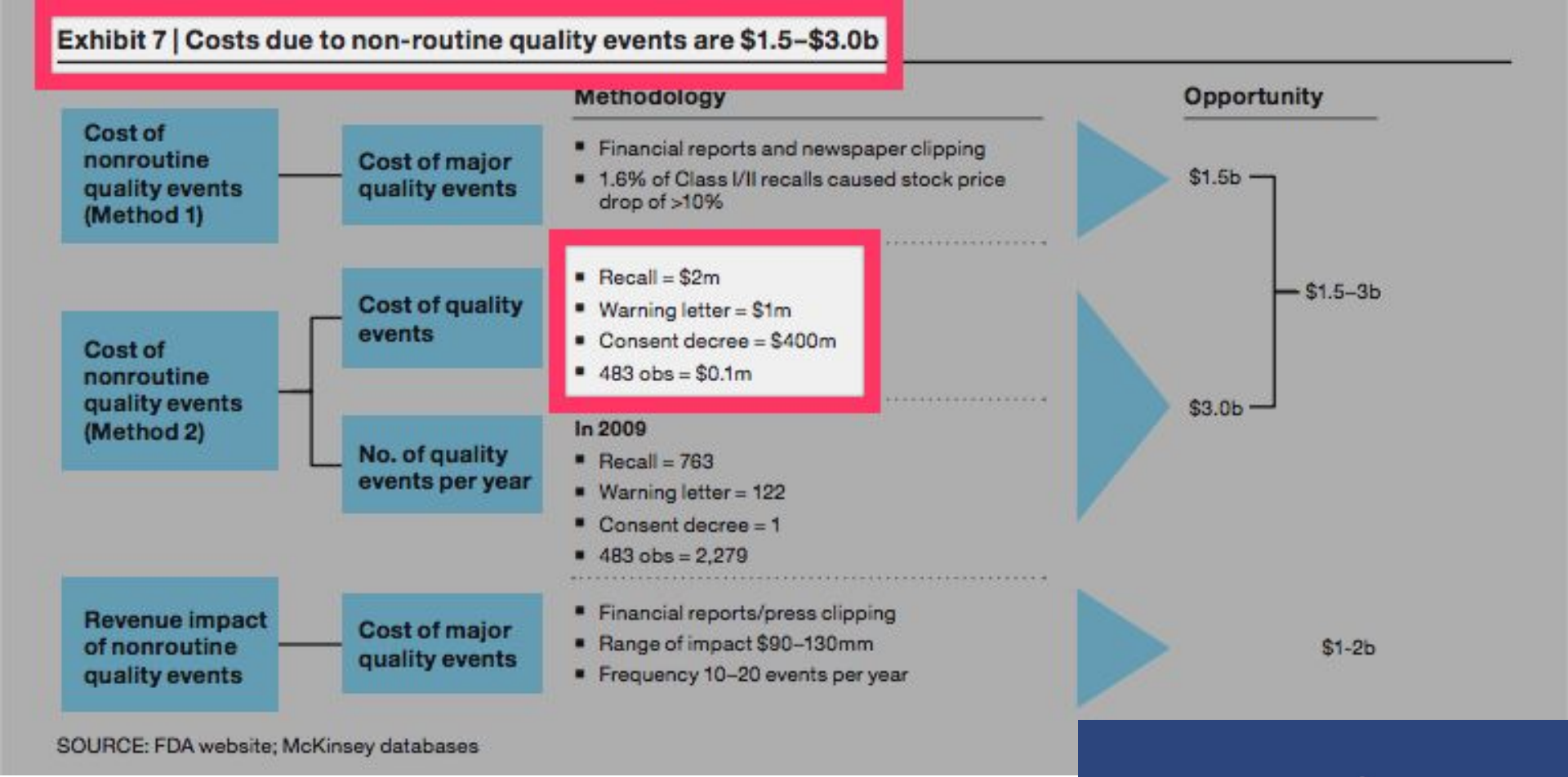
How To Implement (And Maintain) a Bulletproof Medical Device Quality Management System…

Presented By Jon Speer

*“Non-compliance is **THE** single **biggest risk** facing medical device companies today.”*

Exhibit 7 | Costs due to non-routine quality events are $1.5–$3.0b



SOURCE: FDA website; McKinsey databases

McKinsey&Company

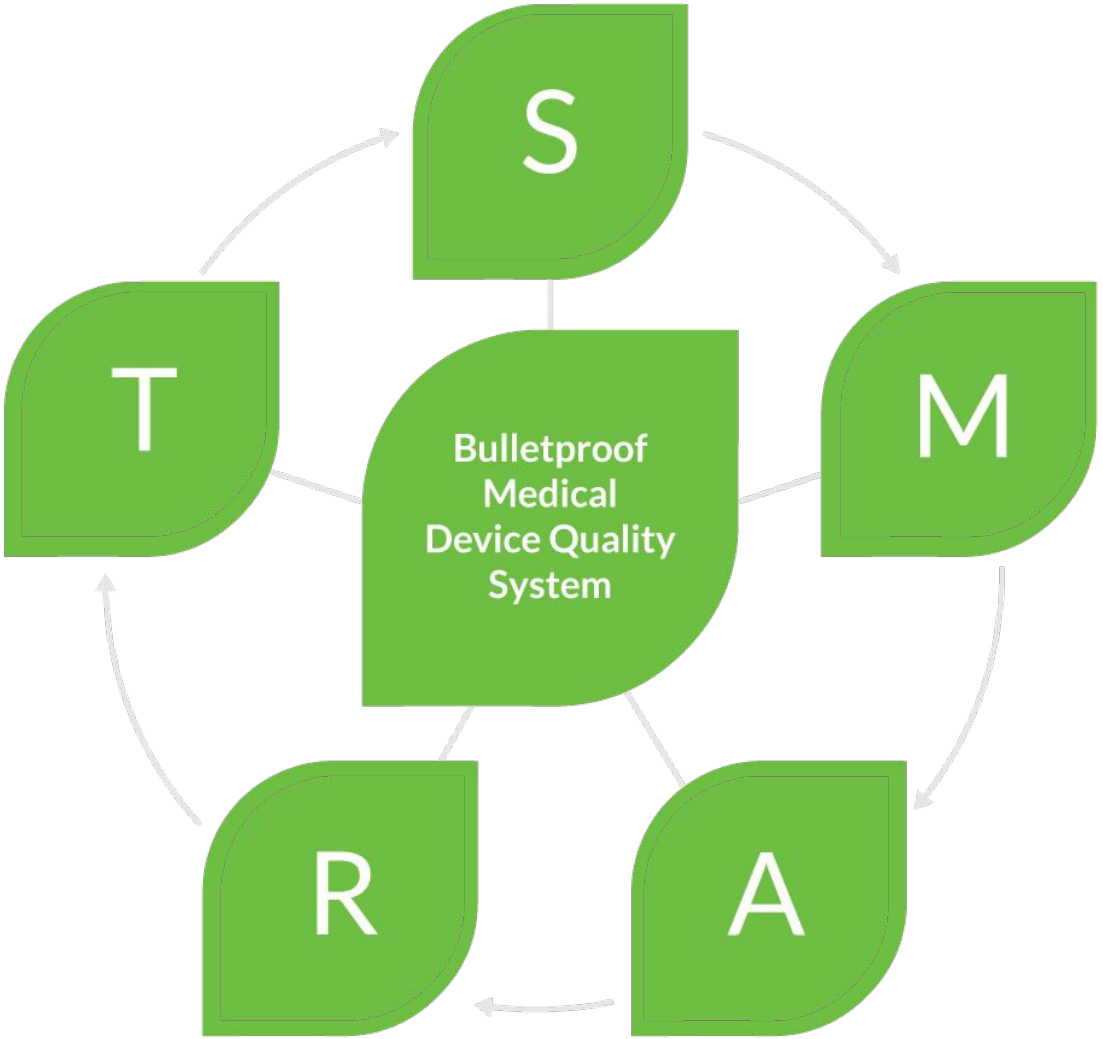
24 Aug 2016 FDA News

FDA Embarks on Warning Letter “Rampage”

FDA: Foreign Device Inspections on the Rise

Posted 17 March 2016

By Michael Mezher


S
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Today I'm going to teach you **how to implement a quality system** at your medical device company that will allow you to…

It doesn’t matter if…

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 can sleep at night because you're not worrying about the potential costs of non-compliance we just covered.

Who is Jon Speer

- 18+ years in the med 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


Me speaking at 10x Conference
(with a tamer beard)
EXIT
THE 10x MEDICAL DEVICE CONFERENCE
Thank you, Sponsors!
TÜV SÜD
armanino
PMI
MedTech STRATEGIST

A few of the devices I've helped get to market...

COOK MEDICAL

Long Island Technology Group

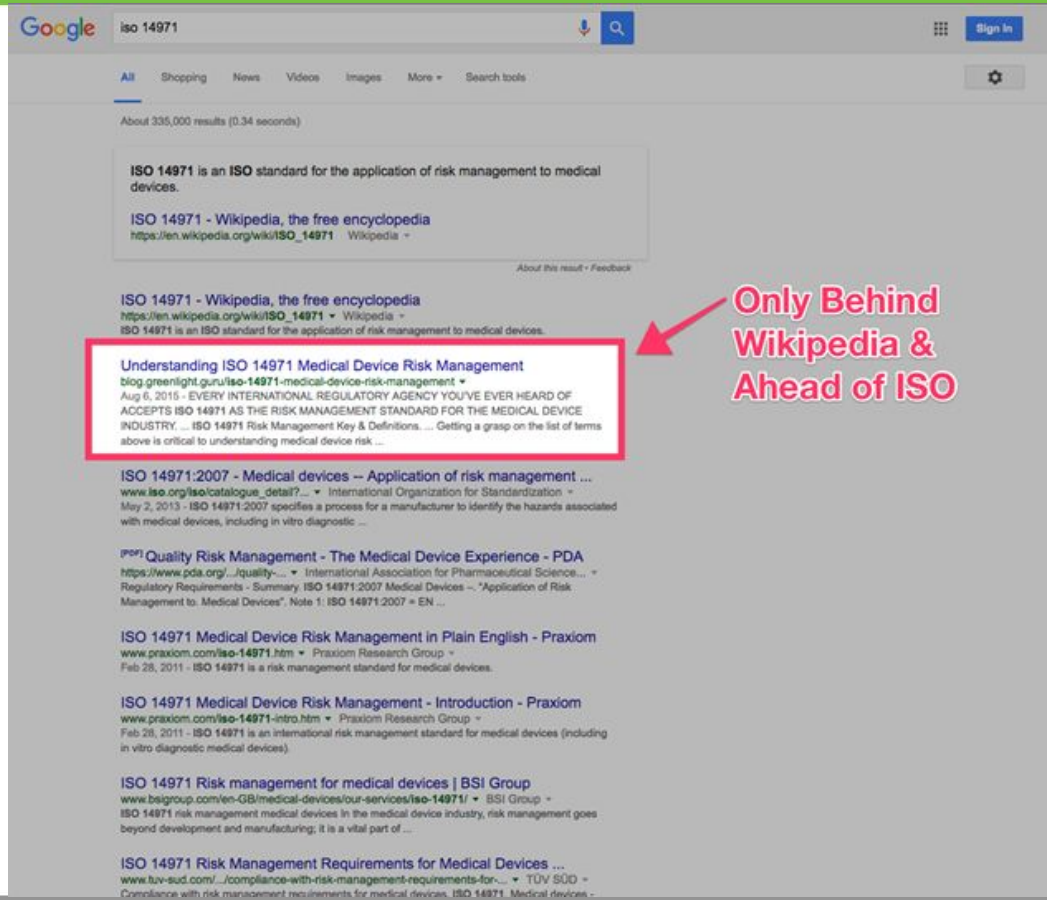
CORK MEDICAL PRODUCTS


MASS DEVICE
MedCity News
MED DEVICE ONLINE
Qmed
QUALIFIED Suppliers to the Medical Device Industry
MDT
MEDICAL DESIGN TECHNOLOGY
MedTech Intelligence
MPO
MEDICAL PRODUCT OUTSOURCING
OrthoStreams
QUALITYDIGEST

Some of the **guides I've written...**

...have been **read more than 100,000 times**

ISO 14971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ISO 14971 is an ISO standard for the application of risk management to medical devices.
ISO 14971 - Wikipedia, the free encyclopedia
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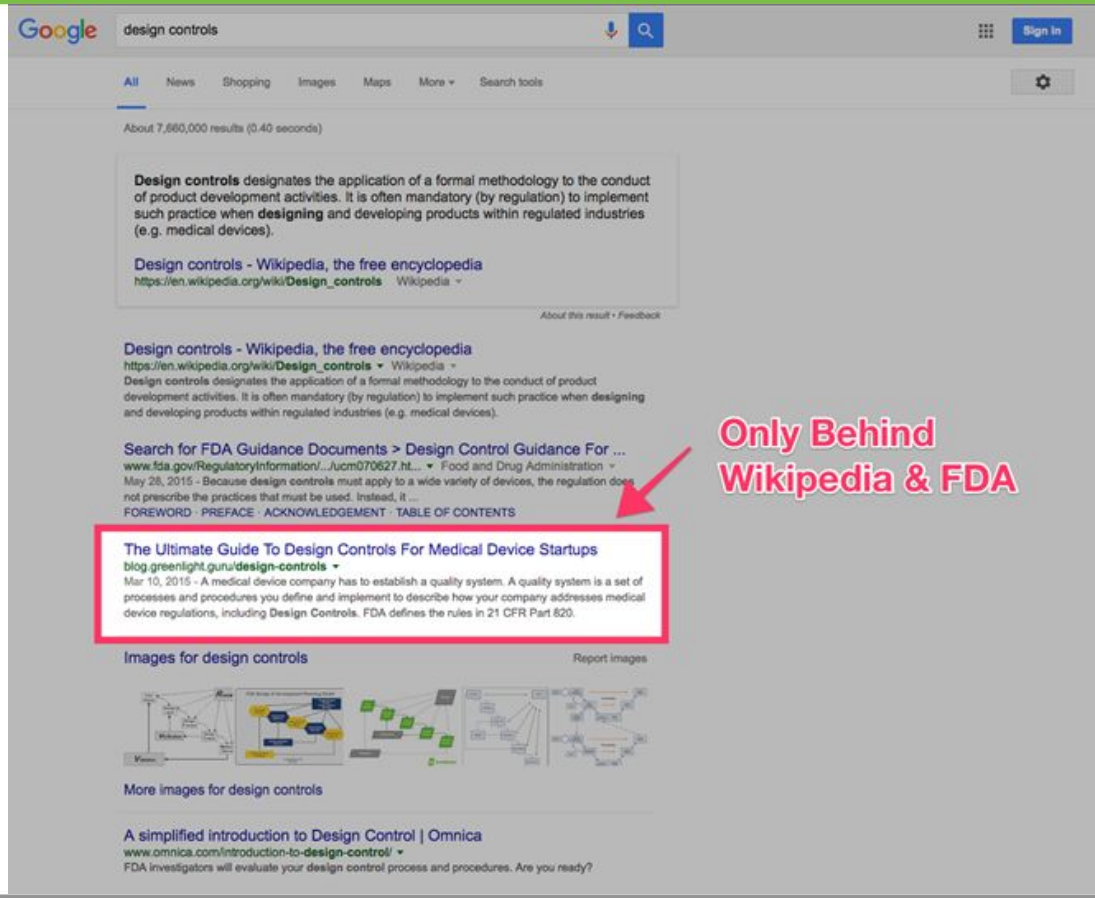
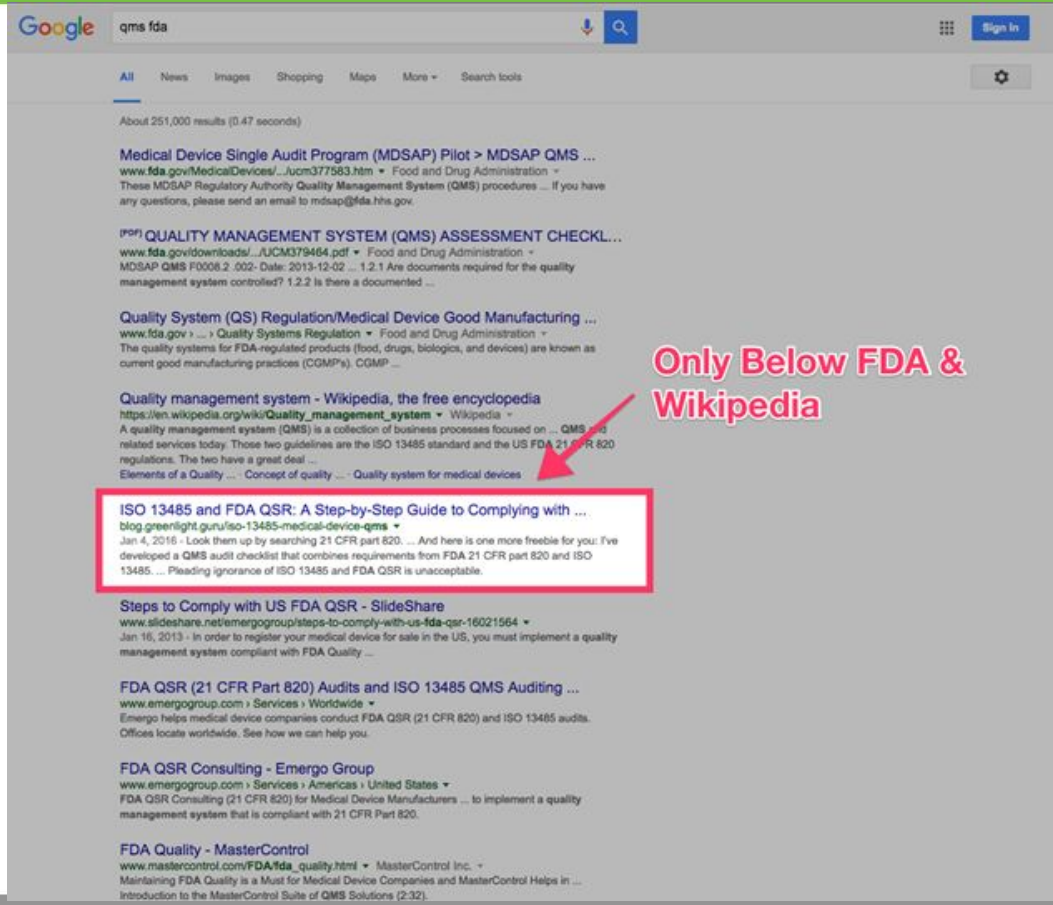
ISO 14971 is an ISO standard for the application of risk management to medical devices.
Understanding ISO 14971 Medical Device Risk Management
blog.greenlight.guru/iso-14971-medical-device-risk-management
Aug 6, 2015 - EVERY INTERNATIONAL REGULATORY AGENCY YOU'VE EVER HEARD OF ACCEPTS ISO 14971 AS THE RISK MANAGEMENT STANDARD FOR THE MEDICAL DEVICE INDUSTRY. ... ISO 14971 Risk Management Key & Definitions. ... Getting a grasp on the list of terms above is critical to understanding medical device risk ...
ISO 14971:2007 - Medical devices -- Application of risk management ...
www.iso.org/iso/catalogue_detail?... International Organization for Standardization
May 2, 2013 - ISO 14971:2007 specifies a process for a manufacturer to identify the hazards associated with medical devices, including in vitro diagnostic ...
[PDF] Quality Risk Management - The Medical Device Experience - PDA
https://www.pda.org/.../quality-... International Association for Pharmaceutical Science...
Regulatory Requirements - Summary. ISO 14971:2007 Medical Devices -- "Application of Risk Management to. Medical Devices". Note 1: ISO 14971:2007 = EN ...
ISO 14971 Medical Device Risk Management in Plain English - Praxiom
www.praxiom.com/iso-14971.htm Praxiom Research Group
Feb 28, 2011 - ISO 14971 is a risk management standard for medical devices.
ISO 14971 Medical Device Risk Management - Introduction - Praxiom
www.praxiom.com/iso-14971-intro.htm Praxiom Research Group
Feb 28, 2011 - ISO 14971 is an international risk management standard for medical devices (including in vitro diagnostic medical devices).
ISO 14971 Risk management for medical devices | BSI Group
www.bsigroup.com/en-GB/medical-devices/our-services/iso-14971/ BSI Group
ISO 14971 risk management medical devices In the medical device industry, risk management goes beyond development and manufacturing; it is a vital part of ...
ISO 14971 Risk Management Requirements for Medical Devices ...
www.tuv-sud.com/.../compliance-with-risk-management-requirements-for-... TÜV SÜD
Compliance with risk management requirements for medical devices. ISO 14971. Medical devices -
Only Behind Wikipedia & Ahead of ISO

Design Controls



QMS FDA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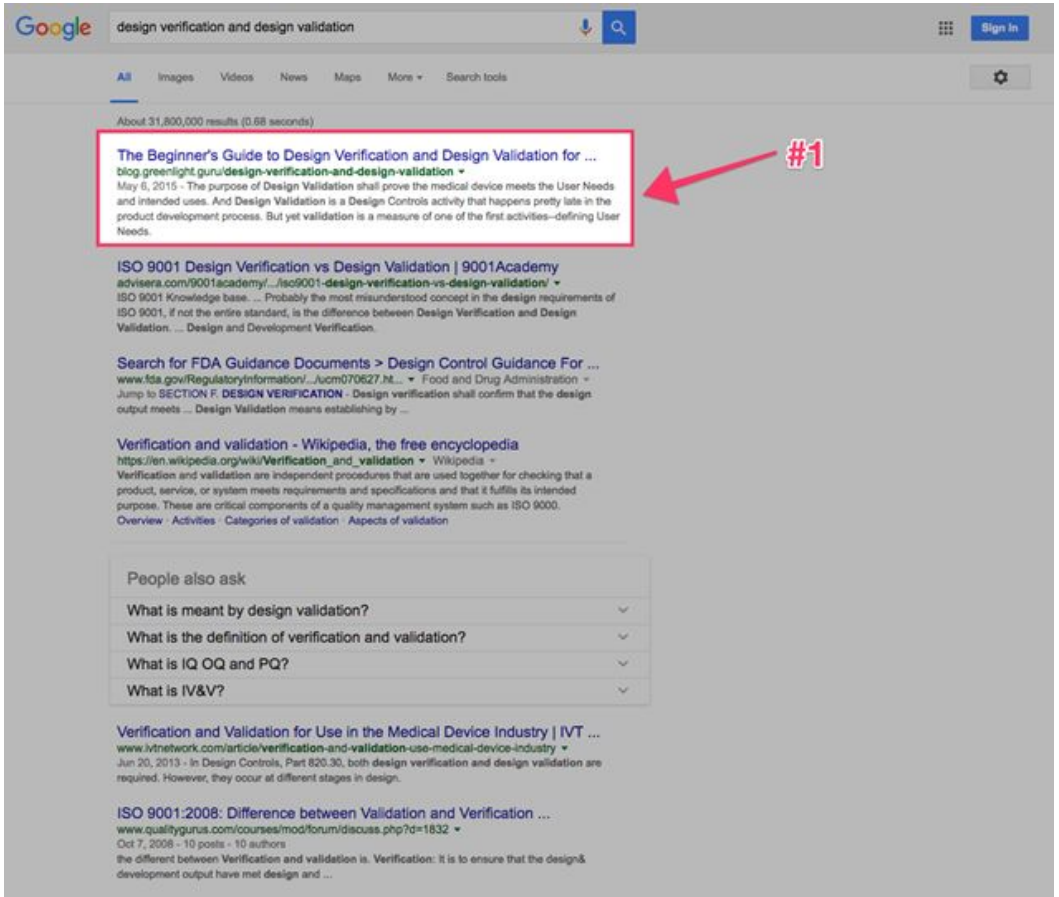
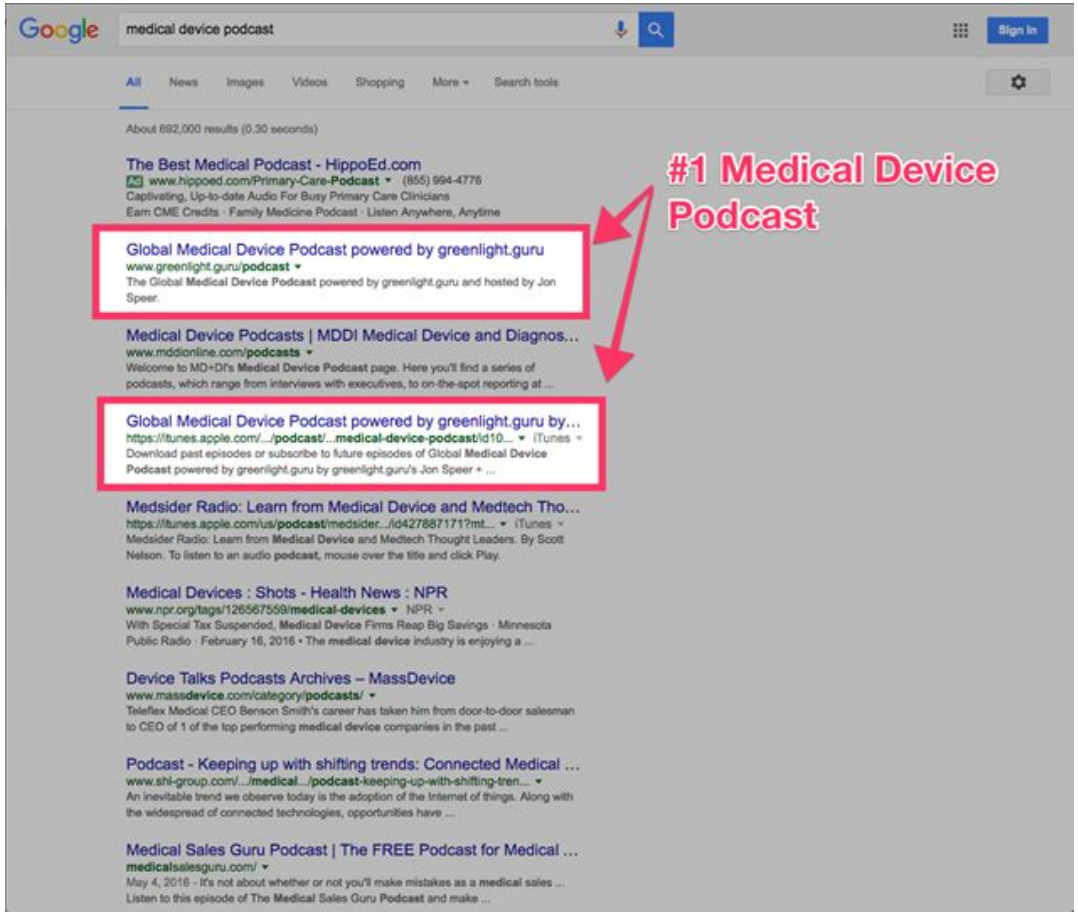
Medical Device Single Audit Program (MDSAP) Pilot > MDSAP QMS ...
www.fda.gov/MedicalDevices/.../ucm377583.htm
Food and Drug Administration
These MDSAP Regulatory Authority Quality Management System (QMS) procedures ... If you have any questions, please send an email to mdsap@fda.hhs.gov.
(PDF) QUALITY MANAGEMENT SYSTEM (QMS) ASSESSMENT CHECKL...
www.fda.gov/downloads/.../UCM379464.pdf
Food and Drug Administration
MDSAP QMS F0008.2 .002- Date: 2013-12-02 ... 1.2.1 Are documents required for the quality management system controlled? 1.2.2 Is there a documented ...
Quality System (QS) Regulation/Medical Device Good Manufacturing ...
www.fda.gov › ... › Quality Systems Regulation
Food and Drug Administration
The quality systems for FDA-regulated products (food, drugs, biologics, and devices) are known as current good manufacturing practices (CGMP's). CGMP ...
Quality management system - Wikipedia, the free encyclopedia
https://en.wikipedia.org/wiki/Quality_management_system
Wikipedia
A quality management system (QMS) is a collection of business processes focused on ... QMS and related services today. Those two guidelines are the ISO 13485 standard and the US FDA 21 CFR 820 regulations. The two have a great deal ...
Elements of a Quality ... · Concept of quality ... · Quality system for medical devices
ISO 13485 and FDA QSR: A Step-by-Step Guide to Complying with ...
blog.greenlight.guru/iso-13485-medical-device-qms
Jan 4, 2016 - Look them up by searching 21 CFR part 820. ... And here is one more freebie for you: I've developed a QMS audit checklist that combines requirements from FDA 21 CFR part 820 and ISO 13485. ... Pleading ignorance of ISO 13485 and FDA QSR is unacceptable.
Steps to Comply with US FDA QSR - SlideShare
www.slideshare.net/emergogroup/steps-to-comply-with-us-fda-qsr-16021564
Jan 16, 2013 - In order to register your medical device for sale in the US, you must implement a quality management system compliant with FDA Quality ...
FDA QSR (21 CFR Part 820) Audits and ISO 13485 QMS Auditing ...
www.emergogroup.com › Services › Worldwide
Emergo helps medical device companies conduct FDA QSR (21 CFR 820) and ISO 13485 audits. Offices locate worldwide. See how we can help you.
FDA QSR Consulting - Emergo Group
www.emergogroup.com › Services › Americas › United States
FDA QSR Consulting (21 CFR 820) for Medical Device Manufacturers ... to implement a quality management system that is compliant with 21 CFR Part 820.
FDA Quality - MasterControl
www.mastercontrol.com/FDA/fda_quality.html
MasterControl Inc.
Maintaining FDA Quality is a Must for Medical Device Companies and MasterControl Helps in ...
Introduction to the MasterControl Suite of QMS Solutions (2:32).
Only Below FDA & Wikipedia

Design Verification and Design Validation



The #1 Medical Device Podcast



Over 10,000 listens in the last 12 months alone…

I’m not **showing you this to brag**, I simply want you to understand I’ve been around the block a few times and **can help you**.

My Goals for Today

1

You can learn how to implement and maintain a quality system at your medical device company that allows you to sleep sound at night and not have to constantly worry about a potential audit because you've implemented a system that ensures you're compliant with all the ever changing regulations like FDA 21 CFR part 820 and the brand new ISO 13485:2016.

My Goals for Today

2

You can get your products to market faster with less risk and allow you time to do your actual job rather than basically being a glorified secretary spending all your time documenting work and chasing down signatures. Not to mention the millions of dollars in forgone revenue you lose each month you're not to market but your competitors are.

My Goals for Today

3

And that you can implement this system and be confident in it no matter if this is your first time going through the medical device product realization process or if you already have a quality system implemented at your company.

Why This is Important To You…

Case Study 1

SANDSTONE DIAGNOSTICS, Inc.

FDA 510(k) Clearance

(2 months sooner than planned)

MENU SEARCH MedCityNews 88 SHARES

DIAGNOSTICS

Sandstone Diagnostics gets FDA clearance for DIY fertility testing kit for men

By STEPHANIE BAUM

Post a comment / 88 Shares / Jun 9, 2016 at 11:53 PM

Case Study 2

Nanofiber SOLUTIONS

Jed Johnson PhD, CTO ISO 13485 Certification

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

Case Study 3

RECOVERY FORCE

Stryke Industries
Disruptive Defense Technologies

Home About Us Team Members Connect
Services Capabilities News

May 20th, 2014
Stryke Industries

STRYKE and Recovery Force Target Warfighter Needs

- Accelerated product development - 510(k) submitted
- Virtual team
- Less reliant on consultants

We're **going to be speaking with each one of them** later on today's presentation…

How This Will Work

- We’re going to run for about an hour and a half
  (90 minutes)
- Type in your questions as you think of them
- Get out your notepad, open up evernote, and start writing things down - we’re going to be covering a lot

My Free Gift For You At The End:

My proven, audit tested, quality management forms, templates and procedures for design controls and risk management.
(Literally a $4,500 value)

When you leverage **my proven S.M.A.R.T. 5 Phase QMS Implementation System**, here's what will happen…

...Basically you'll no longer be struggling with any of the typical QMS problems like…

Is This For You?

If you're a winner and you always want to stay one step ahead of the competition

If you want to be preventive and seek opportunities for improvement verse corrective and deal with problems

If regulations aren't your favorite thing but you know you must keep up with all of them (and you might be a bit afraid you don't know, what you don't know)

If you're a person of action and will be part of the less than 10% that will actually act on what they learn

Who this is NOT for…

If you're not willing to do the work or keep up with the maintenance, this won't work for you. If you have your QMS on cruise control and are not interested in keeping up with best practices.

If you're so stuck in your ways that you're not open to new ways of thinking and leveraging new tools and technology then this isn't for you

If you're only here because your boss made you and you have no real desire to be better then you're not going to learn anything

If you're looking for a no-touch, automated way to pass an audit without having to do anything, this isn't the webinar for you either

Let me level with you…

Unless you really geek out about this stuff like I do, there's nothing sexy or fun about quality and compliance.

My objective for you in this training session is to teach you how to make compliance as painless, efficient and risk free as possible.

As we get into the material here, let's first cover the real business costs of compliance and non-compliance...

- Cost of internal labor
- Cost of a consultant
- Opportunity cost of time to market
- Potential cost of non-compliance

There are often millions of dollars at stake.

… by walking through an example case study of a medical device project from start to 510(k) clearance.

The cost of internal labor…

On average, a team can expect to **lose 179 hours** over the course of an 18 months medical device project on zero value-add activities like coordinating, updating documentation and maintaining traceability.

Using the US industry average of $150,000 annual cost per project manager fully loaded, you're looking at a **cost of about $12,600**.

The cost of part time consultants…

Between hours spent collaborating, travel, design reviews, maintaining traceability, updating documentation, compiling design history file and more, you can expect to waste **676 consulting hours** on average per medical device project.

At a rate of $150 per hour, you're looking at a **cost of $101,400**.

The opportunity cost of time to market…

This is where compliance really can become painful. Let's say you have an average expected deal size of $950 and your sales forecast call for 5,000 units to be sold in each of your first 3 months to market.

We've already been able to identify 855 hours of saved project time. While this certainly does not mean that the project will finish 855 hours earlier, we can reasonably estimate (and back up through case studies) that two months could be shaved off the product timeline.

That's two months earlier to market, with more features, and ahead of the competition. This represent **$791,000 in lost revenue**.

This doesn't even include the cost of additional burn rate.

The potential cost of non-compliance…

The cost of non-compliance can be tricky to calculate but given that **69% of 510(k) submission are rejected the first time** and they take on average at least a month to tell you whether or not they've accepted your submission, you're look at another month of lost revenue + burn rate.

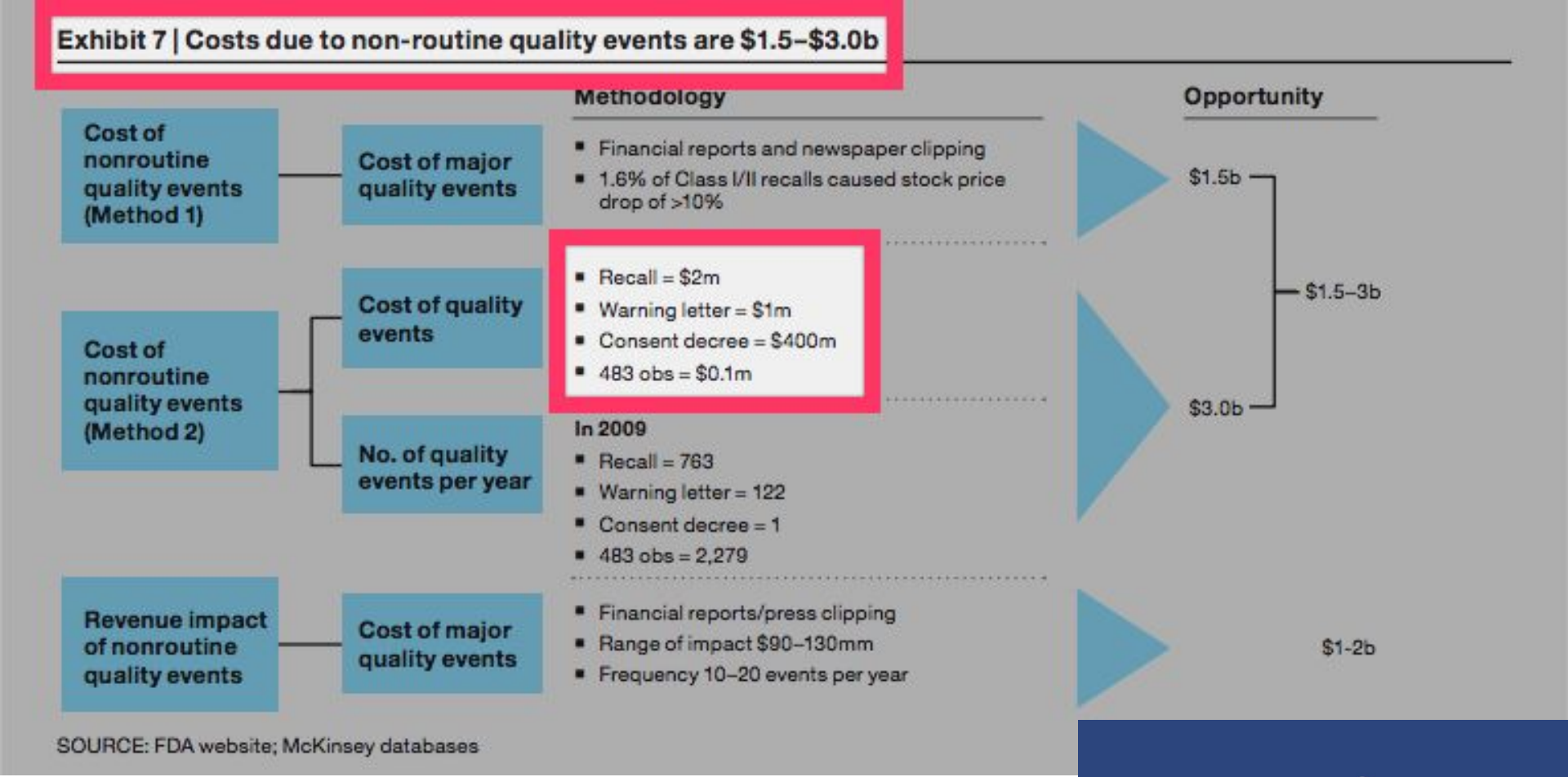
This represents **at least another $395,000 in lost revenue** if your 510(k) is rejected.

The potential cost of non-compliance…

Now I get that you're not a huge multinational corporation, but conservatively you're looking at a bare minimum of **$50,000 to address a 483 observation** and could easily still be looking at **$1M to remedy a warning letter** if you were to get one.

And we haven't even talked about the possibility of getting a 483 or warning letter yet. Let's take a look at a report McKinsey put out to get a handle of how much one of those might cost.

Exhibit 7 | Costs due to non-routine quality events are $1.5–$3.0b



SOURCE: FDA website; McKinsey databases

McKinsey&Company

So that provides a snapshot into what compliance could cost over the course of an 18 month product development project.

What would it mean to your business if you **lost at a minimum of $114,000 of expenses** and at **two months or $791,000 of lost revenue** on every product development project?

A Bulletproof Medical Device Quality System Must…

Leverage the best…

1. **People**
2. Processes
3. Technology

Let me share the 2 cornerstones of my QMS philosophy….

1. Keep your QMS simple
2. Right-size your QMS

1 Keep Your QMS Simple

"A QMS should meet the intent of regulations and sufficiently describe a company's processes. No More. No Less."

2 Right-Size Your QMS

"The QMS you have in place should be tailored to the size and type of company you are."

2 Right-Size Your QMS

The common mistake is small medical device companies implement an overly burdensome QMS. The problem usually stems from hiring a quality resource who used to work at a very big company and they come in and implement a QMS similar to what was in place at the company they were at before.

While many small companies may believe having a big company QMS in place is an advantage, this is actually a huge disadvantage as it is becomes over burdensome and will not scale for a small med device company.

And it’s those 2 cornerstone that make my system work...

Realize this...

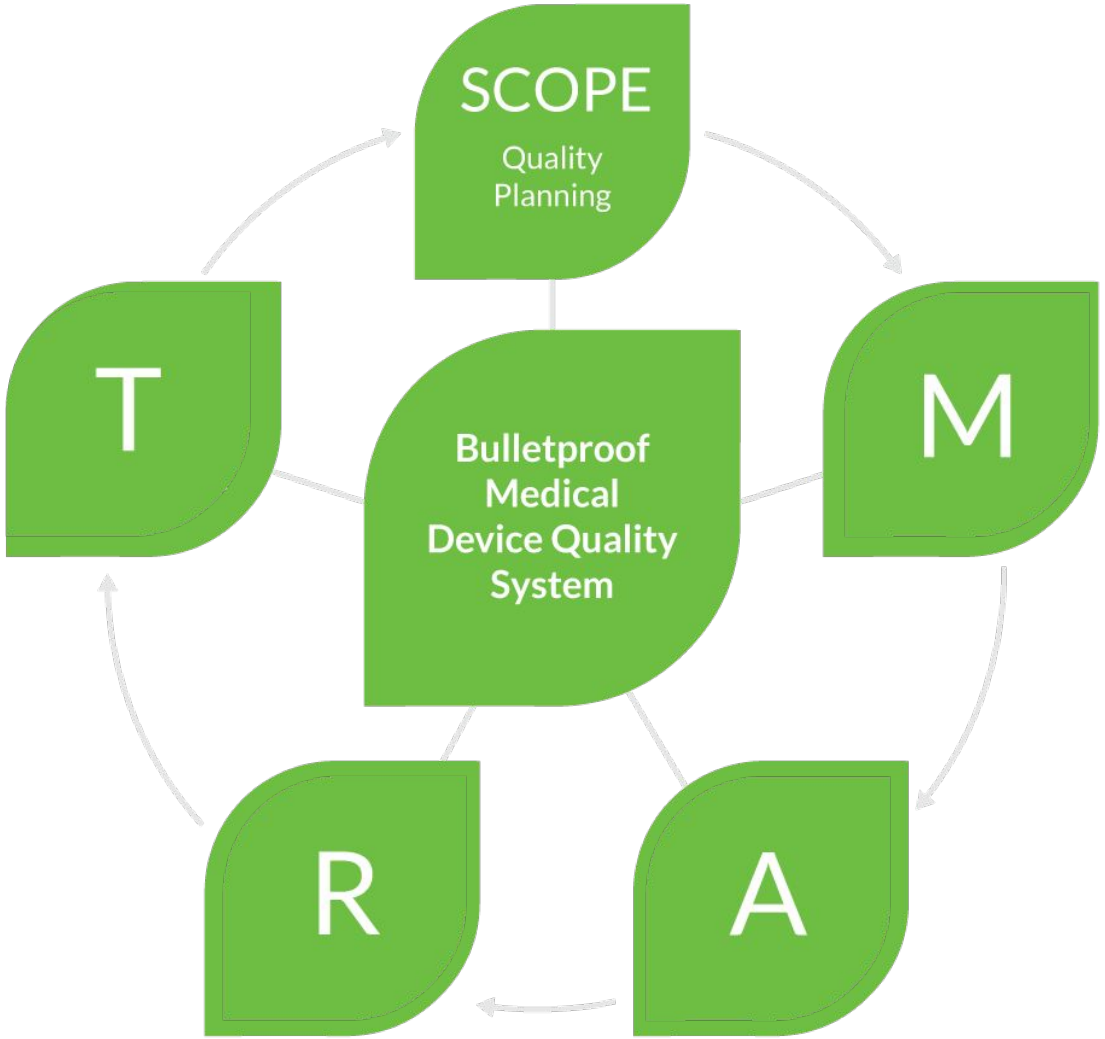
A best practice QMS implementation achieves *two, primary missions*:

1. Aligns with applicable regulations
2. Describes the processes and practices within your company

A Bulletproof Medical Device Quality System Must...

Leverage the best…

1. People
2. **Processes**
3. Technology


SCOPE
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1 The SCOPE Phase: Quality Planning

The steps you take to map out QMS efforts

How To Determine What Regulations Apply To Your Device?

First why does this matter?

- Product classification will determine what you have to do BEFORE you can sell your product.
- Product classification will help you establish what is required during product development and Design Controls.
- Product classification is an important component in determining how much it will cost to bring your product to market and give you some idea of how long it will take.

What You Need To Know About the New Risk-Based Changes...

- ISO 14971 is the risk management standard
- New ISO 13485:2016 says now all quality processes must be “risk-based”
- FDA placing a much greater emphasis on risk and says to reference ISO 14971

1

SCOPE Phase Myth #1

"A startup medical device company doesn't need to worry about implementing a QMS until they have received regulatory clearances and plan to go to market."

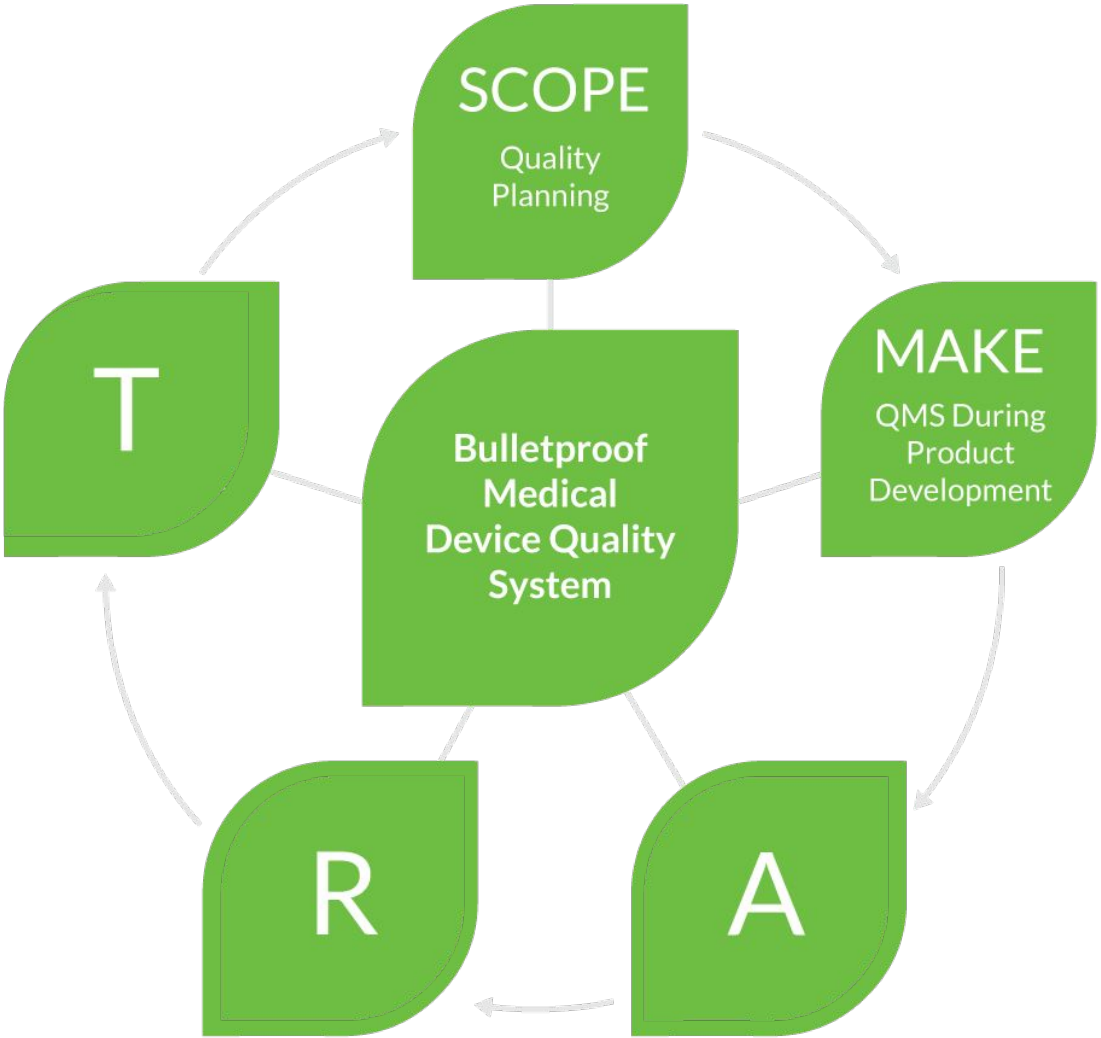
1

SCOPE Phase Myth #2

"Once a company has an established QMS, there is little to no need to go back to re-evaluate or revamp a quality system."

SCOPE Phase Best Practices…

- Perform a Gap Analysis.
- Leverage the results of your internal and external audits.
- Define the scope of your QMS initiatives in a Quality Plan.


SCOPE
Quality Planning
MAKE
QMS During Product Development
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Bulletproof Medical Device Quality System

2 The MAKE Phase: QMS During Product Development

The steps you take to ensure your QMS addresses activities happening during design and development

Quality processes you need to have in place by the MAKE phase…

- Design Controls / Design & Development
- Risk Management
- Supplier Management
- Document Control & Records Management

2 MAKE Phase Myth #1

"If your company is a contract manufacturer, then product development related QMS processes probably do not apply to you."

MAKE Phase Myth #1

There are several design controls elements that most definitely apply to contract manufacturers.

Two examples:

- Design Outputs are the preliminary Device Master Record.
- Design Transfer represents the stage of product development where the product is transitioning to manufacturing control.

2

MAKE Phase Myth #2

"An established medical device company with an established QMS does not need to invest time or resources on QMS procedures applicable to design and development."

This is not true for a few reasons...

Reason 1: Design control deficiencies are the single biggest reason for 483 observations during FDA inspections.

CFR Clause	QS Subsystem	# 483 Observations	% of 483s
820.30 - Design Controls	DES	536	15%
820.100 - Corrective and Preventive Action	CAPA	474	13%
820.198 - Complaint Files	CAPA	435	12%
820.90 - Nonconforming Product	CAPA	222	6.3%
820.80 - Receiving, In-Process, and Finished Device Acceptance	P&PC	195	5.5%
820.75 - Process Validation	P&PC	180	5.1%
820.70 - Production and Process Controls	P&PC	153	4.3%
820.184 - Device History Record	DOC	152	4.3%
820.22 - Quality Audit	MGMT	145	4.1%

Reason 2: Risk Management

ISO 14971 is the medical device industry's best guide for risk management. Yet very few medical device companies have actually implemented risk management processes that comply and meet the requirements of ISO 14971

Reason 3:

Design Controls + Risk Management

Most medical device companies have antiquated and cumbersome product development processes in place. Most make capturing design controls and risk management overly burdensome and complicated.

2

MAKE Phase Myth #3

"A medical device startup should focus on preparing a regulatory submission and deal with design controls and risk management later. Design controls and risk management are not important to a regulatory submission."

Make Phase Risk #3

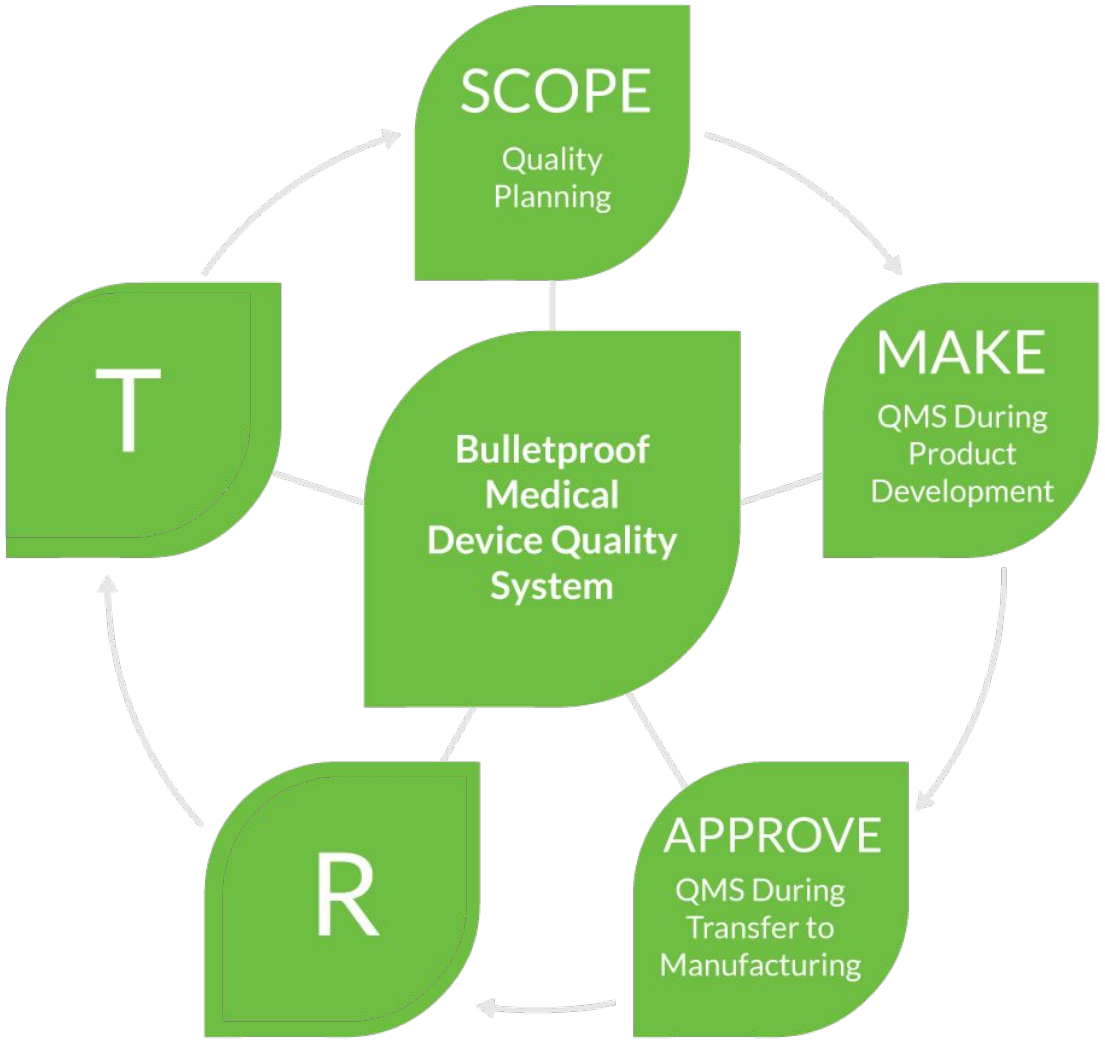
It does not matter if you are preparing a FDA 510(k) or CE mark technical file, the details of design and development activities are crucial to the objective evidence required to demonstrate a product is safe, effective, and meets the indications for use.

This is the whole premise of design controls and risk management.

And because of this, the QMS procedures related to these activities must be defined and implemented.

MAKE Phase Best Practices…

- Streamline your design and development process.
- Focus on traceability of your design and development from the beginning.
- Fully integrate design controls and risk management processes.


SCOPE
Quality Planning
MAKE
QMS During Product Development
APPROVE
QMS During Transfer to Manufacturing
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Bulletproof Medical Device Quality System

3 The APPROVE Phase: QMS During Transfer to Manufacturing

The steps you take to ensure your QMS addresses initial pilot production as well as activities leading up to and including clearance of regulatory submissions.

Quality processes you need to have in place by the APPROVE phase...

- Training
- Purchasing
- Device Master Records (DMR)
- Production & Process Controls
- Labeling & Packaging
- Receiving, Incoming,
- In-process and Final
- Inspections
- Identification & Traceability
- Device History Records (DHR)
- Change Management
- Non-Conforming Materials
- CAPA
- Management Responsibility

3 APPROVE Phase Myth #1

"Regulatory submissions must include all details of manufacturing processes."

3 APPROVE Phase Myth #2

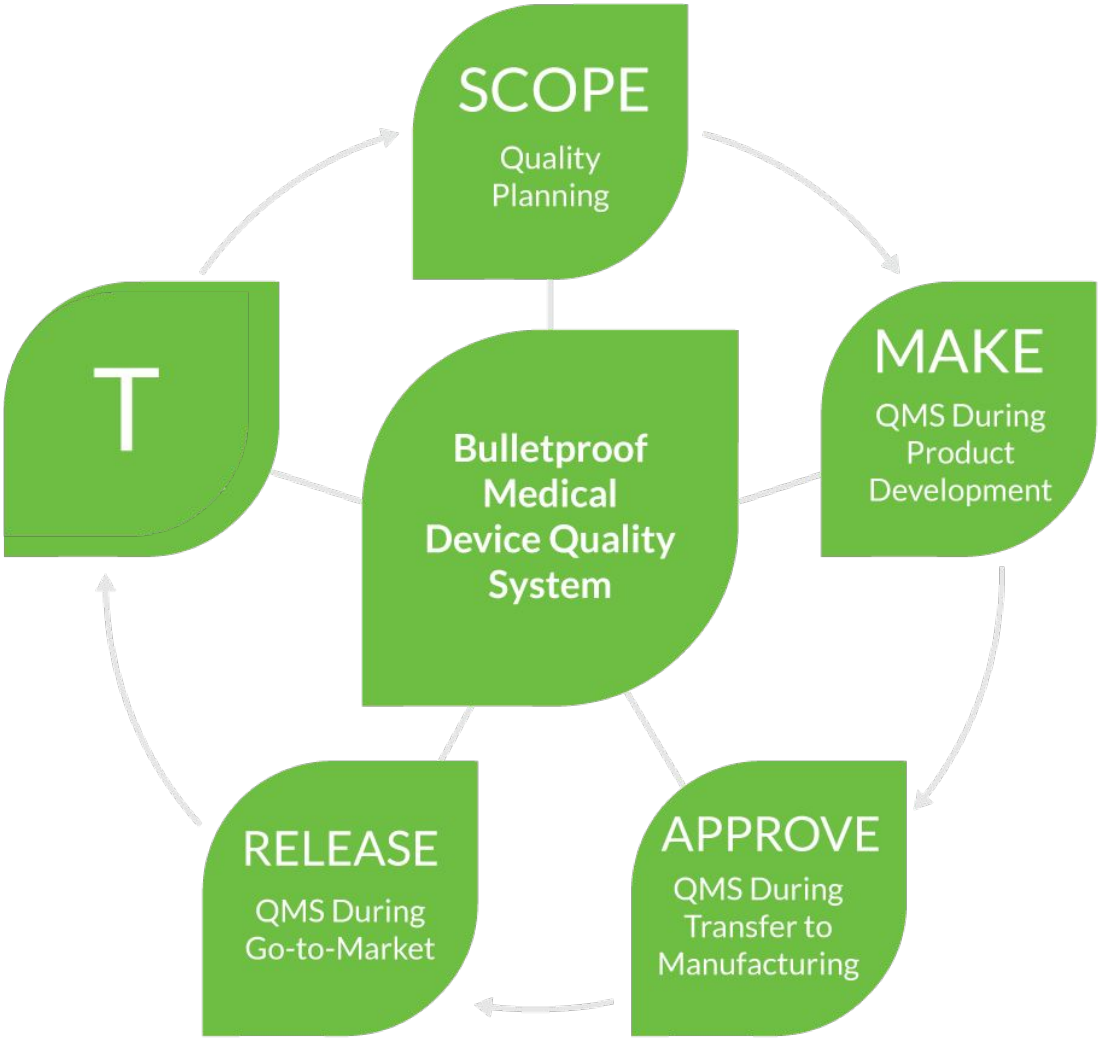
"You have to wait until you receive regulatory clearance before you can begin manufacturing."

3 APPROVE Phase Myth #3

"You don't need to have design controls and risk management implemented before you file your 510(k)."

APPROVE Phase Best Practices…

- Strived to be in a position to start selling my product the day after you receive regulatory clearance to do so.
- And this is one of the major underlying principles of the SMART QMS process. Align your company's QMS with regulatory expectations and do so in a manner that is streamlined and efficient so that you can get to market as fast as possible.
- Use and follow the RTA checklist guidance


SCOPE
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QMS During Product Development
APPROVE
QMS During Transfer to Manufacturing
RELEASE
QMS During Go-to-Market
T
Bulletproof Medical Device Quality System

4 The RELEASE Phase: QMS During Go-to-Market

The activities you take to ensure your QMS is fully implemented and ready for production and market release.

The remaining quality processes you need to have in place by the RELEASE Phase…

- Process Validation
- Software Validation
- Calibration
- Preventive Maintenance
- Handling, Storage,
- Distribution, & Installation
- Servicing
- Complaint Handling
- Adverse Event Reporting / MDR
- Corrections & Removals
- Customer Feedback
- Analysis of Data
- Internal Auditing
- Quality Manual

4 RELEASE Phase Myth #1

"Once a DHF is completed and transferred to manufacturing, there is no need to keep this current and up-to-date."

RELEASE Phase Myth #1

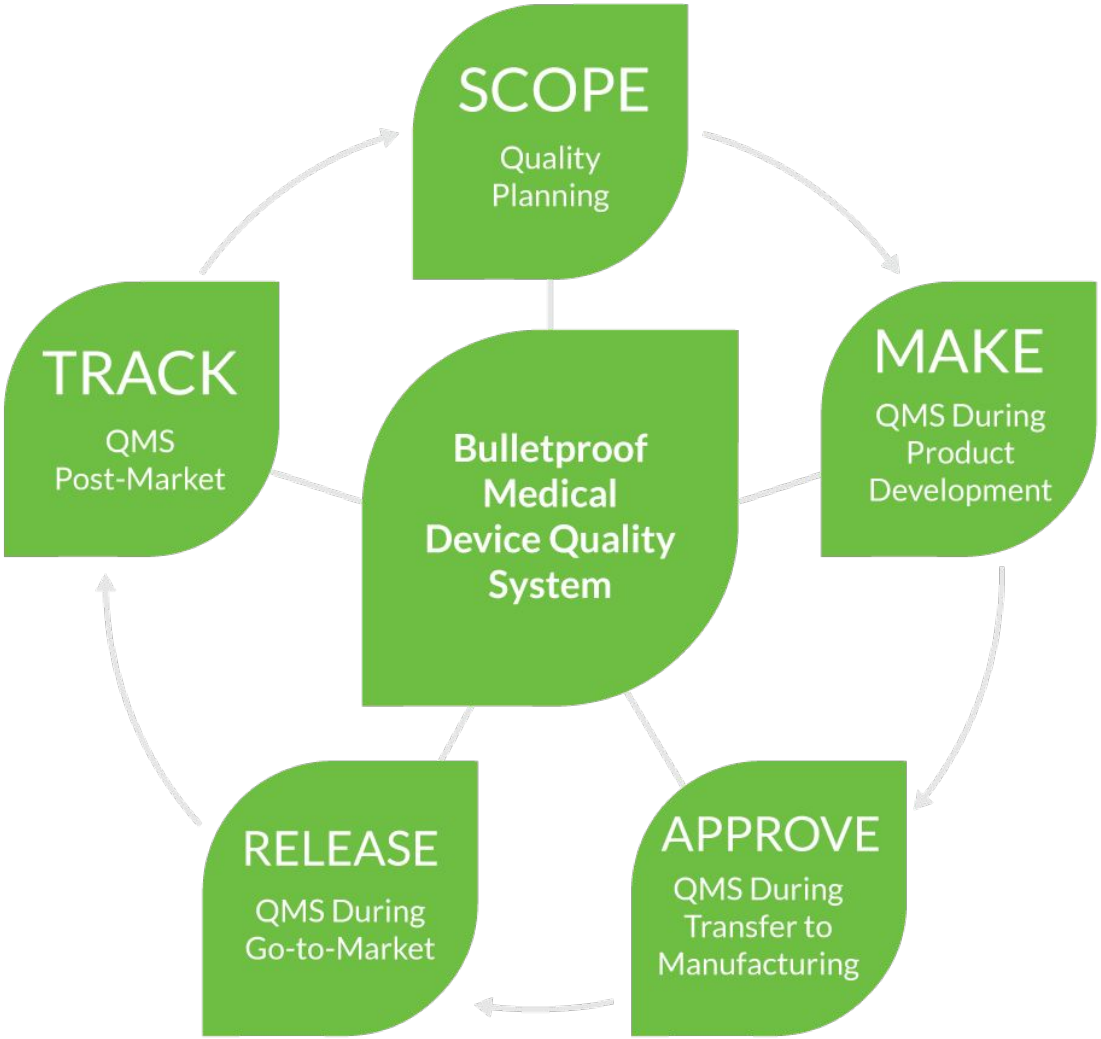
It is my opinion that a DHF should be an accurate reflection of the current version of the product. Any time a change is made, there are certain criteria which must be considered and addressed, including:

- Impact on form, fit, and function
- Verification and validation
- Risk management
- Regulatory

RELEASE Phase Best Practices…

- Ensure your design controls and DHF are maintained as “living” throughout the entire product life cycle.

- Ensure your risk management file is maintained and living.


SCOPE
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QMS During Go-to-Market
TRACK
QMS Post-Market
Bulletproof Medical Device Quality System

5 The TRACK Phase: QMS Post-Market

The activities you take to measure and monitor the performance and health of your QMS as well as measuring and monitoring the performance of your products in the marketplace.

Quality system procedures you will use to track the health of your QMS during the TRACK Phase…

- CAPA
- Analysis of Data
- Internal Auditing

You will also be monitoring the health of your products during the TRACK Phase via…

- Non-conformances
- Complaint Handling
- Adverse Event Reporting / MDR
- Customer Feedback

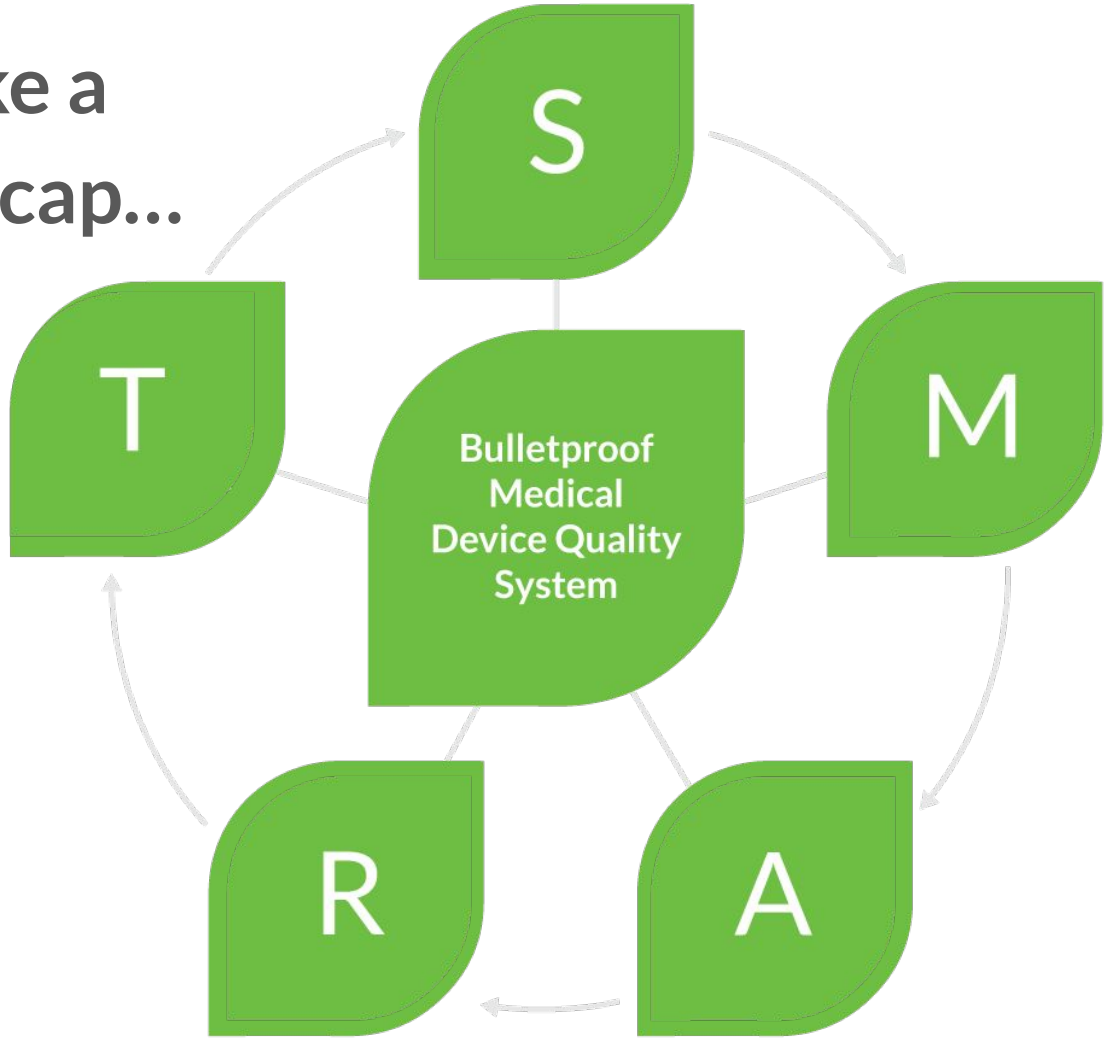
5 TRACK Phase Myth #1

"Once a product is launched and QMS is implemented, you don't have to worry about updating your QMS unless there is an issue identified during an ISO audit or FDA inspection."

TRACK Phase Best Practices…

- Tweak and adjust your QMS to continually improve efficiency.
- Tracking overall quality system effectiveness is a way to ensure your QMS stays simple and to focused on being right-sized.
- Identify a handful of key performance indicators, or KPIs, and use these to help drive QMS improvement initiatives.

Let's take a quick recap…



A Bulletproof Medical Device Quality 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**

Traceability + objective evidence

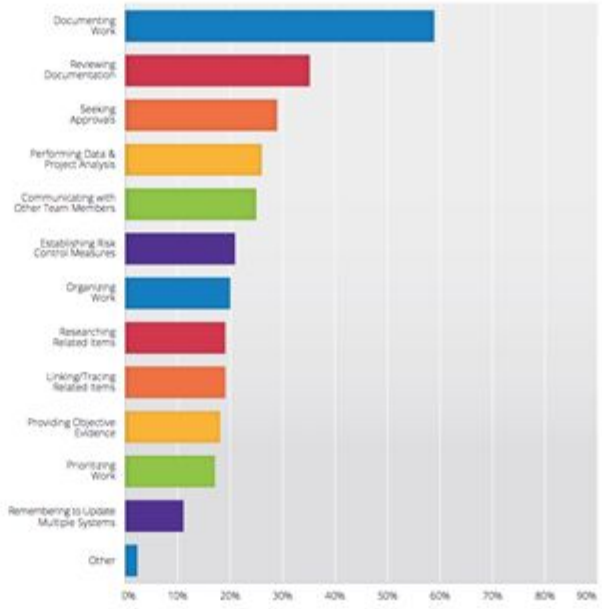
= everything

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

But traceability and documentation take sooo 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.

If you've ever **felt like this,**

There's a reason, **I have too...**

I felt **overwhelmed**…

I was **frustrated**…

So I had **a choice**...

I could…

...**continue doing what I was doing**, using, broken outdated practices and technologies...

Or...

I could search for a better technology...

So I could have given up there, gone back to the status quo...

...instead a made a choice that would forever change my life and the medical device industry…

I founded and built greenlight.guru based on my S.M.A.R.T. 5 Phase QMS Implementation System

So what's ***the secret***?

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, most innovative, market leading companies understand this…

LNS Research Quality Maturity Model

MARKET LEADER Ability to define markets, transform business models, and disrupt incumbents	5
AGILE Ability to meet and exceed current market demands. Fast follwer as markets transform.	4
PROACTIVE Ability to meet and exceed current market demands. Potential to meet future market demands.	3
CONTROLLED Ability to meet and exceed current market demands. Inability to meet future market demands.	2
AD HOC Inability to meet current or future market demands.	1

Let’s revisit the financial picture…

The right **tax consulting** has the ability to save you the most money, time, headache, and potential risk.

For just one project, here's what's at stake

Cost of internal labor	179 hours x $70/hour	$12,600
Cost of external consultants	676 hours x $150/hour	$101,400
Opportunity cost of time to market	Two Months at $395k/month	$791,000
Potential cost of non-compliance	For a 483	$100,000
Total		**$1,005,000**

But don’t just **take our word for it...**

Case Study 1

SANDSTONE DIAGNOSTICS, Inc.

FDA 510(k) Clearance

(2 months sooner than planned)

MENU SEARCH MedCityNews 88 SHARES

DIAGNOSTICS

Sandstone Diagnostics gets FDA clearance for DIY fertility testing kit for men

By STEPHANIE BAUM

Post a comment / 88 Shares / Jun 9, 2016 at 11:53 PM

Case Study 2

Nanofiber SOLUTIONS

Jed Johnson PhD, CTO ISO 13485 Certification

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

Case Study 3

RECOVERY FORCE

Stryke Industries
Disruptive Defense Technologies

Home About Us Team Members Connect
Services Capabilities News

May 20th, 2014
Stryke Industries

STRYKE and Recovery Force Target Warfighter Needs

- Accelerated product development - 510(k) submitted
- Virtual team
- Less reliant on consultants

greenlight.guru

You've just heard with your own ears that you can implement and maintain a bulletproof quality system that will give you peace of mind knowing you're compliant with all the new regulations and will stand up to any audit...

Will enable you to get your products to market faster, with less risk saving you millions in foregone revenue each month you're not to market but your competitors are…

And that you can implement this system and be confident in it no matter what your personal experience level or where your company is at in the product realization process.

But let’s take a deeper look at specifically how greenlight.guru stacks up against paper-based systems and legacy, enterprise solutions...

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…

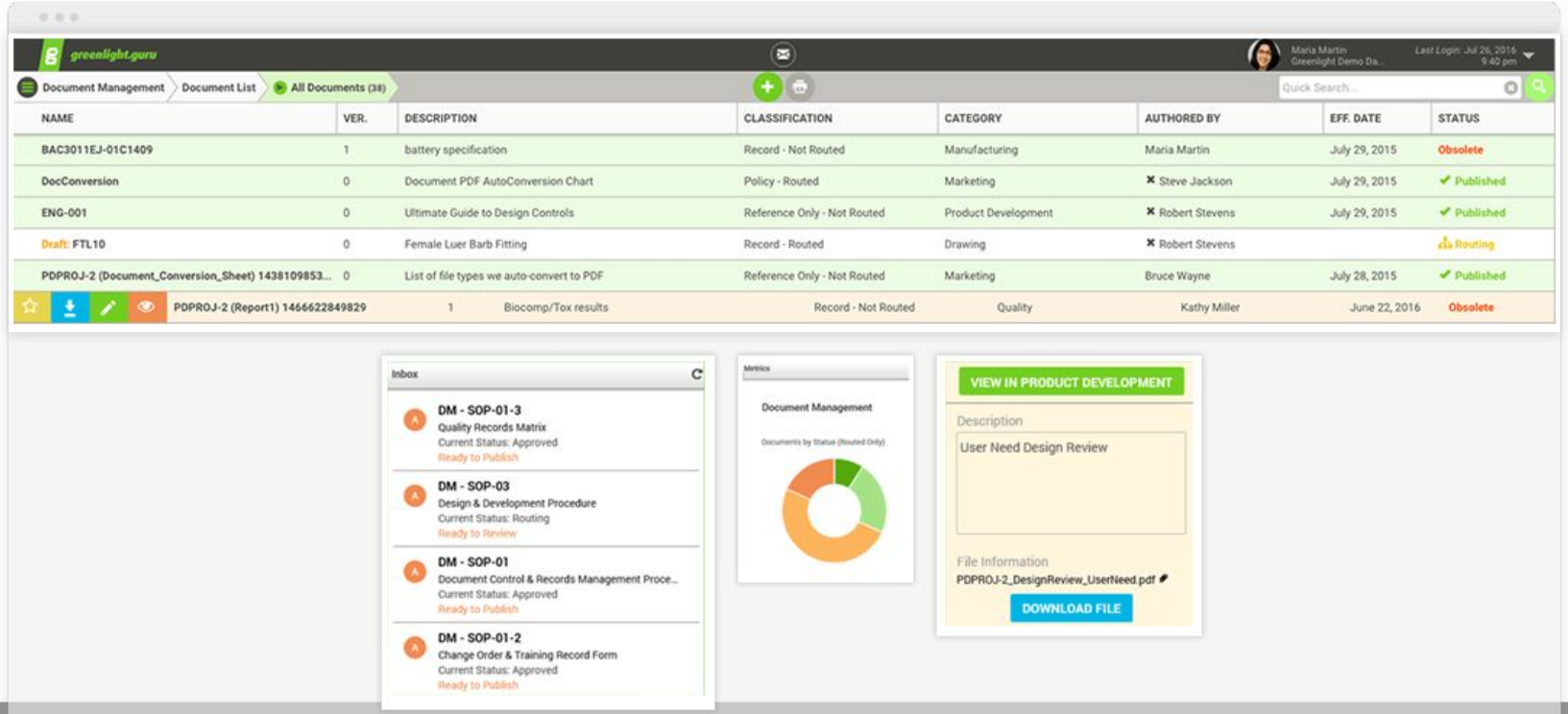
- Comply with all the latest regulations by leveraging technology with the latest best practices built in
- Easily manage and mitigate risk
- Improve your time to market by increasing efficiency and effectiveness of processes
- Empower stakeholders with real time access to complete and accurate data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

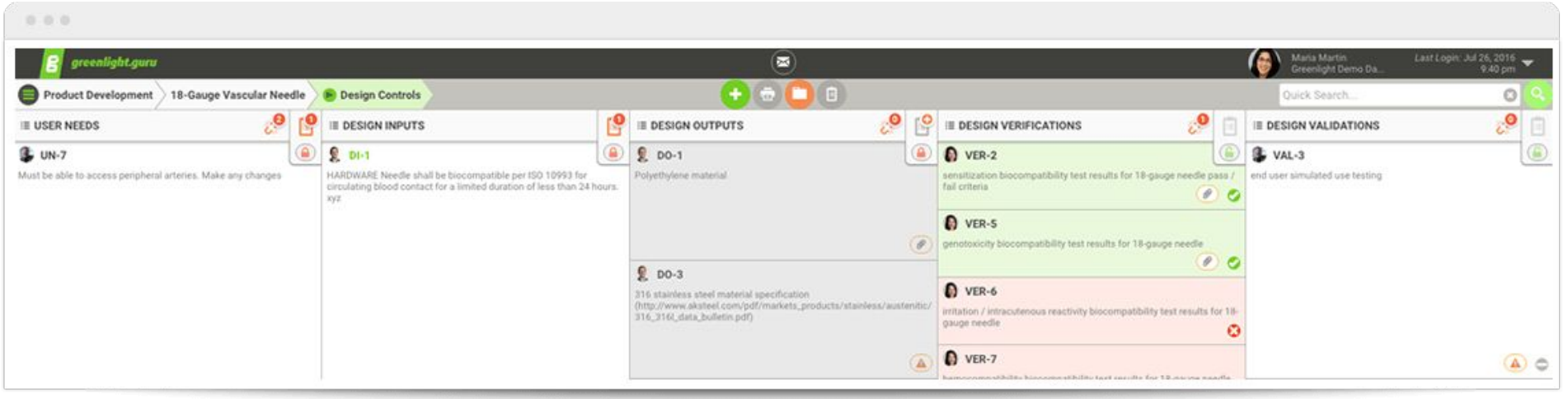
Document Management & Control in greenlight.guru



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

- 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 basically impossible to use
- Cost and time of implementation and maintenance are often not well understood
- No team of medical device experts to literally walk you through every step of the process
- Not specifically built for medical device
- Not a true partner that's invested in your success

Design Controls + Risk Management in greenlight.guru

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.
- Work flows 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.

So today I’ve shown you that if you’re willing to put in the work and leverage my proven system...

...that you can have a bulletproof quality management system that **will save you millions of dollars** and give you peace of mind...

You've seen that it's possible to implement this system whether you currently have a QMS in place or if you're just starting from scratch..

So if you're ready to talk about implementing this strategy while leveraging the best technology at your company...

Here's what to do next:

1. Go to **www.greenlight.guru/apply-webinar** to schedule you free quality management orientation session with one of our specalists.
2. Fill out the application to tell us a little bit more about your situation and why you think we'd be a good fit to help your company now.
3. If we think we can help you, we will call you at the scheduled time for your orientation session.

Go To: greenlight.guru/apply-webinar to schedule your free 1-on-1 orientation session

Just so you know, currently we have a waiting list of medical device companies looking to be onboarded to the greenlight.guru platform so they can implement and leverage this exact system.

Go To: greenlight.guru/apply-webinar to schedule your free 1-on-1 orientation session

After you attend the orientation session, we'll send you for free....

My proven, audit tested, quality management forms, templates and procedures for design controls and risk management.
(Literally a $4,500 value)

Go To: greenlight.guru/apply-webinar to schedule your free 1-on-1 orientation session

Why We Are Doing This

- greenlight.guru's mission is to help improve the quality of life and we do this by helping our customers get safer products to market faster with less risk.
- I've been in your shoes. I know what it's like to spend way too much time on menial tasks when all you want to be doing is building amazing products.
- Founding greenlight.guru was my way to solve this for myself now…
- I want to help solve this problem for you.

Go To: greenlight.guru/apply-webinar to schedule your free 1-on-1 orientation session

We have 30 orientation sessions available this week.

Go To: greenlight.guru/apply-webinar to schedule your free 1-on-1 orientation session

Only those that are serious about improving their QMS, getting to market faster and are genuinely interested apply…

Go To: greenlight.guru/apply-webinar to schedule your free 1-on-1 orientation session

If we are a good fit for each other, our goal is for your company to be able to implement a bulletproof quality management system in as little as 8 weeks.

Go To: greenlight.guru/apply-webinar to schedule your free 1-on-1 orientation session

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.

Go To: greenlight.guru/apply-webinar to schedule your free 1-on-1 orientation session

Let us help address your specific needs on the call.

Apply Now at:
www.greenlight.guru/apply-webinar

And I'll leave you with what a few of the country's hottest medical device startups have been saying about the results they've received after implementing my S.M.A.R.T. system with greenlight.guru…

zenflow

Y Combinator

Nick Damiano, CEO & Co-founder

"The team at greenlight.guru has developed a real solution to help medtech companies get products to market faster while minimizing the paperwork burden. Their combo of useful and well-designed software and expert advice has played a pivotal role in helping us establish and maintain our quality system quickly and easily. The future of medical device quality systems and documentation is going to look a lot different than the past, and greenlight.guru is at the vanguard of this new era."

SONAVEX

JOHNS HOPKINS
TECHNOLOGY VENTURES

David Narrow, CEO

“I’ve been thrilled with my experience working with greenlight.guru. I am new to quality systems and compliance, and greenlight.guru has made this transition very easy. The well-organized user interface and tracking features make the software simple and worry-free; I genuinely recommend it to anyone in the industry.”

sweetbio

ZeroTo510 Medical Device Accelerator

Kayla Rodriguez, Co-founder & COO

"We are ecstatic about our partnership with the greenlight.guru team and the performance of thier cutting-edge solutions. The sleek design eloquently and easily guides us through a traditionally complicated, intense and error-prone process. As a young company, this partnership with greenlight.guru has already saved us significant time and dollars on regulatory and we know the savings will be exponential as we grow! Our product will be to market months faster and greenlight.guru is a critical piece of our success."

Fogarty Institute for Innovation

Gabriel Sanchez, CEO

“We dug deeper to see how other friends we knew were handling their QMS needs, and after adding up time, consultant fees, etc. we felt GG was the right tool for the job.”

Michelle Zwernemann,

Director of Product Development,
Infinite Biomedical Technologies

“The traceability matrix was a huge selling point since I was in the process of trying to train my team on design controls and they had generated spreadsheets that were extremely impenetrable.”

MYOLYN

Matt Bellman PhD,
Co-founder & CTO

I can't tell you how much of a burden on me has been lifted by working with greenlight.guru. You're a life saver."

CLEAREAR

Leland Stock,
Director of R&D

“The tools that greenlight.guru has created are perfectly suited for the fast paced, lean environment our medical devcie start-up works in. The design control, document management, and risk management features are intuitive and efficient and allow our small team to work smarter while keeping the core information of our company organized, accessible, and controlled.”

Jon Gardner, R&D Engineer, CardioQuip

“ Compliance-related stress levels are down, and we seem to have a bit more “ clout” when dealing with competitors, partners, compliance testing labs, etc. because greenlight.guru has enabled us to have better compliance-related conversations.”

Rian Wendling,
Director of Regulatory Affairs, SimplicityMD

“ greenlight.guru has made the design control and risk management process extremely easy to understand and explain to people not familiar with the process and helped them to understand how all of the steps are linked.”

Divya Mavalli,

Quality & Document Control Associate,
Medical Device Resource Corp

“ Our company president was frustrated about our CAPAs. He decided greenlight.guru would help us in completing DHF, cloase CAPA and handle compliants effectively.”