EBOOK

WHY PAPER-BASED QUALITY MANAGEMENT SYSTEMS ARE NO LONGER AN OPTION

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greenlight guru

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It's time to face facts: a paper-based quality management system is no longer an option.

Technology is rapidly changing the way medical device companies can create, deliver, and store records and documentation. There is simply too much at stake to rely on paper. Productivity, time, money, and potential compliance issues are all affected by the QMS (quality management system) in place.

> Growing companies need to embrace technology, but they also have to choose wisely.

Finding and implementing an eQMS (electronic quality management system) is a scary prospect for a lot of companies. It involves change, and that kind of change can take months to complete. But a system that keeps records up-to-date, provides easy access to documents, has best practice workflow built-in, aligns with medical device regulations, and makes validation effortless is top priority.

Before choosing a new system, organizations need take into account how documents are shared, how changes and updates are tracked, and how they can overcome compliance and validation challenges. The right choice will streamline processes and procedures, increase visibility, and improve risk management.

LET'S START WITH THE DANGERS OF PAPER DOCUMENTS

How many companies have all their operations in one physical location? I speak with hundreds of medical device companies a month, and it's rare to find one whose entire team is in a single building. A paper-based system is inconvenient, especially for a company with a distributed team – it dampens teamwork and collaboration.

Collaboration on paper is hard, and medical device companies rely on collaboration to create products and serve customers. Wasting time on paper-based documents puts a real damper on the ability for teams to get their jobs done. Instead of focusing on ensuring medical device product and process quality is top-notch, company resources are spending valuable time dealing with inefficiencies that paper-based approaches create.

The medical device industry is well behind the rest of the world when it comes to embracing technology, but most companies are already using some form of electronic system without realizing it. Sending an email attachment? That's creating an electronic document. Scanning a document with a signature? That could be a sensitive document that's now in an inbox with little security or validation.

There's also the matter of ensuring documents are current and accurate. In many cases, an electronic version of a document is thought to be the most up-to-date, but how can you really ensure it is without revision tracking?? Solutions like Dropbox and Google Drive may offer high-level tracking, but not in a fashion that's compliant with FDA 21 CFR Part 11 nor that can be validated.

Finally, paper documents are costly to manage. Every new ream of paper added to a filing system means paying people to manage it, paying for space to keep hard copies, and paying for the mistakes that can happen as a result of a paper-based system. That can be a real resource drain, and the result makes it harder for you to do business.

THEN, THERE ARE AUDITS AND ACCURACY

Every medical device company needs to be audit-ready at all times, but paper-based systems make that nearly impossible. Paper-based documents get lost all the time. What happens when you lose something and it's never recovered? What happens if an auditor asks for a document and you can't find it?

Many years ago I had to explain to an auditor that we lost a CAPA document, which was, to say the least, difficult and very embarrassing to admit. A lack of stringent document control process can take a massive toll on internal resources as well as external reputation.

That lack of control can also cost significant time — something that is already a precious commodity for leaders in the competitive medical device space. As I mentioned earlier, emailing documents can introduce errors. If you're sending a document for someone (or even multiple stakeholders) to sign, for

instance, it can go through several inboxes before it can be put back together. If that document is missing signatures, the process has to start all over again. With an ad-hoc filing system that isn't validated, audits will always be unpleasant.

Risk-based quality management should also be at the top of your list. The expectation is that, as you go through the design and development of your devices, you need to comply with ISO 14971, the industry standard for risk management. Mitigating risk means having a way to recognize immediately when something might be non-compliant, and that's hard to do with a paper-based system.

But more importantly, you need to integrate your risk management efforts with design controls. That's something you simply cannot do using the traditional paper method. How do you link a risk assessment spreadsheet into design control activities? Write a macro or insert a hyperlink? That creates yet another system you need to validate. The moment you start making changes, it creates even greater challenges.

REGULATORY CHANGES AND VALIDATION CHALLENGES

If it sounds like I'm saying you should worry about the regulatory changes, I'm not. Just the opposite: embracing them and learning more about them will actually help you choose the right QMS for your medical device company.

The industry has been afraid of regulations like Part 11 since its existence, and for good reason: it can take a lot of time and effort to stay compliant. Part 11 offers guidelines for using technology in quality systems. Those guidelines can seem overwhelming — especially if you're considering switching from a paper-based system to an eQMS.

Why would going electronic be more of a hassle than staying with paper? Because a lot of the software tools on the market aren't designed for the medical device regulations, like Part 11. Nor are they available out of the box. They require customization and configurations with a lot of setup and continual maintenance. Not only do you have to spend months in implementation and setup, taking your team members away from their key initiatives, now you have to focus on the compliance piece. What if the EU or the FDA updates their regulations? Every time you make one change to something, there's a Part 11 and validation component to consider.

Think about all of the updates that might need to be made while your QMS is being implemented. Now, think about all of the apps and other programs that are in your tech stack. Platforms like Dropbox and Google Drive change all the time, and there's no way to receive insights into the changes made. Do you want to validate your tech systems every single day? It's simply not feasible or practical.

If you're using a general purpose management system like Sharepoint, you won't avoid constant validation. That's why embracing regulations is so critically important: the more you understand, the informed you can be when choosing an eQMS. And that means your company will be saving more time and money.

IT'S TIME FOR YOU TO MAKE THE MOVE

Regardless of what solution you choose, here are the things you need to keep in mind throughout the process:

- **Paper is no longer a sustainable choice.** Paper is not only costly in time and resources, it can introduce errors that make it harder to do business.
- **Accuracy is top priority.** From design and development to CAPAs, every document you generate must be 100% accurate. The dangers of inaccurate documentation range from loss of time and money to running afoul of regulations. Either way, you can't afford to skimp on accuracy.
- **Policies and procedures are good things.** Older regulations like Part 11 have tripped up companies before, but they can also serve as guidelines to choose the right systems.
- **Validation can waste time.** That's why choosing technology that doesn't require constant validation is important—even if a tool doesn't cost a lot in money, it could drain away those cost-savings in the time spent to maintain validation.

WHAT'S NEXT?

It's clear that paper-based QMSs are a thing of the past – especially for growing medical device companies that want to accelerate their ability to scale. Recognizing the need for a change is the first step toward better visibility and

high efficiency. Choose a platform that requires no customization or configuration and is already compliant with regulations and all of the potential setbacks of moving from paper-based to digital disappear.

This is why Greenlight Guru exists. Our platform is built specifically and exclusively for the medical device market. After more than 20 years in the industry, we've built a team and a platform that prioritizes regulation compliance. It also aligns with FDA 21 CFR Part 820, ISO 1345:2016, and EU MDR/IVDR. It's just one of the ways Greenlight Guru serves our customers and the customers they also serve.

We understand the need for consistent validation. That's why we've worked with FDA Case for Quality to keep up with the latest regulatory trends and always implement the most impactful improvements to our platform.

Greenlight Guru also provides Part 11 validation packages, to every single customer, at no charge. Every time make a change to the platform we assess, evaluate and update the validation package. That means you're always in compliance – with little to no effort required on your end.

Despite your best intentions, there's simply no way to avoid receiving complaints or having non-compliance events. But how you choose to address those issues — and the systems you put in place to ensure you minimize them — is what counts.

> *Interested in learning more about how the Greenlight Guru eQMS platform is helping medical device companies all across the globe reduce risk and focus on quality?* ***View our software here.***

NEWSLETTER BLURB

Hi there,

It's becoming clearer than ever that paper-based quality management systems are unsustainable. But choosing the right digital system can cause as many headaches as staying offline.

> There are several issues to consider when choosing to make the move to an electronic quality management system (eQMS). Learn more about them in our post this week:
> **Why Paper-Based Quality Management Systems are No Longer an Option.**

Cheers,
Nick Tippmann
Director of Marketing
Greenlight Guru (Quality Management Software for Medical Devices)

CONTENT UPGRADE

Planning the migration from paper-based QMS to eQMS

This is an extra resources to go along with the original article: Why Paper-Based Quality Management Systems are No Longer an Option

More medical device companies are realizing that paper-based systems don't scale, so they're moving to electronic quality management systems (eQMS).

Still, not every eQMS is created equal.

Choosing the right eQMS means looking for features and capabilities that ensure security, save time, align with major regulatory standards and require little validation. Here are the four most important elements of an effective eQMS.

- **A central document storage system.** The pitfalls of paper-based systems include a lack of storage for documents, as well as a way to determine which documents are accurate and current. An effective document storage system isn't just easily accessible, it's also easily searchable.
- **Integrates design controls and risk management.** The right eQMS should replace a cobbled-together tech stack and should also integrate your design controls with risk management. This not only ensures compliance with the new regulations but enables you to build safer, higher quality devices.
- **Streamlined validation.** Having to manually validate software tools regularly is a waste of time and opens you up to potential violations. Look for a solution that removes that barrier by providing medical device specific validation packages every time the platform is updated.
- **Prioritize ease of use.** There are few things worse than going through a long implementation stage, only to discover the solution is hard to use. Evaluate solutions based on short ramp time and high adoption rate — that way, both you and your team will get the most out of your investment.

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