

EBOOK

15 Reasons Why Medical Device Companies Choose Greenlight Guru

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Medical Device Guru, Greenlight Guru

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MedTech companies are not just companies—they're innovators building the medical devices that are saving and improving our quality of life. But, bringing life-changing medical devices to market, and keeping them on the market, is still harder than it should be.

The fact is that in a dynamic industry like ours, generic solutions don't work. MedTech professionals need an end-to-end quality solution that brings together the right insights and capabilities to keep your quality, regulatory, and clinical data connected.

That's where Greenlight Guru comes in. Built exclusively for the medical device industry, everything we do enables your success. From streamlining processes to helping companies meet regulatory challenges to best practice guidance, our solutions are built with you in mind.

We could name over a thousand reasons to choose Greenlight Guru as your new quality management software platform ([just ask our customers](#)). But, for brevity's sake, we've whittled it down to 15 reasons why choosing Greenlight Guru as an eQMS is the best choice for the future of your medical device business.

1 Built-in Compliance so You Can Focus on True Quality

The number of regulations and organizations that companies have to deal with on a daily basis can seem overwhelming. Compliance requirements aren't always well understood, and companies without deep industry knowledge or in-house subject matter experts can find themselves at a disadvantage.

But with Greenlight Guru, you're covered—from FDA 21 CFR Part 820, to ISO 13485:2016, and criteria for EU MDR—specific workflows are built into the system. The compliance components are captured as part of the steps customers follow when initiating workflows like document management, design control, risk management, CAPA, and more.

Our customers agree—Greenlight Guru’s built-in-compliance provides serious peace of mind. [As one customer puts it](#), “Having an eQMS really helps to speed up documentation, with limited user interaction, allowing our company to remain in compliance and stick to our processes! I can’t imagine having a paper QMS to handle all our documentation.”

2 Better Audit and Inspection Readiness

Every medical device company is subject to routine regulatory audits and inspection—but that doesn’t make audit readiness any less challenging.

We know how fickle the medical device industry can be, because we’ve lived it. We’ve been across the table from FDA investigators and ISO auditors, so we know what an auditor is looking for within a QMS, documents, and records and how they expect information to be presented.

Our objective to help you be better ready for audits and inspections is connected to quality. Because Greenlight Guru is a quality management software solution built specifically for the medical device industry, it means the solution aligns with current medical device regulations, putting you in a much better position from an audit perspective.

Choosing Greenlight Guru means unprecedented visibility—no matter how long you have to prepare for an audit or inspection, whether that be months, weeks, or even days. It’s how one Greenlight Guru customer, [Tenacore](#), migrated their entire QMS off of paper and passed their ISO 13485:2016 Recertification Audit with zero major nonconformities.

3 We Help Your Team Work Efficiently and Effectively

Compliance is critical, but it's possible to stay compliant and save time—without sacrificing the quality of your products. With Greenlight Guru, companies can streamline their processes and accelerate product development efforts up to 35% faster, according to a recent study completed with Hobson & Company, a third-party ROI research firm.

The Greenlight Guru workflow saves hundreds of hours per project during the design process. Imagine getting more than a hundred hours of time back on every project you complete each year—time spent tracking down documents or updating spreadsheets—and translating that to time you can use on other projects.

No matter your commercialization stage, Greenlight Guru helps you do more value-adding work with a complete quality management solution built to drive collaboration, unlock traceability, and give visibility into critical information throughout your product's lifecycle.

4 Design Control and Risk Management Integration

The link between design controls and risk management is critical to developing safe and effective medical devices. By integrating risk management into the design process, manufacturers can identify and mitigate potential risks early, ensuring that the device is safe and effective for its intended use.

At Greenlight Guru, we work with you to develop solutions that establish risk controls early in the product development process, reducing overall risk and creating visibility between requirements. Customers can link risk artifacts with

product management artifacts, providing context during risk mitigation. Companies can avoid expensive rework and save valuable time, identifying issues before they become problems.

“I appreciate how the software emphasizes linking the design control matrix and the risk matrix since they, by default, must be intertwined (according to the regulation),” said one customer in [their G2 review](#). “The software allows that to happen seamlessly and hits the mark on that requirement,”

5 Increased Visibility and Control

How many medical device professionals really know the state of their quality management systems?

Just knowing where the binder is or what the procedures include doesn't mean you have visibility into what's really happening with those processes and procedures. In fact, only [15% of medical device companies](#) say they have a high level of visibility into quality problems.

With the ability to link anything built right into the Greenlight Guru platform, customers gain direct visibility into where their documents are, as well as the state of those documents. Our platform gives companies built-in workflows to manage events like CAPAs, complaints, and nonconformance.

Our most important focus is on providing a single source of truth—the place where the executive management team can make the best decisions. Making decisions with fragmented data just increases business risk. But knowledge is power; and providing executives with more knowledge about the health of their business is a powerful thing.

6 MedTech Professionals Can Advance Their Skills Using Greenlight Guru Academy

In a fast-paced industry like MedTech, staying on top of the latest trends, regulations, and best practices is paramount for a team's success. Continuous learning allows medical device professionals to develop new skills and knowledge, which they can then apply in their day-to-day work.

This can include training on the latest regulatory requirements, emerging technologies, or best practices in the field. By continuously expanding their skill set, professionals can improve the quality of their work and enhance patient safety.

[Greenlight Guru Academy](#) is the premier learning destination for MedTech professionals. With over 300 thoughtfully curated courses, designed by top industry leaders, Greenlight Guru Academy provides an opportunity for all learners to advance their skills with accessible industry knowledge and self-paced models. For learners seeking more, Greenlight Guru Academy provides online events, certifications, and accredited courses.

7 Accelerated Implementation of Software

There's no denying that technology has helped accelerate the medical device development process. But it's also clear that most of the general purpose tools out there weren't designed for the medical device industry; they're clunky, they're not ready out of the box, and they get you stuck focusing on just compliance.

When [Monitored Therapeutics, Inc](#), first came to us as a customer, time was of the essence. The company was scaling rapidly, and with FDA, ISO 13485, MDSAP,

and several customer audits on the horizon, MTI needed to switch to a QMS that was more than just a tool. They required a solution that would be their guide and support them along the way.

Over the next year, MTI successfully navigated 6 audits, scaled their offices 7x, and vastly expanded their team's proficiency levels with training, SOPs, and certification courses. Now, 14 months after implementing the Greenlight Guru platform, MTI is confident in its ability to manage its commercialized products globally and manage the company's quality as it grows and matures.

8 Access to Our Vault of Audit-tested SOPs and Templates

Technology moves quickly, but there's still only about 20 years of history when it comes to quality system regulations, and eQMS is even more recent. Many companies end up choosing a QMS that's bloated with unnecessary details and procedures, but missing the kinds of templates and compliance forms that can help save time and ensure compliance.

An effective QMS should have only what it needs to keep documents and procedures up-to-date. Quite some time ago, we established a library of forms, templates, and procedures that allow customers to find and create the documentation they need. The Greenlight Guru QMS also helps create the Design History File, the last step in the design controls process mandated by the FDA in [21 CFR Part 820](#).

Customers report that they see immediate improvements in efficiency, giving them valuable time back. "Greenlight Guru provides a lot of procedure templates right in the system, which saved us probably 80 hours of FTE time that otherwise would have been spent on document creation," [one customer said in their G2 review](#).

9 Saves Time and Improves Operational Efficiency

The more time you can save, the more money you can make. That's why the Greenlight Guru workflows were all designed around saving time and improving efficiency. The design control workflow is a great example: product development project teams can save hundreds of hours per year with a single source that simplifies information and aligns with regulations.

That can lead to a serious boost in productivity, improve response times for audits and required changes, and improve collaboration—our recent findings showed a 50% reduction in time spent preparing for audits. But how does a system like this save so much time?

Think about companies with paper-based processes: they send emails with attachments, then those files might sit on someone's desk for a week, waiting for someone's signature. Conventional approaches rely on sending documents back and forth via email, with no way to see where a document is or whether it's been signed.

Greenlight Guru's cloud-based workflow means there's no waiting on signatures or wondering where a document is. Companies also have an opportunity to eliminate unnecessary emails and meetings, saving even more valuable time.

10 Visual QMS Takes User-friendly to a Whole New Level

From day one, Greenlight Guru has been focused on delivering a seamless experience; we want our solution to become an invisible part of your team getting things done. In fact, we've focused thousands of hours on user interface and user experience alone, with a full time team.

That commitment goes a long way towards aligning our product from a compliance standpoint as well. We understand how to apply the FDA and ISO quality system requirements to improving overall UI/UX. Ease of use is key to any of these workflows—and we're devoted to ensuring Greenlight Guru works exactly as it's supposed to.

Being ready out of the box is just one part of making our QMS easy to use, day in and day out. The other part is making quality a foundational element of the platform. Too many solutions take a piecemeal approach to building a platform.

Greenlight Guru has taken the opposite approach: we take a high-level view of the entire QMS universe, considering the entirety of all the workflows that one might need to do. That gives us the strategy to be both granular and big-picture at the same time.

11 Minimal Effort Part 11 Validation with Validation Package

21 CFR Part 11 is one of the most ambiguous topics in medical device regulations. That's because there's varying levels of experience and expertise, both at medical device companies and among auditors and inspectors who evaluate documentation on the topic. We're working closely with FDA's Case for Quality, and we've learned that the historical approach to Part 11 is very dated.

That's led to companies looking for a Part 11 validation package to search for something that simply checks a box. Box-checking can lead to even more problems if a solution doesn't provide reliable validation.

Greenlight Guru has adopted an automated, risk-based approach to validating our Quality Management System (QMS) software and strategically updated our Validation Package to help teams efficiently and effectively implement and adopt the latest enhancements and functionality while assuring compliance with evolving validation requirements.

Our updated validation approach has taken into consideration the FDA's guidance for Computer Software Assurance (CSA) and ISO/TR 80002-2:2017 requirements and best practices.

12 Greenlight Guru Provides Complete Traceability

We're at a point today where traceability has become so important that it's actually a requirement: it's explicitly stated several times throughout ISO 13485:2016 as an essential element of the design and development process.

Traceability is only possible when there's a central location for all data, forms, and documentation. Many organizations rely on several electronic tools to store information, and, over time, that silo-type approach can lead to tacking on tools that don't communicate with each other.

In the [2023 MedTech Industry Report](#), respondents echoed these concerns, saying, "We need a single source of truth rather than the many unconnected tools we use today. Our current systems don't allow for traceability over processes and departments. We need a true QMS."

The Greenlight Guru platform connects all of your data and information into a single source of truth. A closed loop quality system ensures that data is consistent throughout the process. Its end-to-end quality management system design also eliminates the need for working in programs like Excel, Word or Dropbox—all those systems can be replaced.

Now, users can edit their traceability matrix, update the matrix in just minutes instead of days or weeks, and make related items traceable with automatic links. And with a completely traceable platform like Greenlight Guru, companies can develop and maintain best practices, and improve processes, and significantly reduce non-compliance risk.

13 Our Electronic Data Capture Solution Is Best in Class

Clinical data is essential to determine the safety and efficacy of medical devices, identify potential risks or adverse events, and evaluate the overall performance of the device. By collecting and analyzing this data, manufacturers can make informed decisions about the design, development, and marketing of their products, ultimately ensuring patient safety and improving outcomes.

As medical devices become increasingly complex and innovative, regulatory authorities in the US and EU have tightened their requirements for clinical data collection in order to ensure patient safety and device effectiveness.

For medical device manufacturers seeking to obtain regulatory approval, designing and implementing high-quality clinical trials is critical to their success. And doing so will require an electronic data capture (EDC) solution, purpose-built for medical devices.

[SMART-TRIAL by Greenlight Guru](#) is the leading clinical data collection toolbox, purposefully built for MedTech. Customers can collect and manage clinical data in pre and post-market clinical studies, including registries, cohorts, surveys, human factor testing, design validation, and more.

And just like all our Greenlight Guru products, our EDC solution meets the regulatory requirements of the FDA, EU, and most other countries, and ensures compliance out-of-the-box with GCP and ISO 14155:2020.

14 Helps Companies Save Money

Throughout this piece, we've talked about how Greenlight Guru helps companies save time and boost efficiency to generate more revenue. But companies can also save a significant amount of money as well.

One of the reasons our platform is a money saver is that we can help reduce the need for more headcount—especially when it comes to document management. Traditional document control tools are often labor-intensive, relying on more people to increase throughput. Greenlight Guru's simplified workflows are built-in and tailor-made for medical devices to improve the user experience.

Companies can also see savings through the power of data and analytics. As part of the postmarket workflows, for example, there's an analytics dashboard for customer feedback, performance, audits, CAPAs, and more.

It automatically creates charts and graphs to help identify and track trends so companies can stay ahead. It even helps cut costs by eliminating the costs associated with generating and storing paper records: copying and filing of paper, the space to store it in, and the employees to maintain it.

15 Medical Device Gurus Are an Extension of Your Team

No other eQMS solution has the customer success team that Greenlight Guru does. Our in-house Gurus bring a breadth of knowledge and years of experience in the medical device industry when working with companies. When it comes to your QMS, there's no challenge too big or too small that our customer success team can't help you overcome—whether it's going through ISO certification or preparing a 510(k) submission.

We offer our [Guru support services](#) to help customers gain clarity around regulatory requirements and leverage industry best practices to confidently meet your objectives at each stage of your medical device journey. Our Gurus are available to meet for recurring Strategic Guru Advising meetings, or through our on-demand Guru Assist program, for whenever you need a sounding board on best practices.

We offer tech-enabled support that goes above and beyond showing customers how to use the software. And, based on the positive feedback we've received, it's one of the most valuable elements of Greenlight Guru.

“Our Guru is very knowledgeable. Previously we could spend hours hunting for an answer to a question we might have, whereas now we just spend 15 minutes sending an email to our Guru at Greenlight to ask for help with a question.

The Gurus are also very helpful even in things like what kind of terminology to use, as they know the kinds of key words or sentences that the regulators might look for in a given document or submission.”

Choose the Best QMS for Your Medical Device

These fifteen reasons medical device companies choose Greenlight Guru represent just a fraction of the reasons our customers choose us to help them deliver the best medical devices on the market.

We're committed to providing quality management software specifically for the medical device industry, bolstered by the experience of our team, our dedication to quality, and our mission to build the best quality ecosystem available.

Want to learn even more reasons to choose Greenlight Guru? Contact us today to Schedule Your Free, Personalized [Demo of Greenlight Guru!](#)

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