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# 5 DOS AND DON'TS

WHEN CHOOSING A QMS SOLUTION  
FOR YOUR MEDICAL DEVICE COMPANY

# OVERVIEW

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As a medical device manufacturer, your quality management system is the heart of your operations.

A QMS contains everything that internal teams, partners, and regulators alike need to know in order to get your product to market and achieve its intended purpose delivering better outcomes for clinicians and patients.

The choices you make around the QMS you decide to implement will resonate throughout your product's lifecycle.

While there is no set, one-size-fits-all QMS structure, there are a number of best practices medical device companies should consider when choosing a quality management solution.

# ACCOUNT FOR MEDICAL DEVICE REGULATORY REQUIREMENTS

The regulatory process for medical devices is understandably stringent. Regulators have the important task of making sure every device that is sold in the market is safe and effective for its end users. For your device to join those ranks, you'll need to identify which regulatory requirements will apply and incorporate those processes into your QMS to assure compliance. This should be an ongoing consideration throughout the entire lifecycle of your medical device.

## DO: Determine The Applicable Regulations for your Medical Device

There are many different regulatory requirements that may apply to your medical device depending on the market where your device is sold. Some regulatory standards are specific to certain markets, while others hold equal weight in multiple regions around the world.

Devices entering the US market need to meet FDA regulations under [21 CFR Part 820](#), while devices sold in the European market must adhere to the new medical device regulations under [EU MDR](#) effective May of 2020.

Industry standards, like [ISO 13485:2016](#) (QMS requirements for medical devices) and [ISO 14971](#) (risk management for medical devices), are recognized in markets around the world. Although they are not

governed as specific market regulations, recommended best practices encourage adherence to both to improve process efficiencies and ensure compliance.

Best practices also suggest that medical device companies obtain their ISO 13485 certification as additional regulatory agencies, [including the FDA](#), will be harmonizing their requirements with this industry standard.

Your QMS and quality processes will be heavily influenced by these industry standards and regulations, so it's essential for your company to research the regulatory requirements that apply to your specific device when planning your product roadmap, and ideally before implementing or updating your QMS.

## DON'T: Underestimate the Role of Regulatory Changes & Compliance

Make no mistake—regulatory compliance will make or break your project. It's not enough to have a great idea or a stellar team—you must be able to demonstrate to an auditor or inspector that your product and your procedures are safe and effective above all else.

Noncompliance is a costly burden to bear—one of the most commonly cited triggers for a 483 observation from the FDA is [failure to comply with CAPA](#), along with issues around complaint records, process validation, design validation, and nonconformances.

Failure to comply or keep up with changing industry regulations can

leave your company spending excess time and money to remediation efforts.

EU MDR is an upcoming regulatory change that will have a far-reaching effect on the medical device industry, which goes into effect on May 26, 2020. These new requirements include significant changes to post-market surveillance, device classification, and more, that companies must implement into their QMS for regulatory compliance.

We've written an [Essential Guide to Preparing Your QMS for EU MDR](#) to help you prepare for these changes to ensure compliance.

# DECIDE IF YOU'LL TAKE A LEGACY OR MODERN APPROACH

A legacy system is ad hoc in nature and uses general-purpose tools, like physical paper (just like it sounds), digital paper (Excel/Word), and document storage (SharePoint/Dropbox). They're perceived as a low-cost, low-effort QMS solution, but are known for being cumbersome and difficult to manage as a company scales. A modern QMS solution is a software-based system purpose built to address the specific needs of its users and their niche market.

## DO: Consider the total costs of a QMS solution

Quality management systems come in a wide range of different price points.

Legacy systems may seem relatively inexpensive, compared to a purpose-built solution, but over time that becomes less true. The support needed to manage legacy systems can be time consuming and resource intensive, oftentimes requiring a human element to maintain.

Modern systems are purpose-built to streamline product development and quality processes, while also removing the burden of ongoing maintenance and 21 CFR Part 11 validation of the software.

When calculating your time to market, you need to take a few things into consideration, including the needs of your team who will be using the QMS. Will they need to work amongst themselves in real-time, or can they manually update the information they need by using a more traditional paper-based system?

As your company scales and processes mature, your QMS will need to follow suit. As a result, the number of people that will need to collaborate on and access information related to quality activities within

the QMS will increase. This is why right-sizing your QMS with your company is so important.

A right-sized quality system allows you to better control costs throughout the lifecycle of your medical device. Greenlight Guru's purpose-built QMS software is built to grow with your company. This modern approach enables users to work simultaneously and in real-time through an integrated closed-loop system that provides full traceability of all quality processes.

With a legacy system, teams can experience challenges due to lack of visibility into multiple concurrent processes within their QMS. Your team can't function effectively if they don't have access to the right documentation or processes, especially when it happens during an audit. This all too common scenario can be costly and time-consuming to address. Time is money, and setbacks like this can significantly increase your total project costs.

In today's modern day and age, the costs associated with a legacy approach are difficult to predict and full of risk, with a strong likelihood of costs exceeding the purchase price of the quality system itself.

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## DON'T: Compromise quality for the sake of cost

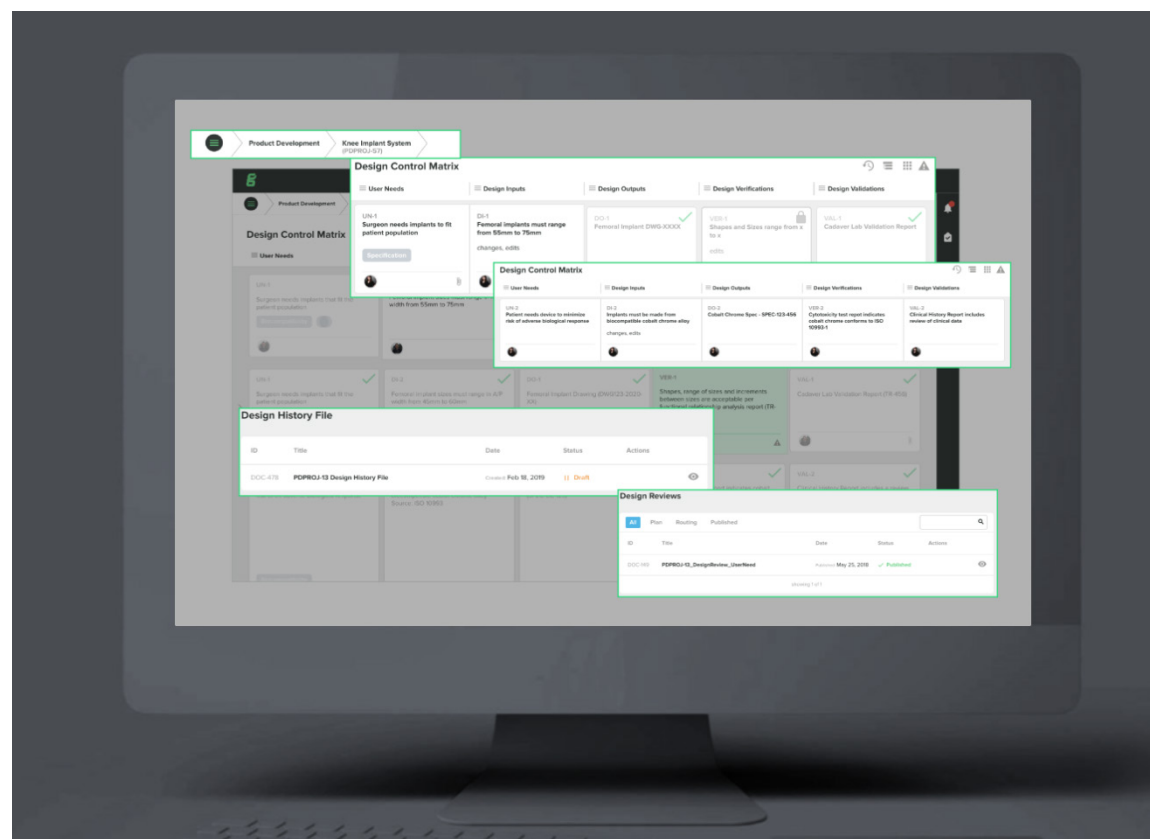
When it comes to choosing between different QMS solutions for your medical device company, there's a difference between being frugal and cheap. A common rule of thumb is, when it comes to choosing between a QMS that is fast, cheap, and effective... you can only pick two!

Technically speaking, it is possible to use a digital paper tool to manage your quality system, if that's how you choose to preserve funds. However, as your company scales, resource inefficiencies will be compounded as your team tries to navigate through disconnected processes to cobble together a design history file for example. No more preserving funds when you have to pay these resources

for this time consuming work.

Attempting to manually trace your design controls to your risk with disconnected processes is nearly impossible with a general purpose solution. An ad hoc traceability matrix would require a huge level of effort, with very little certainty as to the accuracy of it.

Companies that have adopted a modern approach to their QMS find themselves saving hundreds of hours per year by using a purpose-built system that integrates design controls and risk with post-market quality events for full traceability of processes.



Greenlight Guru's Multi-level Design Control Software for Medical Devices

# ASSURE TRACEABILITY THAT ENABLES A CLOSED- LOOP MEDICAL DEVICE QMS

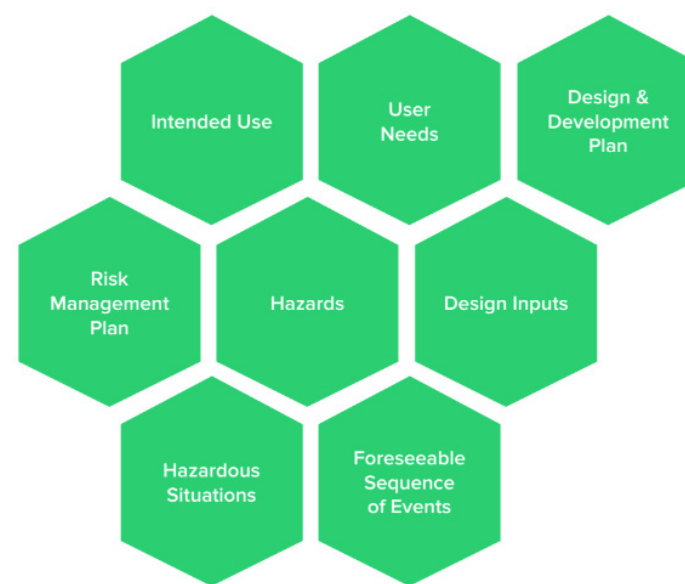
A closed-loop quality system is one that connects the devices, people, and processes across all stages of the total product lifecycle (TPLC) from beginning to end. This type of system allows you to respond to issues in real-time and proactively monitor and mitigate risk, while also enabling full traceability amongst your product development and quality events.

## DO: Fully Integrate Design Controls, Risk Management, and Quality Events

Design controls are arguably the most important part of your product development lifecycle. Design inputs alone should take up to 30% of time spent, and there's a good reason for that. These inputs will form the base from which you'll develop your entire product. This fundamental process needs to be handled with care before your project progresses into later phases of the product lifecycle.

A strong focus on design controls leads to a true quality approach to product development that ensures you're safely creating a functional, useful medical device that meets the indications for use.

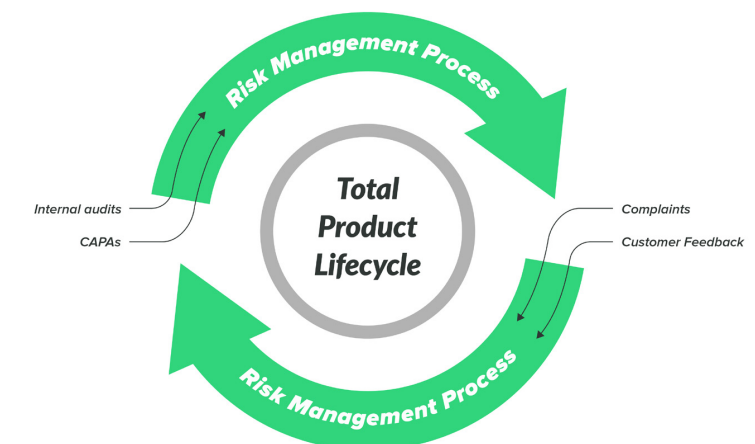
When properly implemented and managed, design controls reduce product risk significantly and help inform your risk controls. A fundamental aspect of risk management is clear, consistent documentation. The intended use of your device will inform your needs, which in turn help to establish both your design and development and risk management plans.



Having a closed-loop quality system ensures full traceability between your design and development activities and post-market surveillance activities, while also allowing you to effectively manage quality events that occur throughout the product life cycle.

Quality events, such as internal audits, CAPAs, complaints, customer feedback, and nonconformances, are all connected to your established risk management processes and should be managed within your QMS.

If your device's risk is impacted by a post-market quality event, traceability is key for identifying the root cause. A closed-loop system allows you to connect those processes for updating your Risk Management File to ensure you are delivering a safe and effective product.



By implementing a closed-loop QMS software equipped with full lifecycle traceability, like Greenlight Guru, you will gain visibility into your quality processes to understand how they connect to one another. This enables a proactive approach to assessing and identifying issues before they become systemic.



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## **DON'T:** Let disconnected systems affect your ability to scale

Failure to deploy a closed-loop solution can lead to downstream ramifications due to the significant burden required for your team to document and demonstrate traceability throughout your QMS.

Imagine the burden and effort required to document product development and quality activities if your company takes the legacy approach to quality. Imagine how that burden and level of effort will grow as you increase your NPD velocity, expand into new markets with different regulations, and your team becomes distributed.

If your quality system can't scale, neither can your company.

For companies taking a legacy approach to managing a QMS that doesn't facilitate closed-loop quality, it's common to add QA/RA headcount for simply keeping up with quality and compliance documentation efforts as the company tries to scale.

In addition to the burden put on your team, electing to go with a legacy approach that uses several disconnected systems rather than a closed-loop quality solution can lead to QMS breakdowns that ultimately create business, brand, and patient risk.

One example that comes to mind is the case of a medical device company which lost \$400,000 due to improper risk management and failure to prepare for inspections.

In essence, the company failed to comply with ISO 14971, and had no risk management plan or procedure, no provable risk controls,

and no defined risk acceptability. It may be surprising for emerging companies to learn that it's actually possible to get to market without documented design controls.

The trouble isn't getting to market, but being prepared for the subsequent audits or inspections to follow.

In the case of the aforementioned company, their launch to the US market was predictably followed by an FDA inspection, which found major aspects of their development process missing from their QMS. Along with a lack of risk management controls, the company had no design history file, and no assigned staff member tasked with implementing their QMS.

These mistakes cost the company nine months in time spent and \$400,000 in consulting fees, testing, and efforts to remediate the situation. While this is an extreme example, there's simply no need

to fumble around in the dark when it comes to risk management and regulatory compliance.

Even companies unfamiliar with applicable regulatory requirements can partner with a medical device specific software solution designed to facilitate compliance. Purpose-built solutions can simplify the process of achieving a closed loop quality system so that you can easily demonstrate traceability between design and post-market surveillance, monitor risk, and stay nimble as your companies scales.

# ASSESS QMS SOFTWARE SOLUTIONS

In a niche vertical, such as the medical device industry, the complex nature of the quality and regulatory landscapes makes finding the right solution a hefty task for device makers. For companies taking a modern approach with a QMS software solution, it's important to assess the software provider and the industries it serves.

## DO: Choose a purpose-built solution

Choosing a solution that has industry-specific knowledge built-into the system is instrumental to the long-term health of your QMS.

Manufacturers should opt for a purpose-built QMS solution that has the protective guardrails in place to address the specific needs of medical device companies.

Lucerno Dynamics is one medical device company that can speak to the importance of a purpose-built solution. After receiving feedback during an internal audit that Dropbox couldn't be validated, they began searching for a medical device specific QMS software that would

streamline their efforts in achieving ISO 13485 certification under a very tight schedule.

After implementing Greenlight Guru, the only QMS software purpose-built for the medical device industry, Lucerno was able to expedite efforts with their ISO certification, as well as simplify cumbersome processes to remain in compliance, allowing them to focus on efficiencies that supported future growth plans. Greenlight Guru lifted the burden by reducing the need for Lucerno to allocate significant resources to implement and validation the software.

**IT'S A GREAT BUSINESS RELATIONSHIP.  
I WISH ALL BUSINESS RELATIONSHIPS  
WERE LIKE OURS WITH GREENLIGHT.  
IT WOULD MAKE LIFE SO MUCH EASIER.**

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Tonia Bryant, Director of Quality and Regulatory Affairs, Lucerno





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## **DON'T:** Overlook implementation and validation efforts associated with general-purpose QMS solution

General-purpose software solutions can be a risky option for device makers. Although these options are commonly considered, there are major burdens and hidden costs associated with implementing and validating these solutions.

When implementing a general-purpose QMS software solution, an unbelievable amount of time and resources can be consumed by configuring and validating the software to fit the complex needs of medical device companies. Sometimes this will require multiple attempts to get right. It's common to hear stories of this taking anywhere from six months to a year for a company to implement a custom configured QMS software.

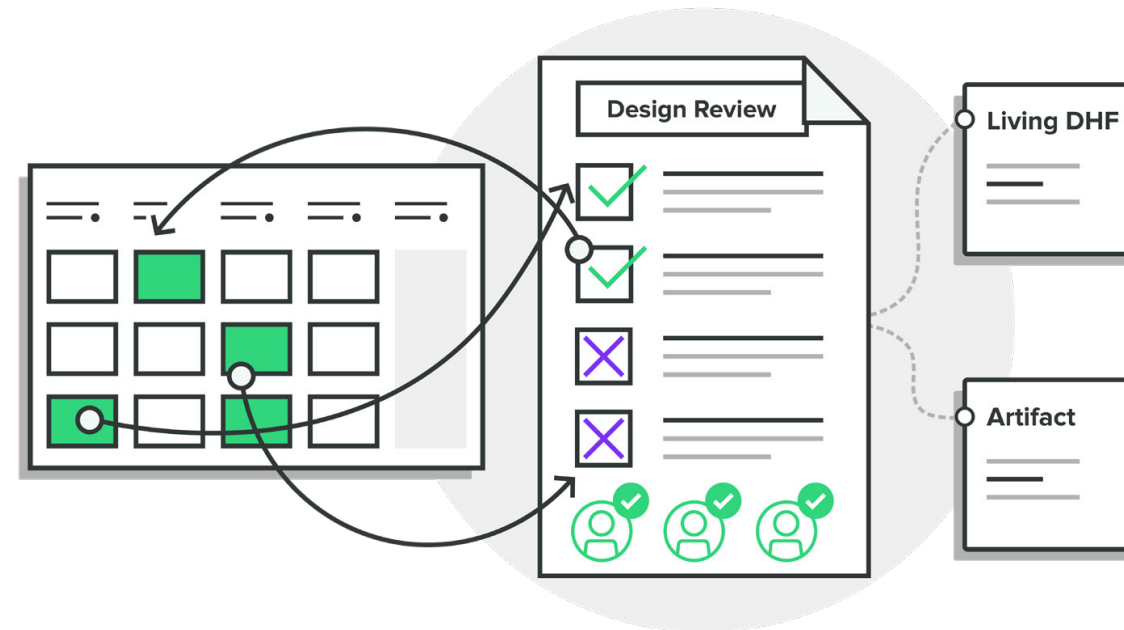
As changes occur, the reconfiguration and customization of your QMS can significantly hinder your company's ability to work and scale efficiently.

In addition to prolonged implementation and validation times, general-purpose systems lack the built-in controls and guardrails that purpose-built solutions provide.

Greenlight Guru's out-of-the-box medical device QMS is built by medical device professionals, for medical device professionals.

Our software solution provides companies with the built-in controls and necessary to produce safe and effective products - without the hassle of customization and validation.

With integrated Design Controls and Risk Management, Greenlight Guru's closed-loop, fully traceable QMS software enables companies to streamline processes throughout their product lifecycle.



# PARTNER WITH MEDICAL DEVICE INDUSTRY EXPERTS

The medical device industry is experiencing a tsunami of regulatory changes in response to the emergence of new technologies. Previously known best practices are being replaced by more efficient approaches, and new methodologies are being tested in every facet of the industry. A shrewd manufacturer knows to pay close attention to all of them.

## DO: Choose a partner with a proven track record of success

In addition to staying abreast of regulatory changes that may apply to your medical device, it's just as important to stay current on the best practices for your pre- and post-market quality activities. When choosing a QMS solution, look for a partner with a proven track record of success with bringing a medical device to market.

Choosing a trusted partner to serve as an extension of your team can position your company on a trajectory for success. This important

advisory role can help you navigate through the winding roads of the rapidly changing medical device industry.

There's a lot to learn as a medical device manufacturer. While there are any number of QMS providers that can offer the essential tools you need to have a functioning QMS, finding one that provides the human connection of a trusted partner with experience in the commercialization, development and manufacturing of medical devices is an invaluable component of a QMS solution.

## DON'T: Underestimate the value of staying ahead of regulatory changes

A partnership with a medical device QMS software provider comes with endless benefits. These trusted business relationships will serve companies in multiple facets, helping new employees to navigate through quality processes within their QMS software,

as well as provide insight into changes that are occurring in the regulatory landscape of the industry.

Some companies come into this industry with little to no experience with medical devices and the accompanying regulations. Some may understand the basic requirements needed to bring their medical device to market, but that may be the extent of their regulatory knowledge. The many nuances of medical device regulations can be foreign and difficult to navigate even for an experienced manufacturer.

The ongoing success of a medical device company hinges on their ability to understand and follow current regulations, as well as stay ahead and prepare for regulatory changes. One way to accomplish this is to entrust this task to regulatory experts with whom you trust. An industry specific QMS provider can offer companies specialized expertise to assure compliance amidst the ever changing medical device regulatory environment.

Greenlight Guru is more than just a QMS software for medical devices, our purpose-built solution also includes QA/RA expert services offered through our in-house Guru team. These quality and regulatory experts act as an extension to a company's team with around the clock service and guidance, mastered from their decades of experience with successfully developing and manufacturing medical devices.

# FINAL THOUGHTS

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When it comes to managing the quality of your medical device, there are many key considerations to factor into your decision when choosing a QMS solution. The quality system itself is just as important as the QMS provider services that are offered in conjunction with the total solution package.

Based on the unique needs of your business and medical device, you should pay close consideration to these recommendations as they will help guide you in choosing the best QMS solution for your medical device company.