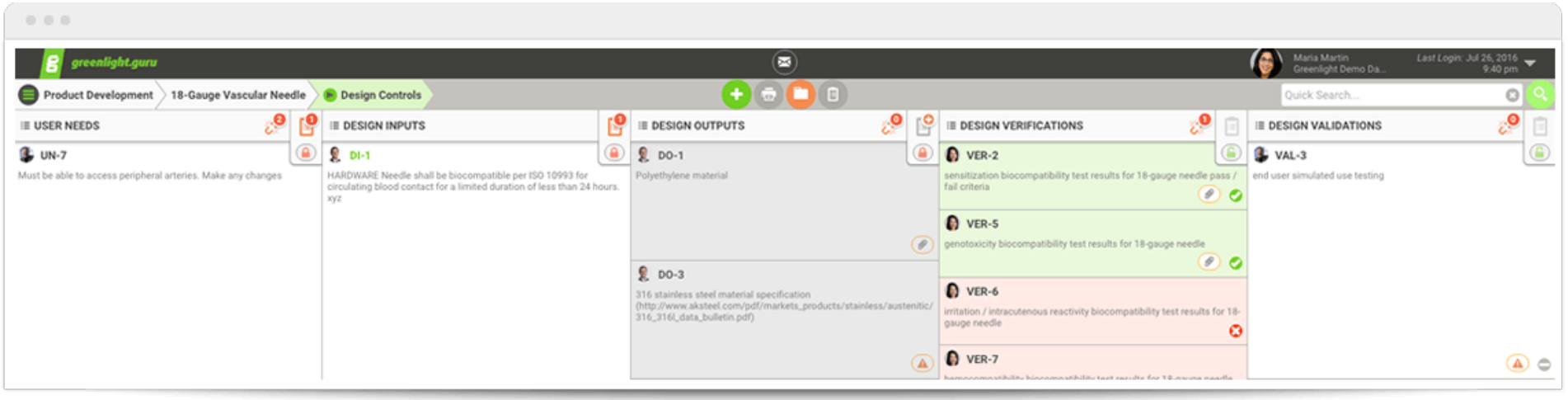
Document Management & Control in greenlight.guru



Here are just a few more of the issues you'll run into using a paper-based QMS...

- Limits traceability
- Hinders team based work
- Complicates design transfers between teams
- Error prone
- Complicates risk management
- Provides zero value to the development of the product
- Way too slow to perform risk analysis
- Very hard and time consuming to update or edit traceability matrix
- Lost or missing documents during an audit
- Getting signatures approvals is a hassle

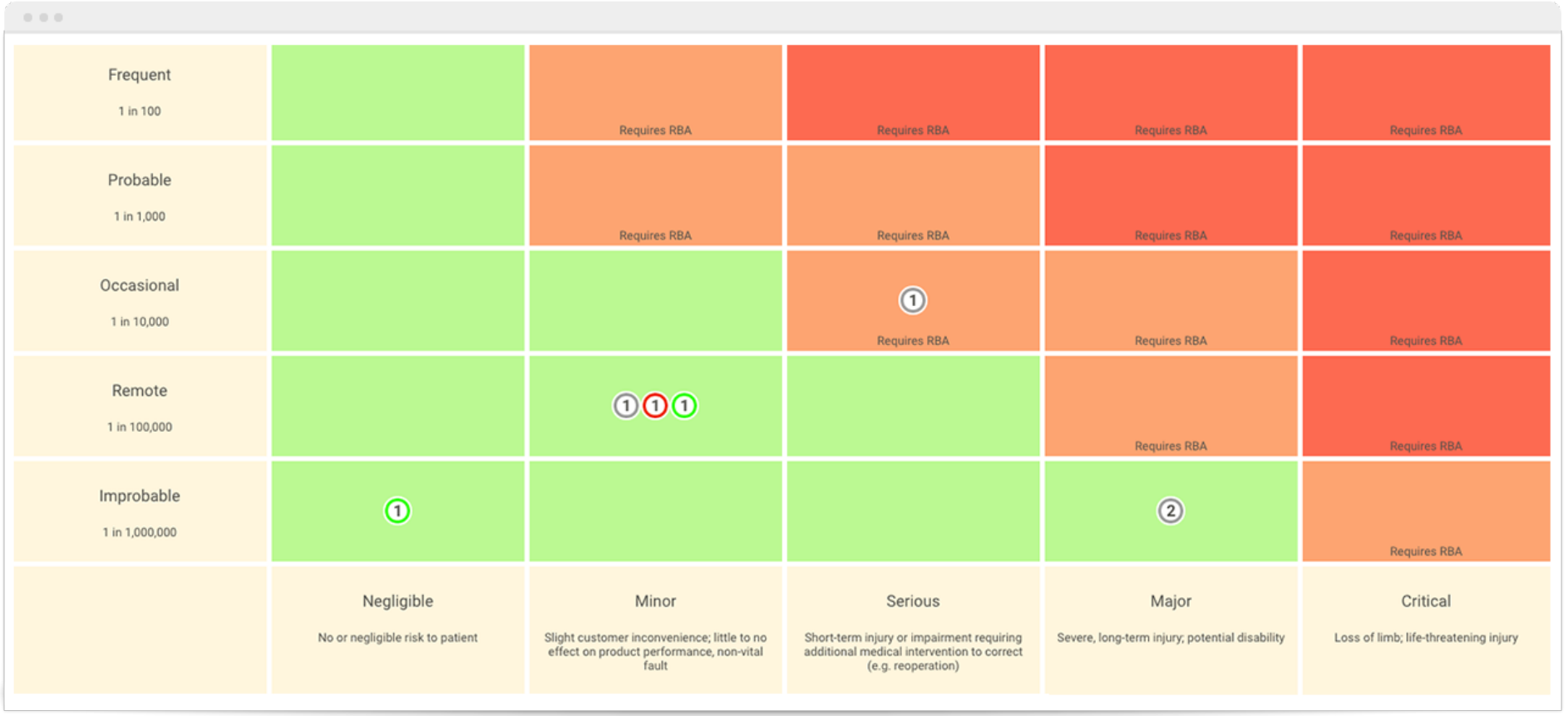
Design Controls + Risk Management in greenlight.guru



Problems with low power legacy solutions and battleship, enterprise solutions…

- Complicated and hard to use
- Cost and time of implementation and maintenance are often not well understood
- No team of medical device experts to walk you through every step of the process
- Not specifically built for the medical device industry
- Not promptly and continuously updated to new industry standards like ISO 13485:2016

Design Controls + Risk Management in greenlight.guru



	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
Frequent 1 in 100		Requires RBA	Requires RBA	Requires RBA	Requires RBA
Probable 1 in 1,000		Requires RBA	Requires RBA	Requires RBA	Requires RBA
Occasional 1 in 10,000			1 Requires RBA	Requires RBA	Requires RBA
Remote 1 in 100,000		1 1 1		Requires RBA	Requires RBA
Improbable 1 in 1,000,000	1			2	Requires RBA

When you combine award-winning technology like greenlight.guru with industry best practices you get...

- Alignment with medical device industry regulations and requirements, including FDA 21 CFR Part 820, FDA 21 CFR Part 11, ISO 13485, and ISO 14971
- Workflows and best practices integrated to improve overall efficiency
- Intuitive user interface and usability
- Quick and easy implementation and training
- Technical and customer support to address medical device industry needs
- Expertise to ensure the eQMS solution continues to align with changing medical device industry regulatory needs

Remember a Bulletproof Medical Device Quality Management System Must…

Leverage the best…

1. People
2. Processes
3. Technology

You've already got #1 covered. We can help you with #2 & #3.

5 Steps to Take Now to Make for a Smooth Transition

ISO
13485:2016

5 Key Steps

1. Get a copy of ISO 13485:2016

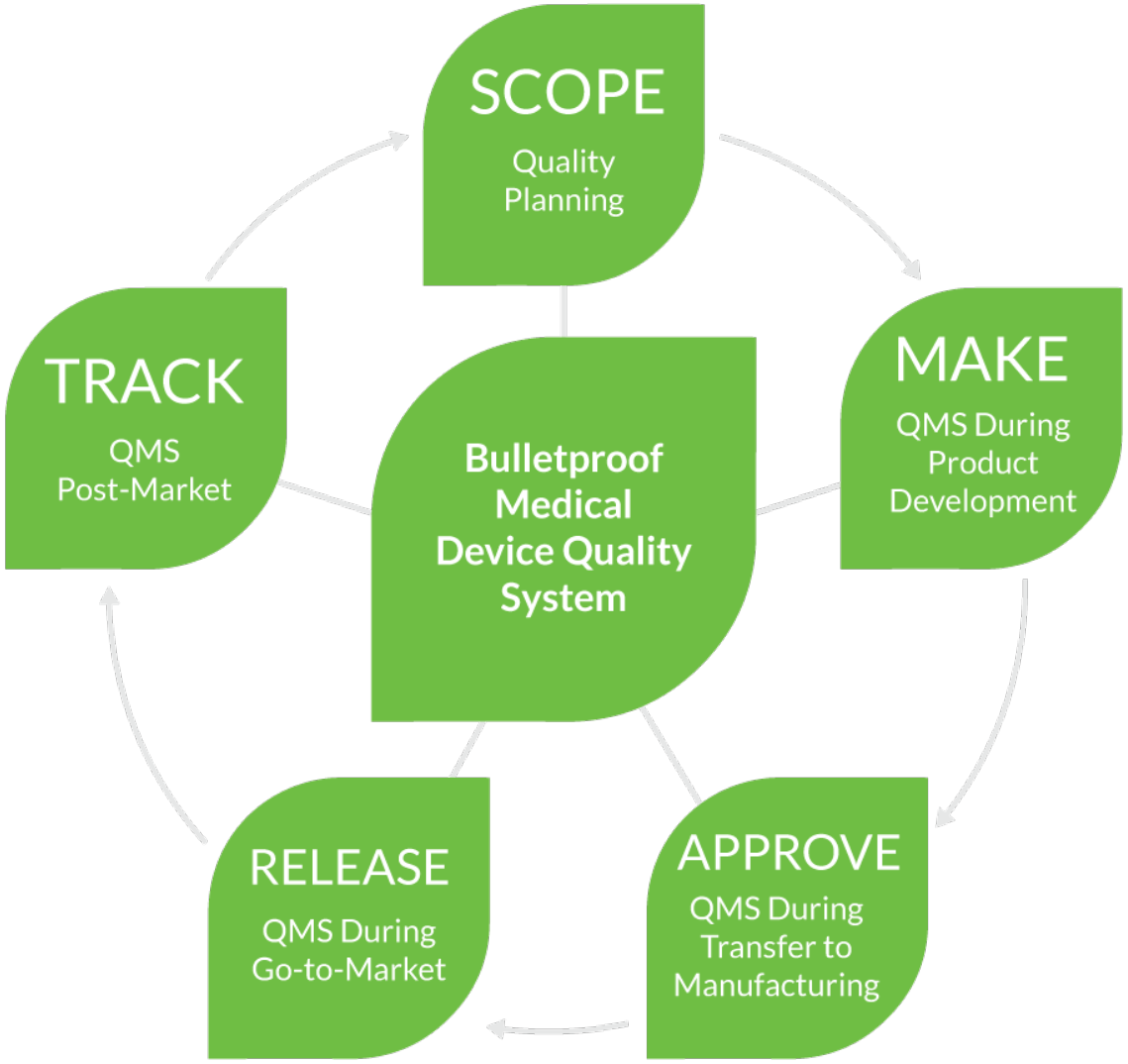
2. Understand differences between ISO 13485:2003 & ISO 13485:2016
   - **Annex A**—comparison between 2003 & 2016 versions

3. Conduct a gap analysis of existing QMS versus ISO 13485:2016
   - Get Your Free QMS Audit Checklist & Schedule Your Free 30 Minute QMS Strategy Session at http://www.greenlight.guru/qms-audit-checklist
4. Contact your ISO registrar; determine their timeline for certifying to 2016 version

5. Establish a Quality Plan
   - Based on gap analysis + registrar timeline

As Promised – Your Free QMS Audit Checklist

Go To: greenlight.guru/qms-audit-checklist
to get your free QMS audit checklist & schedule
your free 30 minute 1-on-1 QMS strategy session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ISO 13485:2016 – Key Takeaways

- Focus of this change is clarifications for use of the standard (implicit is now explicit)
- Basic changes to incorporate risk-based decision making
- Set up to align documentation, clinical and other requirements with EU (MDD)
- Expansion of supplier controls and post-market requirements in feedback
- Drive to Medical Device Single Audit Program (MDSAP) (FDA set to implement in 2017)

Take Action!

- Appoint a team and project manager
- 5 Key Steps
  1. Get a copy of ISO 13485:2016
  2. Understand differences between ISO 13485:2003 & ISO 13485:2016
  3. Conduct a gap analysis of existing QMS versus ISO 13485:2016
     - http://www.greenlight.guru/qms-audit-checklist
  4. Contact your ISO registrar; determine their timeline for certifying to 2016 version
  5. Establish a Quality Plan
- Prioritize efforts
- Establish a schedule
- Don't wait . . . start now!

Questions

What other concerns can we answer?

Go To: greenlight.guru/qms-audit-checklist
to get your free QMS audit checklist & schedule your free 30 minute 1-on-1 QMS strategy session