

THE BUYER'S GUIDE TO

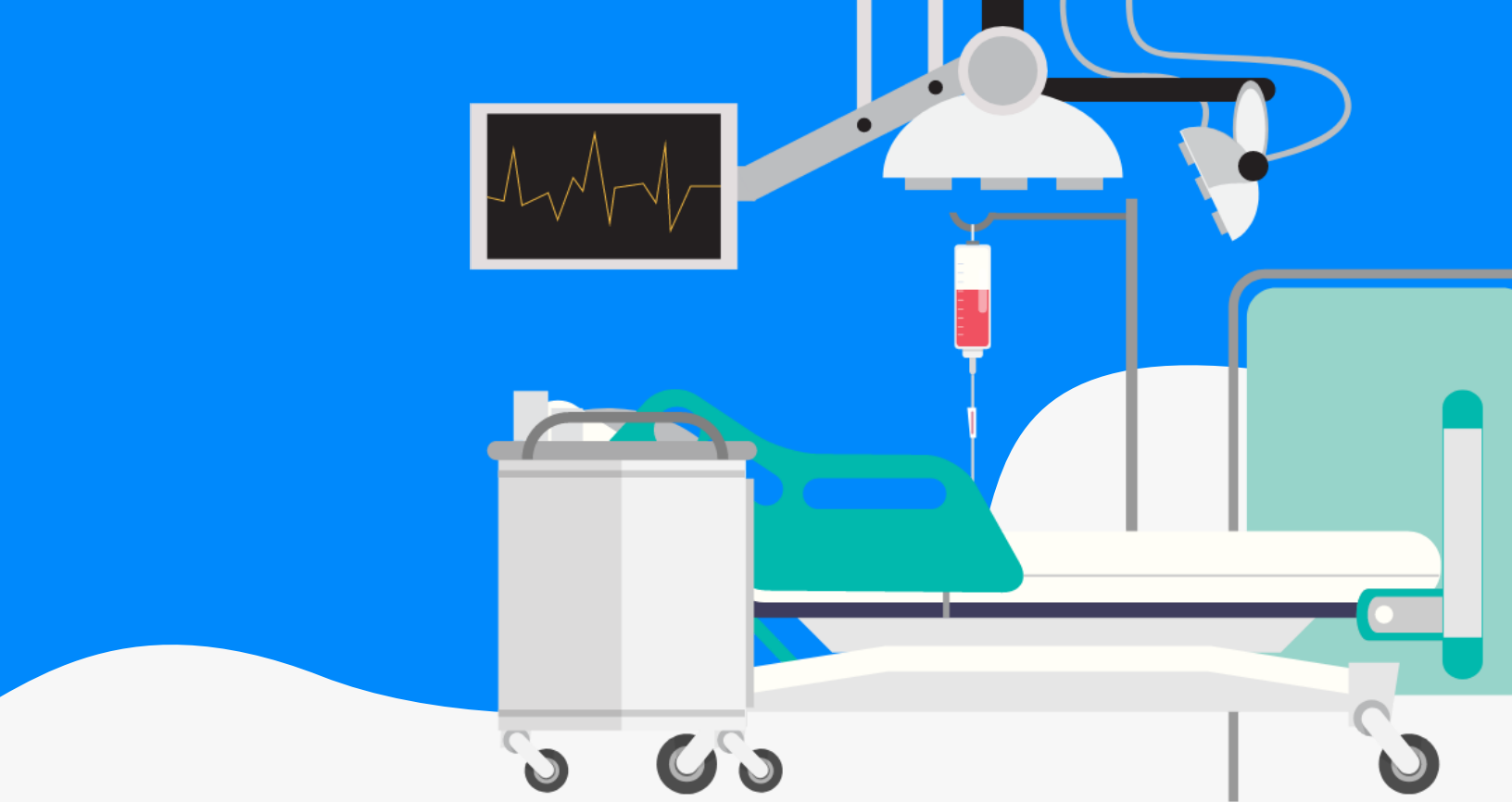
QMS for Medical Devices

IN 2021



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Introduction

Being a manufacturer of medical devices today is not easy.

Although the healthcare product manufacturing industry is booming, manufacturers are faced with new challenges on a regular basis. From changing regulatory requirements and industry standards to new technological demands from buyers and product users - staying ahead of the competition is just hard. If you're still using paper and spreadsheets for your medical device manufacturing business processes, you're likely behind in the race.

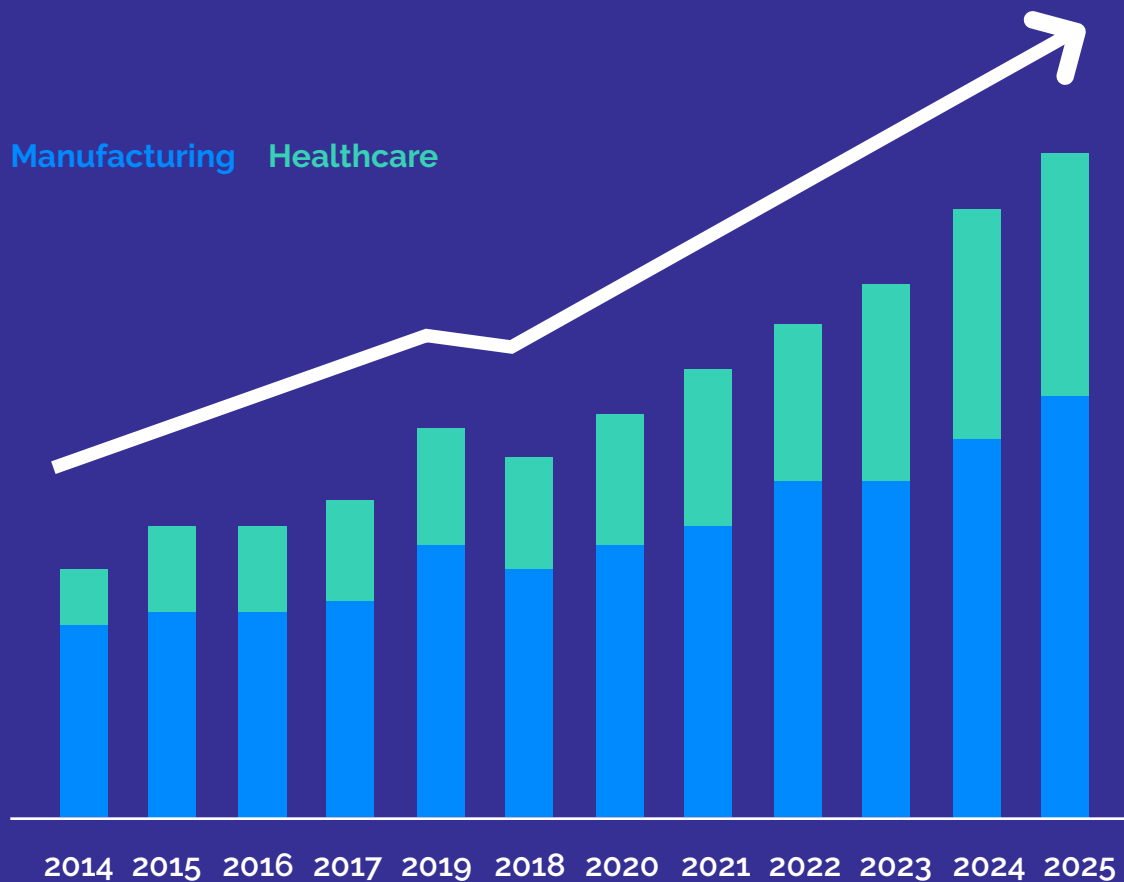
If it helps, you are not alone. Old habits die hard, which means change is difficult. After all, Excel and Word have been around for a long time. You're used to them, they've worked for you, and the very thought of selecting and integrating new software into your business can be quite daunting.

The good news is that to become and stay compliant you need to implement solutions that actually make your team's work easier and more efficient. One of the most important tools for compliance and operational efficiency is a Quality Management System (QMS). Specifically, one that serves your current and future quality management needs, and supports other regulated business processes.

At first glance it looks like a timestaking and expensive activity - transferring all your data, processes, routines, and users to a new digital solution can be quite an undertaking. However, in 2021 you have little choice. In fact, **using quality management software is not only a good idea, it is the standard for regulated manufacturing industries.**

Driven by regulation and technological innovation, more and more manufacturers in different industries are seeking out better and smarter quality management solutions that enable them to grow their bottom line. **The global QMS software market was already valued at USD 7.3 billion in 2018 with an expected 9.8% CAGR between 2019 and 2025, according to a 2019 market size, share and trends analysis report.**

U.S. quality management software market size, by application, 2014-2025 (USD Billion)



For a medical device manufacturer, choosing the QMS that is right for you can be a daunting task. There are many options and a lot of criteria to take into consideration.

This eBook includes:

The definition and roles of QMS for a medical device manufacturing business

The contribution QMS can have to your business

Regulatory requirements and their impact on your choice of QMS

The criteria to consider when choosing the QMS to serve you in 2021 and beyond

What is QMS (Quality Management System / Software)?

A QMS is a framework that integrates and documents the responsibilities, procedures and policies necessary to ensure the manufacturing organization meets quality and compliance standards. ASQ defines it as **“A formal system that documents the structure, processes, roles, responsibilities and procedures required to achieve effective quality management”**.

Quality Management System

Process & Production Control

- + Customer Requirement
- + Supplier Quality
- + Identification / Traceability

Design Control

- + Risk Management
- + Inputs / Output
- + Verification / Validation

Change Management

- + Design Change Management
- + QMS Change Management
- + Risk Review

Management Control

- + Management Review
- + Inspection Readiness
- + Internal Audit

Production & Surveillance

- + Complaint Handling
- + Risk Monitoring
- + Vigilance

Corrective & Preventive Action

- + Eliminate Nonconformances
- + QMS Improvement
- + Verify Effectiveness

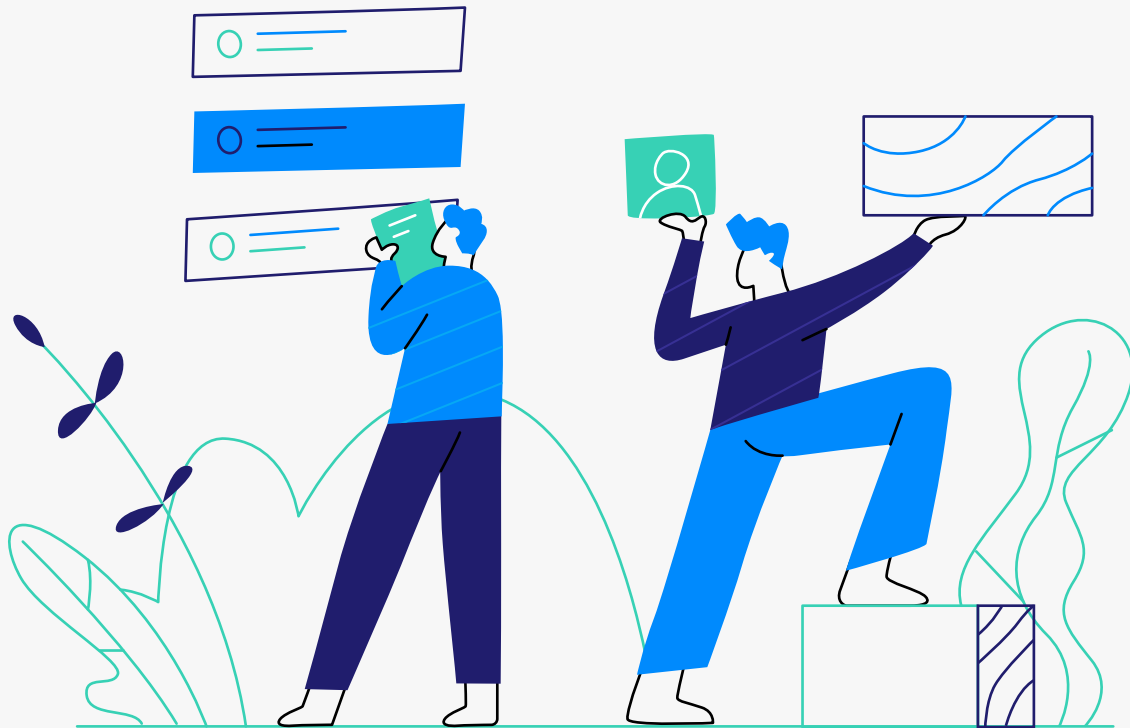
The life sciences manufacturing industries are under a growing level of scrutiny from regulators. Therefore, QMS systems are now required to meet the specific standards of every local regulator. In other words, **to sell your products to regulated markets you must adopt a solution that complies with regulatory standards.**

You need to choose a system that helps you stay in control of documentation, internal audits, regulatory demands, quality assurance processes and risk assessment. **The system must help you efficiently navigate corrective and preventive procedures, as well as provide relevant insights to executive level managers and team managers alike.** These are needs that a legacy paper-based QMS simply cannot serve.




The Business Benefits of QMS

Regulatory compliance can be a daunting topic. Before we delve into the intricacies of ISO and FDA regulations for medical equipment manufacturing, let's review other ways QMS can have a positive impact on your bottom line.



Optimize Process Execution & Enable Collaboration

Philosophically speaking, an organization is a collection of people, processes and knowledge. QMS solutions are, first and foremost, a tool to enable the optimization of processes that make up and surround the business of medical device manufacturing.



An effective QMS implementation enables integrated communications between teams in R&D, manufacturing, customer success, logistics and others. It allows team managers and quality managers to get a view of all quality assurance related activities in the organization in a single view.

Eliminating long email threads and frantic searches for documents across computers and servers, QMS enables **collaboration across departments. Integrated communications help in determining effective quality assurance procedures, assignment of tasks for different parts of the process, and customization of the system to the needs and business goals of the organization.** This is especially critical with globally distributed teams and overseas participants in the supply chain that require easy access to key information in real-time.

Accurately Process and Archive Documents

Medical device manufacturing involves a great deal of paperwork. There are documents related to patents, suppliers, batches, materials and quality assurance checklists, among others. Processing, analyzing and storing these documents in a single intelligent QMS can connect and safeguard precious information that can provide invaluable business insights.

Document and Analyze Customer Feedback

When it comes to manufacturing of any product in any industry, one of the main challenges is bridging the gap between the manufacturing process and the consumer. **With a QMS in place, you can better connect customer feedback to quality assurance processes and discover where and how you can improve customer experience through changes to your QA processes.**



Perform Smarter Risk Analysis & Business Decisions

The process of QA in manufacturing has a unique relationship with batch rejection and discovery of manufacturing flaws that combines corrective and preventative measures. On one hand, it aims to uncover and report non-conformities. On the other, it strives to minimize them. That's where risk assessment and analysis come in. Often performed automatically or semi-automatically in QMS software products, **informed risk analysis helps companies make smarter decisions that ensure both customer safety and business growth.** Moreover, integrated risk management best practices in your processes and systems is a requirement for ISO 13485:2016 certification.



QMS for Regulatory Compliance in Medical Device Manufacturing

The life science industry is among the most heavily regulated manufacturing fields worldwide. It makes sense that they would be since, unlike many other industries, when it comes to medical devices and drugs, human lives are at stake. Though many manufacturers see regulatory demands as a necessary evil, they can in fact be a driver for a more scalable and successful medical device manufacturing business.

To sell medical devices in most countries in the world, you must meet local regulatory demands. Among these demands are in-depth documentation and proof of compliance. In fact, both leading standards for medical device manufacturing for the US and EU, (FDA 21 CFR Part 820 and ISO 13485:2016) list the requirements for QMS implementation. Local regulations in other countries (like Canada) have their own (rather similar) requirements you should familiarize yourself with if you wish to sell there.

It may seem a bit overwhelming at first, but the good news is that complying with ISO 13485 demands for QMS makes compliance with the FDA's guidelines much easier as of 2019.

As defined on the [International Organization for Standardization \(ISO\) website](#), "ISO 13485 is designed to be used by organizations involved in the design, production, installation and servicing of medical devices and related services. It can also be used by internal and external parties, such as certification bodies, to help them with their auditing processes."

ISO 13485 was revised in 2016 to put a greater emphasis on risk management and risk-based decision making, as well as changes related to the increased regulatory requirements for organizations in the supply chain.

The ISO 13485:2016 standard for QMS solutions touches on a number of topics and procedures.

Document Control

Teams across the company need to document each stage of the process. It's also required to have a system in which documents are reviewed, revised and approved. Records of implementations must also be saved. **The ISO standard presents clear directions on creating and maintaining compliant quality manual management, medical files for each device group, and the processes for document versioning and record analysis and archiving.**

Process Control

In any efficient business, processes are overseen and workflows are put in place to ensure everything is done in the right order, by the right people, and according to the pre-defined schedule. For medical device manufacturing, the **QMS performs the roles required by ISO 13485 to allow for the validation and verification of quality assurance processes.**

Risk Management

Risk management is required from planning to customer success. For example, in the design and development stage, you're required to assign ownership to different product lifecycle stages, understand the potential risks, then schedule and conduct risk management reviews. On the other end of it, you need to track customer feedback. When you get a complaint, **you need to document the challenge, when it happened, which product was involved, and how the issue was resolved.**

Management Responsibility

For regulation requirements to be met, the organization has to be fully committed to creating effective processes across departments, that lead to the highest quality medical devices. This is especially important in an industry like ours, where people's lives are impacted. It's critical to secure c-suite support that can lead this transformation and maintain it long term.

Resource Management

First, you have the physical and virtual resources, like buildings, equipment and software. These **resources need to meet regulatory requirements** themselves, like keeping equipment clean and ensuring cybersecurity for SaaS tools. Second, you have human resources you need to nurture. **Providing professional training for your team and documenting this training is essential.**

Product Realization

Many aspects are involved in planning how your product will be designed, manufactured and distributed. You need to decide on quality criteria for each aspect, from the equipment you use, through work conditions, to protecting customers' privacy. Then, you need to **set processes your team must follow to meet these requirements, monitor compliance, and document everything** along the way.

Measurement Analysis and Improvement

Setting KPIs for each part of the process is key for measuring how you're doing along the way. Schedule regular times to analyze how things are going, and you'll be able to catch risks, quality issues and noncompliance before they become a problem. Improving processes and execution will become much easier.

Choosing the Right QMS in 2021 and Beyond

A QMS can make your job much easier when it comes to compliance and assuring quality. However, if you choose one that's a good fit for your specific needs it will do so much more. Here are some important aspects to consider when comparing options.

Define Your Company's Needs and Goals

You can accelerate the process by **only looking at QMS solutions that were designed specifically for medical device manufacturing quality management**. That will shorten the list of potential solutions significantly, and will likely ensure collaboration with a provider who gets your team's complex responsibilities. In addition, solutions that are uniquely suited for the medical device manufacturing industry include built-in validation features and processes. This saves both time and money you would otherwise have to invest in validation.

Analyze Existing Processes & Integration Requirements

What does your quality assurance management look like today? What are your current challenges? How does your team collaborate? Where can quality assurance processes and documentation activities benefit from a QMS? Most importantly, **understand the current needs, habits and preferences of the individuals working with the system hands on.** Those have just as much impact on the success of your business as compliance with industry standards.

In addition, it's important to remember that QMS is not the only system used in the process of manufacturing medical devices. ERP, CRM and other systems in the organizations need to draw data from the QMS and write to it. **When evaluating the QMS for your needs, consider its integration options and ability to work seamlessly with other systems.**



Compare Solutions' Conformity Assessment Approaches

A conformity assessment is a process that verifies your company indeed meets regulatory requirements. **According to article 11 of the Medical Devices Directive (MDD), you need to choose between multiple conformity assessment options based on your company's specific situation.** [You can find article 11, which details the options, on page 13 here.](#) Do your research to understand the best one for you, then verify that the QMS you choose offers the best tools to implement it.

Estimate Operations Volume & Aim to Scale

Software and service licenses for medical device manufacturing QMS solutions are usually priced per-user. Having hundreds or thousands using the solution will likely impact license and implementation costs. However, some QMS providers out there offer a solution fit for small to medium manufacturers. These plug and play QMS applications can offer the quick implementation and low operational costs that legacy enterprise-focused QMS cannot.

In addition, many of these cumbersome enterprise QMS suites come with a plethora of unnecessary features that make using it both inefficient and expensive. In choosing your QMS solution, **look for one that will provide reasonable pricing with a scalable license and offers a “fully baked” solution that will grow with your business.**



One of the main trends of Quality 4.0 is the shift to cloud-based QMS applications. One of their main advantages, especially when it comes to growing businesses, is their ability to scale according to business needs while demanding minimal capital investment and maintenance. Automatic updates to match changes to regulation, infrastructure availability and uptime, assurance of information security and system integrity - these are just some of the roles the service provider assumes when you choose a cloud-based QMS over a locally hosted software.

Evaluate Risk Assessment & Analytic Capabilities

According to the [ISO Training Institute](#), the European regulation requires risk-based thinking to be applied across processes, from product planning to customer service. This means being proactive about identifying risks across your operations, so you can be better prepared to minimize, or even prevent, them. One of the benefits of a cloud-based QMS is the easier access to data, especially more sophisticated data. For example, if a machine consistently experiences technical challenges, or leads to defective products, but different aspects of it fail each time, it will be faster to recognize it with a well implemented QMS. **Compare analytics and risk assessment capabilities of different QMS options to determine which one can help you overcome your most critical challenges.**

Take into account the advanced data processing capabilities of the solutions you evaluate. Some QMS providers implement AI and machine learning to enable a data-driven solution of a predictive nature, essentially automating many risk assessment and internal auditing processes.

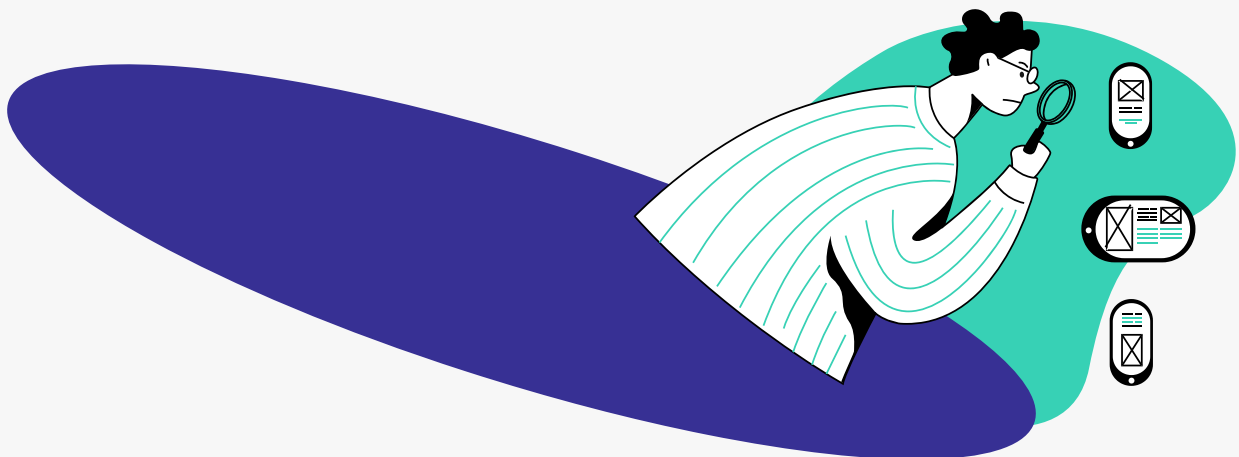
Understand Users' Needs

At the end of the day, real people will be using the QMS to ensure company success. It is advised to talk to the different parties who will be using it to hear their top challenges right now, and what they most need from a QMS to increase performance and results.

Prioritize input from those who will be using the QMS most, or from those who'll be using it for the most critical activities. Do your best to get as many points of view as possible, at least in the initial needs definition stage. This way, every department can point to the most critical features for its specific team.

In addition, be sure to consider infrastructure and supported devices. Having to acquire new computers for each stakeholder in the production process, for example, is a very serious investment. One that can be easily avoided by choosing a QMS solution that allows for secure role-based access to the system from most Internet connected devices in any location.

Then, once you start working with a new QMS, **encourage departments to take time to test it out to make sure it's indeed the best fit for your organization.**



Consider Industry Trends and Market Evolution

Regulations change over time and only tend to get stricter. They often look fondly on the use of new technologies in risk management.

Market demands change over time as well. The need for more sustainable manufacturing, the Internet of Things, artificial intelligence, machine learning and the increasing presence of social media are just a few examples.

Similarly, changes will likely happen in your company too. New products might get developed, new offices could be opened across the globe, operational processes could be changed, the company could merge with another company, buy another company or get acquired itself.

Throughout it all, your quality of devices will remain critical in a high stakes field like ours, and regulatory compliance will remain necessary to keep your doors open as well.

Favor a cloud-based QMS that can scale and shift as your organization and the market change. **One that provides global accessibility from multiple types of devices, visibility and traceability of processes and batch releases, plus data analysis and strategic insights for teams across departments.**



Leverage Automation

One of the benefits of managing processes is creating a series of events, where one action follows another at all times, changing only at certain conditions. **Creating automated workflows of these processes can have your QMS do your work for you.**

You can also create rule-based notifications, to alert activity owners when there's a challenge in the workflow or remind them it's time for a human team member to take action. For example, if a certain amount of customer complaints are received about the same aspect of the product, the QMS can recognize the risk and alert the right team member.

Choose a Provider Who Can Be a Partner

Beyond product features, it's important to look at the provider's willingness to be a true partner for your team. **Consider finding a QMS provider that can adjust to growth and changes in your company, the market and regulation. See if they offer customization to your specific needs.**



Furthermore, look for ways the provider is set to help your company grow. Prioritize solutions that come with an expert team, who's experienced in the medical device industry, who is open to providing your team members with data, and answer any question they have about the solution, ensuring quality and meeting regulatory demands. If their team has conducted audits or has experienced audits from official regulatory bodies, even better.

Most of all, look for a provider who understands that your success is its success, and has trained its team to show up for you accordingly.

Quality 4.0 and Beyond

As technologies get more complex and connected – the Internet of Things, artificial intelligence, augmented reality and robotics, to name a few exciting developments – regulatory bodies tighten their supervision.

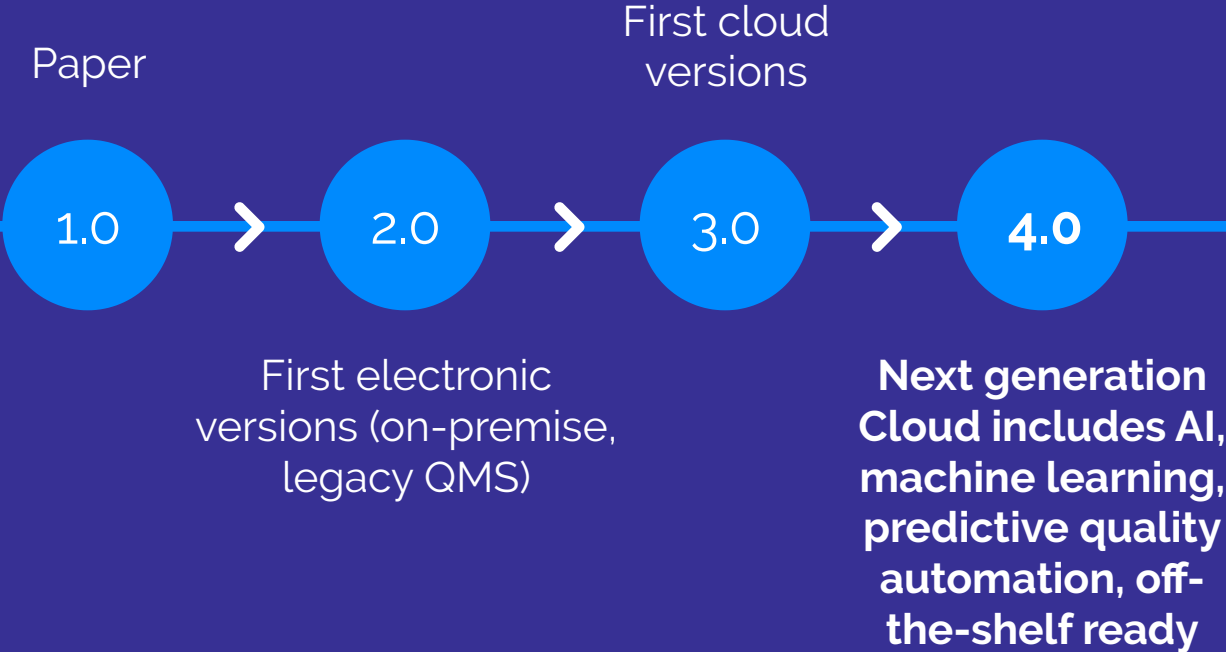
Medical device manufacturers willing to stay agile and embrace the move to digital will be able to build more efficient operations and technologies. They'll make smarter, more data-driven decisions, enabled by easier cross-team visibility, driving safer and better results for patients, and lower costs for clients.

These manufacturers will not only guarantee regulatory compliance that will keep their doors open. **They will gain a competitive advantage, and be able to lead the market through Industry 4.0, Quality 4.0, and beyond.**

Quality 4.0 is quickly becoming the industry standard for QMS. However, since it is a relatively new standard, what Quality 4.0 actually covers can be unclear.

What is Quality 4.0?

Quality 4.0 is a methodology and a standard that attempts to amalgamate technological innovation with best practices to **propel organizational change and impact productivity, profitability, and employee engagement** in a massive way.



What is the impact of Quality 4.0 on QMS?

Quality 4.0 is charged with **introducing innovation through the introduction of new technologies such as machine learning, AI, Cloud Computing, Big Data, and more.** Manufacturers that implement Quality 4.0 are able to transition from reactive to proactive quality management, and get deeper insights by leveraging the power encapsulated in these innovative technologies.

In fact, the ability to conduct in - line quality assurance for closed - loop, proactive quality management transform QMS from a closed and secluded process, managed by a few individuals within the organization, to something that is widely applicable and adopted throughout the organization.

The introduction of Quality 4.0, places Quality Teams and Quality Professionals at the forefront of innovation for the entire organization and allows them to take on an even more influential role, and intersect with almost every department within the organization.

Therefore, companies in general, and quality teams in particular, that want to stay ahead of the curve and be an instrumental force for organizational change, must adopt Quality 4.0 ready solutions sooner rather than later.

Dot Compliance Quality Platform for Medical Device Manufacturers

A quality-driven and scalable solution for regulated business process management.



CORE EFFICIENCY

Set strong foundations to bring safer, high-quality products to the market faster. Easily automate to make data-driven decisions in real time and become continuously audit-ready anywhere.



ENTERPRISE QUALITY

Grow quality management with additional cross-organization processes, connected to a single source of truth that drives efficiency. Reduce risk with better visibility and control.



ANALYTICS +

Go bigger with an intelligent decision-making ecosystem. Easily connect your silos and leverage the power of machine learning, AI and big data technology with predictions, and recommendations.



Record-Fast Deployment That Scales with Your Business

Go live with an all-in-one QMS in a matter of weeks. Our 'out-of-the-box' platform comes with pre-engineered and pre-validated processes allow you to get on board and gain value faster.



Made for Life Sciences Quality Management

Pre-engineered processes configured with best practices that meet regulatory requirements such as ISO 13485, MDR 2017/745 and others, including a CFR part 11 compliance validation package.



Mobile & User Friendly

Accessible from almost any Internet-connected device and built for a superb user experience.



Secured, Updated and Growing

Always on, always safe, always up-to-date and always developing to serve you better.



Leveraging Automation

Automate quality processes, easily collect e-signatures, send alerts and track your efforts in real time. The right automation, at the right time, for the right people.



Built with Salesforce

Integrated and developed using the leading cloud, Salesforce platform™, a trusted technology that supports AI, Big data and machine learning, allowing us to deliver flexible and scalable enterprise solutions with outstanding user experience.



Get the Most Comprehensive Quality Management Software for the Life Sciences

Dot Compliance is a Quality 4.0 ready QMS software that provides a full set of tools and solutions for all your compliance needs

START NOW

