



The Ultimate Guide to Medical Device Quality Management

Chapter

- 1** **Shifting Focus:
Adopting a Data-Centric Quality Mindset**
- 2** **The Platform Effect:
Fully Connecting the Quality Life Cycle**
- 3** **New Ecosystem Dynamics: Enabling Pervasive Quality**
- 4** **The Future of Quality Is Predictive:
Keys to Unlocking Your Data's Intelligence**

1

Shifting Focus: Adopting a Data-Centric Quality Mindset



1.1

Visualising a new data-centred quality paradigm.

When the first Nokia and Motorola cell phones that were affordable and small enough to fit in your pocket hit the market, they not only changed how we viewed phone technology but how we communicated.

Mobile phones went from a novelty that only the wealthy could afford to an indispensable device that virtually everyone has and, in many ways, can't live without. But unfortunately for both Nokia and Motorola, the transformative effects of cellular devices were not at their apex. In fact, the cycle of innovation was only getting started.

The introduction of the iPhone took things to the next level by fundamentally shifting the value of the cell phone from voice to data. By opening new features like text and video messaging, internet access, and other seemingly limitless avenues for the usage and access of data, the iPhone dramatically increased the utility and value of a mobile device and forever changed the way we live, work, and play. As a side effect, tech companies began gathering data on those behaviours.

Now tech behemoths are turning their attention to medical devices. Popular tech gadgets, such as the Apple Watch, have the same functionality that used to only be found in devices in hospitals or doctor's offices. Tech companies have the money and technical expertise to make what are essentially medical devices. Not all of them have the regulatory expertise to make compliant medical devices, but considering Apple just got 510(k) clearance for notifications of atrial fibrillation from the Apple Watch, they are catching up.¹

Even as companies such as Apple make regulatory progress, medical device companies still have more experience with the red tape associated with compliance. What they aren't as accustomed to is making the most out of their data. Tech companies are drowning in data and they've learned how to analyse and use it. Medical device companies can do the same thing. Quality data in particular is essential to these businesses as they struggle to shorten product development timelines and get to market faster while remaining compliant.

Properly using data with advanced analytics and artificial intelligence (AI) requires a solid foundation. Accuracy in analytics and AI is dependent on the accuracy and completeness of the data being used. Unfortunately, med device companies have a bad habit of storing that data on paper, in employees' computers, or other similarly siloed places. Even companies that have digitised with an electronic quality management system (QMS) can have trouble combining all their data.

That's why it's necessary to take things a step further. Bringing together information from every department in the organisation and having the tools to properly analyse it are essential for medical device's future. The digital documentation layer of quality and compliance processes is still critical and will never go away, but advanced technologies are helping medical device organisations unlock the data side of the equation.



1.2

The promise and peril of unstructured data.

As they say, the first step is admitting you have a problem. The primary driver behind medical device's urgency to adopt more data-centric approaches to quality and compliance is best understood through the lens of unstructured data, which accounts for more than 80% of data in the life science development, production, and commercialisation life cycle.² Think about locked PDFs, scanned documents, uploaded images, and so forth — all elements that can be “managed” within today's QMS software solutions, but all elements that contain massive amounts of granular data and insights that are currently difficult to extract and hard to correlate and analyse in real time.

Nothing can be done with unstructured data until it is converted into a useable format. Then, medical device companies can focus on data integrity and improving data quality. This is one of three critical points to understand about the hazards of unstructured data and its impact in the evolving regulatory landscape.

1

Poor data quality is a multimillion-dollar waste.

There's quality data, and then there's data quality. Quality data is simply data collected through quality control and quality assurance efforts. Data quality refers to how good the data is and largely ties back to following good data integrity practices. Ignoring those practices and settling for poor data quality costs organisations an average of \$12.9 million annually, according to Gartner.³ Medical device companies have data that can give them advantages over their competitors — if they can access it. The first step in access is removing any practice that leads to unstructured data.

80%

of data in the life sciences development, production, and commercialisation life cycle is unstructured.

2

Data will play an increasingly important role in regulators' policy enforcement.

As regulators strive to increase their global alignment and coordination, they are adopting new data-driven approaches and increasing data sharing and harmonisation. As regulatory standards are updated and as new regulations go into effect, they are putting increased emphasis on risk, shifting from a one-size-fits-all regulation mindset to a data-driven, segmented approach. This is evident in how the U.S. Food and Drug Administration (FDA) chose to handle inspections during the pandemic. The agency used risk management methods to determine when to request a remote interactive evaluation. Being able to access data quickly has always been important during inspections, but for the FDA's remote records review having it in an electronic format was essential.

3

Unstructured data is a massive blind spot in today's quality and compliance models.

An approach to compliance that focuses on the object that contains the compliance information that regulators seek (i.e., a document) is insufficient in the current regulatory environment. In the eyes of regulatory authorities, quality evidence that cannot be substantiated upon request may as well not exist. Conversely, achieving an audit-ready state that is sufficiently supported by the appropriate digital technology is inherently more efficient and would drastically lower overall compliance costs. Combining audit readiness with effective compliance risk assessments and management would further improve the effectiveness of compliance functions. But adopting this type of approach to quality and compliance requires that a company first overcome the obstacle of unstructured data.

\$12.9 million

estimated annual cost of poor data quality.

1.3

Overcoming data overload.

More data, more insights, more opportunity — got it. Not so fast. Like their peers in R&D and marketing before them, medical device quality professionals can quickly find themselves inundated with too much data. Besides being flooded with machine performance, product performance, process performance, and observational data, we also have access to “internet of things” (IoT) data, social media data, structured customer feedback, and human sentiment data. With all this data available, the expectation is that quality should be able to do more, but turning this data into something actionable is challenging.

As traditional health care companies struggle with using unstructured data, large tech companies are rising to the challenge. The Google Cloud Healthcare Data Engine and Amazon HealthLake are frontrunners in this area.⁵ Both efforts have similar goals in analysing unstructured data and overcoming the interoperability issues that are common with electronic health records.

Medical device companies that continue to pursue a document-oriented approach to quality are just going to fall further behind their big tech competitors. A failure to invest in software solutions that improve data collection, management, and analysis while simultaneously improving the analytics comfort and capabilities of quality professionals will at best only result in inefficiencies, production delays, or product defects. At worst, it'll lead to the harsh consequences of noncompliance or product recalls.

Today's QMS solutions are a giant step forward from antiquated paper-based quality management processes, but they have the capability to be so much better. Getting there requires moving beyond merely digitising document-centric processes and focusing on a holistic approach that allows quality and compliance professionals to access, analyse, and apply insights from structured and unstructured data within the same system across the product life cycle.

\$67.82 billion

Projected value of big data analytics in the health care market by 2025.⁴



1.4

Understanding quality's document dependency.

No self-respecting tech company would ever record and store important information on paper. Even if big tech wasn't a competitor, nixing the bankers boxes and filing cabinets would still be a good idea. The document-centred approach to quality management has been the default mindset in the medical device industry for as long as it's been regulated. The mentality has been predominantly based on the rationale that quality activities are typically rooted in historical information that is maintained in reviewable documents.

And while there is a rich history of statistical data analysis in quality, the traditional models have typically employed point-in-time analysis that provided parameter guidance based on past quality events. The conventional approach

is not effectively supporting medical device companies as they find themselves mired in ever-growing collections of disconnected documents and data.

And those document collections and disconnected data sources are multiplying and fragmenting exponentially. What's more, regulatory agencies are recognising that the one-size-fits-all approach to regulation does not adequately weigh the risks posed to life sciences companies, which has caused the subsequent shift to a data-driven, segmented approach to regulation.

Noteworthy perils of disconnected documents include:

1

Inefficiency

It's difficult to connect documents to multiple processes, and disconnected documents and processes increase the likelihood that quality issues will slip through the cracks. Compound those inefficiencies with the fact that staff time equals money in any business setting. The time employees must spend controlling versions or determining the accuracy of disconnected documents equates to resources that the company can't allocate to other critical areas.

2

Innovation Blind Spots

When the right hand doesn't know what the left hand is doing in a medical device company, it can be a fatal flaw. If you can't get the right document in the correct person's hands when decisions need to be made, your quality data is useless — especially to regulators.

3

Operational Disconnects

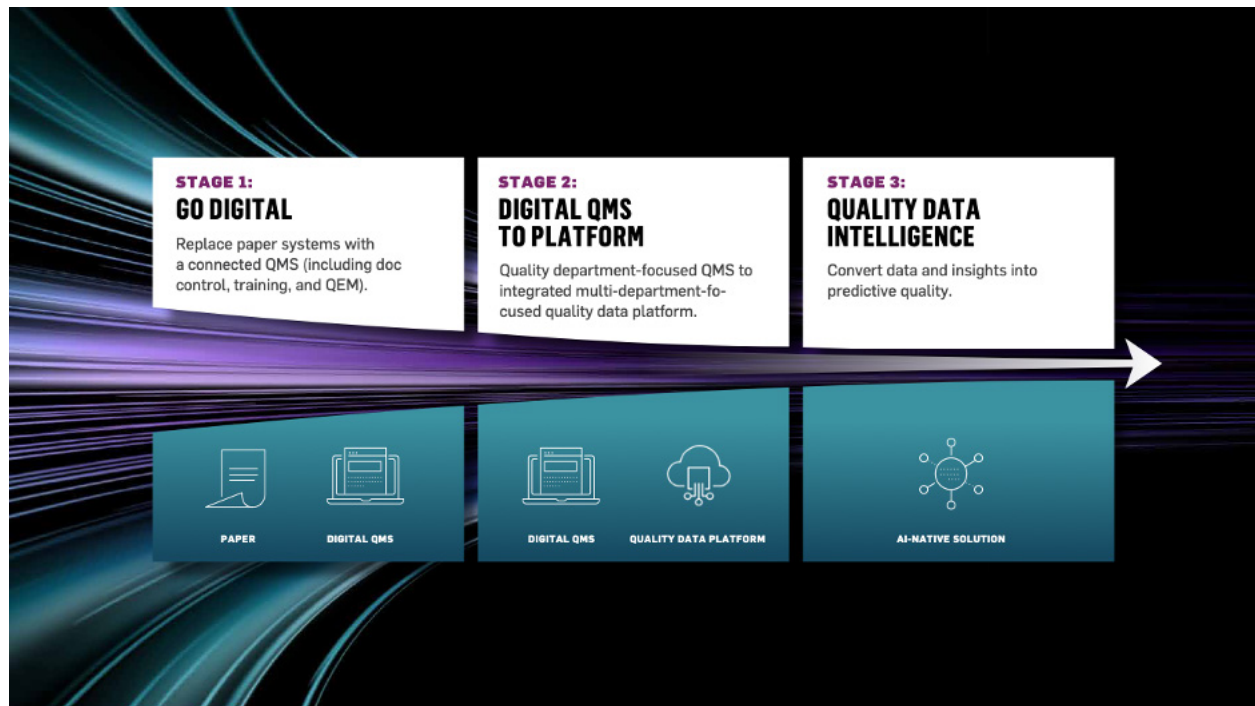
To have any hope of managing product life cycles effectively, your workflows and document approval routes need to be as straightforward as possible. But in document-focused environments, the management of life cycle statuses and changes becomes incrementally more complicated whenever new products are introduced and when modifications inevitably occur.

1.5

Charting a clear path to digital and data maturity.

Every medical device company's quality system can be identified at a specific point on the QMS maturity curve. And it's likely that every company is at least one step behind where they'd like to be. Where is your company? Where would you like to be? And, more importantly,

what do you need to do to get there? Achieving true quality data intelligence requires that you evolve your document-focused quality mindset and systems to become more focused on the availability, connectivity, and analysis of your data.



1.6

Taking pragmatic steps toward digital leadership.

There's only so much an individual can do without the approval and support of the C-suite. Digital transformation is best done holistically, not piecemeal, and that level of vision and planning requires someone further up the organisation's hierarchy. Digital transformation, connected data, and AI are just steps on the same continuum to make better decisions based on data with less error. McKinsey & Company performs an annual survey about AI, specifically looking at the difference between what they refer to as AI high performers and other organisations.

"The most successful companies we see have a CEO who lays the groundwork for support up front. Such leaders ... hire AI-experienced senior talent to fill the leadership positions required to help drive the change, if the talent doesn't already exist in the organization. They also reduce hierarchy, make AI education a priority, and consistently communicate at every level the strategic nature of these changes."⁷

If AI isn't on a medical device company's roadmap, it should be. AI is vital to a company's quality processes, but medical devices increasingly incorporate AI, especially machine learning (ML). Granted, not every device needs AI, but there are other ways to use AI in a medical device business. Every company would benefit from improved predictive/prescriptive analytics and eventual use of AI in their quality management and other business processes. This isn't as scary as it sounds. There's no need to run out and hire AI experts if companies invest in enterprise software systems that have AI built in.

90% of enterprisewide digital transformations in the life sciences are led by new CXOs.⁶

1.7

Connecting the 4 Ps: People, Processes, Policies, and Platforms.

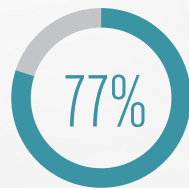
At MasterControl, we are actively focused on the future and helping our customers get the most out of their quality and compliance processes and data — not just at a technology level, but at the operational level. In the medical device industry digitisation continues to be the overarching trend, and quality leaders are learning that they must find new ways of reimagining and redesigning their processes in order to become more data centred.

Overhauling processes is hard enough without worrying about the technology involved. That's why we're working to provide completely connected quality management and predictive and prescriptive insights

into process improvements. With an intuitive user interface, MasterControl products help employees embrace digital transformation and advanced technology such as AI by making it easier to use and providing faster ROI.

As one expert from Deloitte points out, "With AI capabilities increasingly embedded in enterprise software, and an abundance of cloud-based offerings and tools that accelerate AI development, a company no longer needs as many heavy-duty

specialists to get started."⁹ We know how valuable analytics and AI are to medical device companies, which is why we're building those capabilities into our products. Medical device companies can immediately reap the benefits, even as they work to transform their whole organisation.



of companies
are significantly
accelerating their
digital transformations.⁸



1.8

The future of connected quality.

Speaking of analytics and AI, that's really where the quality field in general is headed. That doesn't mean quality professionals have to go back to school to get new degrees, but it does mean becoming familiar with the tools available and the benefits they offer. By automating the more tedious tasks associated with quality management, quality professionals can focus on improving the medical devices themselves and getting them to market faster.

As additional benefits of connecting data on a granular level continue to arise, it becomes easier to visualise scenarios where the power of quality data can be unlocked and harnessed.

While new technology creates new challenges, it also opens the door to new opportunities. The following section and subsequent chapters describe how you can make data-centric quality a reality in your organisation by implementing tools and methodologies that fully connect the entire quality life cycle, extend the quality ecosystem, and unlock the hidden intelligence and predictive capabilities that are waiting to emerge from your data.

- 1 Predict overdue training and provide options for how to avoid it.
- 2 Recommend updates to training based on user error during production.
- 3 Track and trend themes across customer complaints using natural language processing (NLP).
- 4 Algorithms that can determine when investigation is warranted, carry out much of the legwork of an investigation, and in some cases, close the investigation with little or no human involvement.
- 5 Use industry data to create benchmarks and measure where a medical device company is underperforming.
- 6 Predict the time delay of a deviation on a product's release.



1.9

Modernising quality's approach to data.

As mentioned earlier, quality has always been driven by data in the medical device industry and, as regulations and standards continue to be updated to match the pace of the modern digital world, it's never been more important for quality teams to make data-driven decisions.

While quality has always been the leader in statistical modelling and earlier forms of data-driven decision-making, those developments largely occurred in an era when the ability to access and analyse data in real time with prescriptive and predictive models wasn't available. Today, most of the market is lagging in its use of up-to-date metrics that facilitate decision-making.

Without access to pertinent quality data, medical device companies will fall behind their better prepared competitors. But a new approach takes a new set of tools — that's why MasterControl is designed to support your transition from document-centric to data-centric quality and compliance.

To provide even more connection between quality data and other areas of the organisation, we have developed MasterControl Insights. Insights is our analytics tool that incorporates predictive/prescriptive analytics and AI to guide your decision-making. Insights gives users complete control over their data to decide what's important to them and how to visually display it in the most meaningful way. Data's potential is too important to not embrace new technology. Even the regulators agree with that.

The FDA's new Office of Digital Transformation (ODT) is evidence of this. "The agency began these efforts because ... innovation is at the heart of what we do. By prioritizing data and information stewardship throughout all of our operations, the American public is better assured of the safety of the nation's food, drugs, medical devices, and other products that the FDA regulates," said former Acting FDA Commissioner Janet Woodcock. "This reorganization strengthens our commitment to protecting and promoting public health by improving our regulatory processes with a solid data foundation."¹⁰

MasterControl's Connected Quality Advantage.

1

Less Complexity:

- Fewer Siloed Systems
- Standardised Experience
- Faster Global Deployments



2

Smarter Process:

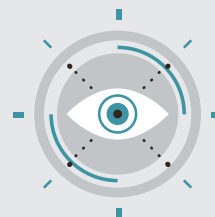
- Flexible Design
- Native Connectivity
- Dynamic Workflows



3

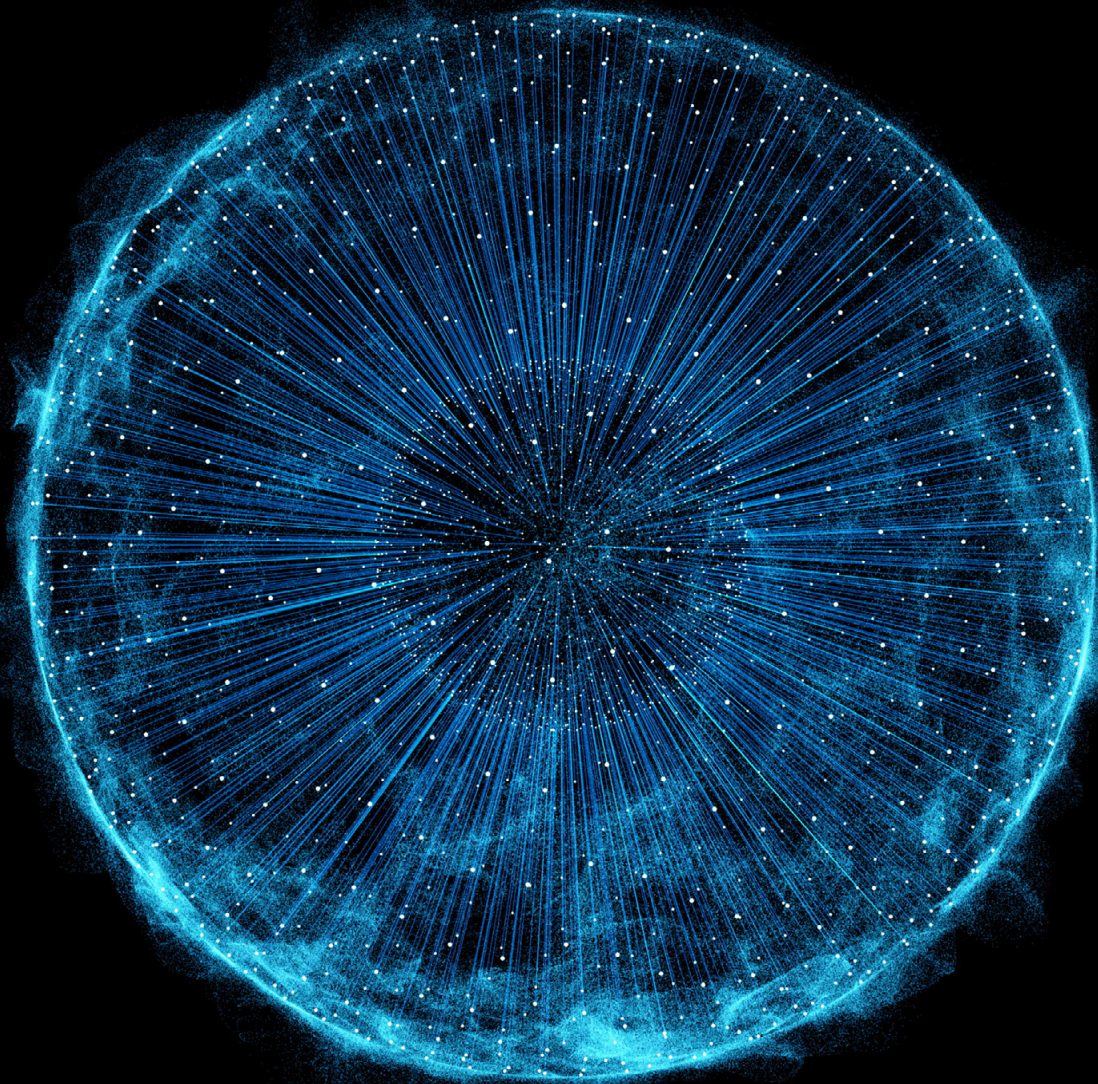
Greater Insights:

- United Architecture
- Single Source of Truth
- Large Data Set for ML/AI



2

The Platform Effect: Fully Connecting the Quality Life Cycle



2.1

Combating complexity with connectivity.

Medical device companies are facing intensifying pressure to accelerate new product introduction pipelines while simultaneously confronted with decreasing margins and products that are becoming more complex and personalised. This is resulting in increasing scrutiny on the industry's siloed approach to systems and processes.

As the industry strives to adapt to the market's velocity, three key trends have emerged as impediments to many companies' attempts to connect the quality life cycle:

1

Diminishing timelines

When competing against companies like Google and Apple, getting to market faster has never been more important. One expert from Accenture noted, "Traditional medtech development cycles cannot compete in the fast-paced world of consumer tech, so it's critical that you become more agile and more efficient."¹¹ Medical device companies that have undergone a digital transformation can move quicker than those still using paper.

“Our 510(k) submission was smooth because we had all the documents in MasterControl. All I had to do was make an e-copy to send to the reviewer, and then to the FDA. It was a fairly simple process for me to negotiate.”

Balaji Sudabattula,
Vice President of Quality and
Regulatory Affairs, BraveHeart

2

Product complexity

Medical devices have never been more complex. Software as a medical device (SaMD), especially AI-enabled SaMD, presents levels of complexity beyond what's required of a typical medical device company. Besides hardware, medical device companies now have to be experts in software development, all while maintaining compliance. This presents an obvious competitive disadvantage when compared to the software development expertise of tech companies. However, medical device companies still have the advantage that "non-medical device manufacturers that are essentially software developers are also becoming part of an already complex, stringent, and fast-changing medical device regulatory ecosystem,"¹³ which is the ecosystem that medical device has always operated in.

21.9% CAGR

**expected growth of SaMD
market through 2027.¹²**

3

Personalisation and Customisation

Personalised medicine and mass customisation are significant disruptors for medical device. Personalised medicine is usually associated with pharmaceuticals, but with the emergence of 3D printing at point of care and the potential of SaMD to adapt to an individual based on data, its effects are being felt in medical device. These new technologies will add to the ever-increasing amount of data medical device companies already have. To handle that data, quality control and quality assurance functions will need to be more automated and demonstrate continuous real-time capabilities. Automation is only one part of the equation, however. Any technology that is implemented to streamline quality data management must also be capable of making that data accessible and relevant across the enterprise.

2.2

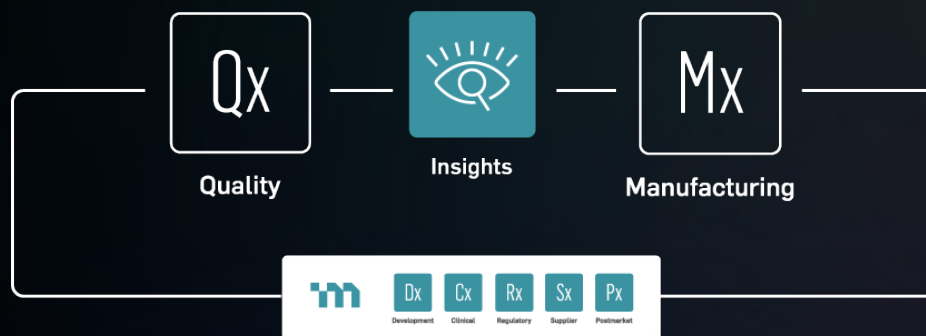
The next level of quality culture.

The demand for acceleration and the enhanced focus on data is bringing software to the fore in the medical device industry. It's no longer enough to simply have a document control system, or a quality event management system. Medical device companies need greater real-time visibility into data and greater control, even as the pace of innovation accelerates. This is only found in systems that connect all areas of quality — training, document control, audit, QEM, etc. The best systems reach even beyond quality to other areas of the organisation.

Rather than piecing together disparate applications to coordinate multiple processes and data streams, this type of software offers the reassurance of native connectivity and unifies all applications and processes within a common architecture and database. Plus, a company can achieve greater governance over its quality management processes by running multiple applications within a natively integrated operating system. This, in turn, allows the company to take a product life cycle approach to quality and compliance.

That approach pulls data together from all areas of quality and the entire organisation. Advanced analytics let medical device companies operate based on that data and measure their progress in fast, reliable ways. When quality professionals spend less time doing data dumps into Microsoft Excel, they can focus on what the data is telling them and act on the suggestions of the prescriptive algorithms. The time saved through digitising and relying on automation lets medical device companies move faster and outpace their big tech competitors.

Fuel Growth With a Connected Platform



2.3

Enabling vision and velocity.

Greater speed comes down to vision — leaders who can see what's happening in real time can make decisive actions quickly. This has never been more important than during the pandemic. COVID-19 forced companies to change how they work, and medical device and other life sciences companies were no exception. "Companies shattered previous vaccine development records due to their ability to capture, store, process, and analyze machine data," said Deloitte Principal Aditya Kudumala.¹⁴ By enabling companies to achieve real-time quality intelligence, digitised systems proved to be the ideal means of establishing quality as a speed-to-market accelerator.

As medical device companies recover from the pandemic and prepare for growth, digitisation provides adaptability and expansion when the need to evolve or pivot becomes warranted. While not as urgent as COVID-19, business processes change and new processes need to be added. A digitised system equips an organisation for the future by providing the consistency of a baseline technical framework that can be expanded upon and leveraged to spur innovation as business flourishes.

“ If you want to understand why [data] is incredibly relevant to life sciences companies, look no further than COVID-19 vaccine development. Companies shattered previous vaccine development records due to their ability to capture, store, process, and analyze machine data.”

Aditya Kudumala,
Principal, Deloitte

A 2021 report from Cognizant looked at the effects of rapid digitisation on the life sciences industry. "In the post-COVID-19 era, 'digital' will mean more than just applying technology to business processes; it will mean reinventing the business by connecting data, knowledge, people, and insights, turning traditional life sciences into a proactive industry." Cognizant's research indicates that the COVID-19 digital transformation will continue as life sciences companies must adapt to keep up with competitors and provide better products and services.

The same report included research indicating how far along (or behind) life sciences companies are in their digital transformation and where they're hoping to be by 2023. Some interesting points include:

73% are implementing or using data analytics, but only 5% have widespread implementation.

68% are implementing or using AI, but only 7% have widespread implementation.

47% are implementing or using process automation, but only 5% have widespread implementation.

If a medical device company isn't at least planning on implementing these technologies, now is the time to start. "Life sciences, we now know beyond a doubt, is far more agile than anyone could have imagined," said Cognizant Chief Digital Officer of Life Sciences Brian Williams.¹⁵

2.4

Connect with confidence.

MasterControl customers experienced that agility during the pandemic. At the beginning of the outbreak, Nelson Labs, a global provider of microbiological and analytics laboratory testing, saw a 1,200% increase in demand for tests and a 2,700% increase in demand for samples. MasterControl was pivotal to helping them keep up.¹⁶

A proven track record of excellence, a commitment to customer success, and an emphasis on innovation have made MasterControl the platform for quality. With more than 1,000 customers around the world, MasterControl has established itself as the leading quality platform provider in the field. MasterControl has also earned the trust of regulatory authorities, many of whom — including the FDA — use MasterControl solutions to meet their own rigorous internal standards for quality management. Companies and regulators alike rely on MasterControl to connect essential data and extend quality beyond just the quality department.

With MasterControl ensuring that all your quality and compliance data is maintained in one location, your entire organisation can move faster and be more responsive. It provides the tools you need to help you increase profitability and drive business intelligence.



3

New Ecosystem Dynamics: Enabling Pervasive Quality



3.1

Maintaining quality in the era of outsourcing.

As a result of the rising timeline pressures, augmented complexity, and distributed supply chain factors discussed in the previous chapter, medical device companies are increasingly adopting asset-light models that are heavily reliant on a broad ecosystem of design, research, and manufacturing organisations. This has them turning to contract manufacturing organisations (CMOs) and contract development manufacturing organisations (CDMOs).

But maintaining dynamic, asset-light operations and outsourcing increasingly more functions means that quality departments must find new ways to increase flexibility and collaboration across more external partnerships without increasing risk.

- **Improved flexibility:**
74% of quality process end users report that launch delays of products and services are frequently caused by inflexible quality processes.¹⁸
- **Greater control and transparency:**
60% of organisations struggle with real-time visibility into CMO production and 40% lack control over product quality.¹⁹

For medical device organisations to successfully outsource more functions, there's no escaping the fact that quality cannot effectively operate in isolation. Quality must be consistent and pervasive throughout the supply chain in order for it to be managed comprehensively and for compliance to be sustainable. To maintain comprehensive control and complete

oversight over quality, you must have continual visibility into all quality activities while they're occurring throughout the entire ecosystem.

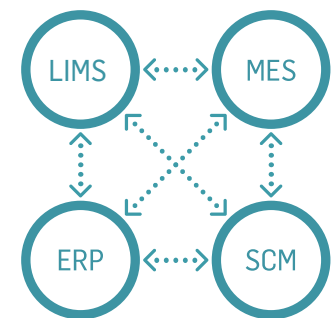
This requires not only a platform that enables you to digitise, automate, and connect quality processes internally, but one that leverages modern integration management capabilities. That is one of the reasons MasterControl has partnered with MuleSoft to provide quality and compliance professionals with an integration platform as a service (iPaaS) layer. The adaptability afforded by the iPaaS integration layer augments MasterControl's capacity to provide simple and reliable integrations of critical data between enterprise systems and outsourcing partners — providing the visibility and control needed to ensure quality and maintain compliance.

MasterControl's iPaaS integrations enable seamless data exchange between systems like:

- 1 Laboratory Information Management Systems (LIMS)
- 2 Manufacturing Execution Systems (MES)
- 3 Enterprise Resource Planning (ERP)
- 4 Supply Chain Management (SCM)

10% CAGR

Projected growth of the global medical device outsourcing market through 2026.¹⁷



3.2

Key questions to ask about QMS extensibility.

As your quality ecosystem matures, you need a QMS that promotes flexibility and responsiveness. To ensure your quality management competencies can keep pace with the dynamics of your ecosystem, take the following considerations into account when evaluating any solution that makes claims about its data and process management improvement capabilities.

13%

of companies have implemented AI or digital solutions because of COVID-19.

- 1 Is it configurable?
- 2 Does it have the necessary modularity and integration features your business requires?
- 3 Does it incorporate risk-based analysis?
- 4 How quickly can upgrades, patches, new features, and enhancements be implemented?
- 5 How burdensome is validation?
- 6 Can the intelligence the system provides be personalised according to users' roles?
- 7 Is it conducive to adapting to the requirements of technological and regulatory innovations?
- 8 Is it geared toward facilitating the future expansion of your business?

Supply chain problems caused by the pandemic reveal the importance of having a QMS that can scale quickly. However, while the pandemic sped up digital transformation, it's not the only factor medical device companies are considering. In November 2020, MedTech Summit and the National Science Foundation (NSF) conducted a survey of medical device and in-vitro diagnostics (IVD) professionals. A mere 13% of respondent said they implemented AI or digital solutions because of COVID-19.

More common reasons included establishing better data (46%), quality (37%), and insights into data sources (34%).²⁰ With these goals in mind, it's critical to determine the data analytics capabilities of a QMS before implementation. Being able to quickly pull together data from multiple systems and manipulate data is vital to medical device companies.

Evan Rife, a manufacturing engineer at Northeast Scientific, mentioned data and making decisions based on that data when talking about why his company chose to implement MasterControl. "The cornerstone of any good decision that's being made is the data that you have when you're making that decision," he said. "So if we can pull as much data as we can out of the process and understand what that data is telling us about our process, we can make more informed decisions about where our gaps are."

The more systems a medical device organisation uses that can easily exchange information, the more accurate data they'll aggregate, leading to better decision-making.

3.3

Extending quality's reach while strengthening control.

A robust quality management system like MasterControl allows organisations to expand quality's scope and impact beyond the quality department to improve efficiency and effectiveness in other areas of the organisation. Quality is a department, but it should also characterise everything at a medical device company. Hence the desire to expand quality's reach. When multiple departments operate on the same system as quality, they can easily exchange information which helps improve quality beyond the final check before a batch is shipped out.

MasterControl offers an array of unique tools that enable you to optimise and visualise your extended quality ecosystem:

1

MasterControl Manufacturing Excellence provides electronic device history records (eDHRs) that are easy to configure and mimic existing paper processes, making them easier to learn and adopt. Device manufacturers that use Manufacturing Excellence can potentially see a 90%-100% decrease in data entry errors. Similarly, review time is reduced by up to 80%, letting them get devices out the door that

much faster. This saves time for both departments and provides eDHRs that are more accurate, and their electronic nature makes them easy to locate during an inspection or audit.

2

MasterControl's robust [Supplier Excellence](#) and [Bill of Materials \(BOM\)](#) solutions facilitate the expansion of and control over quality ecosystems for companies that are increasingly dependent on amassing numbers of CMOs and CDMOs. These comprehensive MasterControl tools allow companies to manage the supply chain from beginning to end and provide a central global repository for managing all contractor and supplier data, documentation, and workflow processes, giving an organisation and its authorised external associates instant accessibility anywhere, anytime.

3

MasterControl Insights is our analytics platform that lets users create customised visualisations and tabular reports. It incorporates data from all MasterControl products, including data about documents, training, quality events, manufacturing, and more. Insights also has AI capabilities that use historical data to help companies operate more effectively. Ultimately, it lets users make data-driven decisions while tracking their key performance indications (KPIs) so they can measure their progress.

4

An [integration-platform-as-a-service \(iPaaS\)](#) layer provided by MasterControl partner and industry leader MuleSoft offers an array of reliable, pre-established connectors that streamline integration development processes between your various business systems as well as with any of your partners' systems to which you may need to forge connections. By leveraging a proven iPaaS platform with a successful track record, MasterControl ensures that your data stays synchronised between systems and enables you to gain greater insights into your overall quality and compliance activities. In addition, iPaaS integrations enhance your ability to extend quality beyond the quality department as you devise connections with other departments or external systems. And the iPaaS integrations can securely and effectively handle any volume of data throughput that may be required. The versatility iPaaS affords augments MasterControl's capacity to provide reliable enterprise system integrations with less effort, risk, money, and time required on your part.

MasterControl's iPaaS-outfitted integrations ensure your quality data will have:

- 1 Consistency across systems.
- 2 Greater value.
- 3 Continual availability.
- 4 Sustained integrity.
- 5 Increased capacity to support and drive decision-making.
- 6 Extended reach across the enterprise.

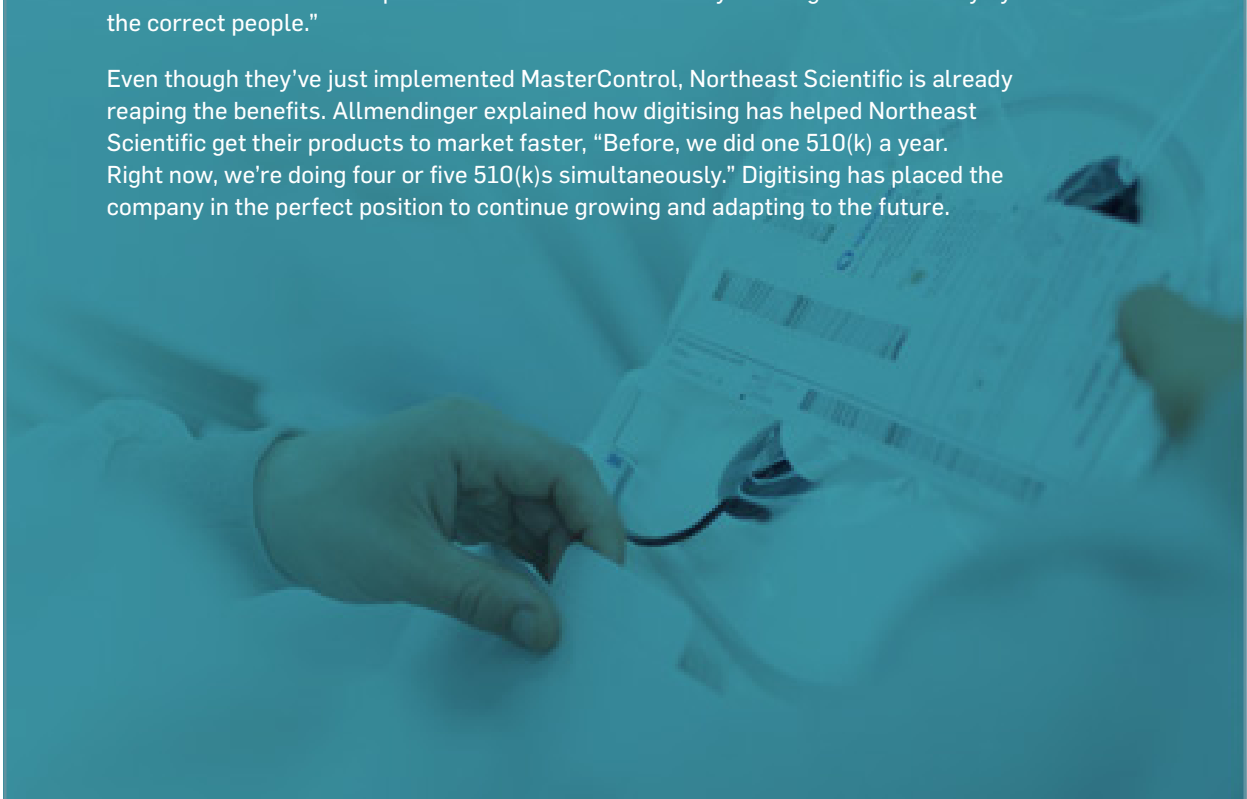
SPOTLIGHT

Northeast Scientific is the market leader in high-end peripheral vascular catheter remanufacturing. As the market grew, they needed a way to scale operations to meet the growing demand, introduce new products, and remain compliant with evolving regulations. That's why they invested in MasterControl Manufacturing Excellence and MasterControl Quality Excellence.

Northeast Scientific CEO and President Craig Allmendinger commented on how the company has been able to speed up its documentation processes by digitising. "It would take months to get SOPs created and filed. Now we're getting the SOPs, validation, and the training done in a third or even a quarter of the time," Allmendinger said.

Matt Farley, the director of engineering, also was impressed by how MasterControl improved the company's training. "One of our biggest pain points with the paper system was ensuring that people are appropriately trained and the processes on the floor are being followed correctly," he explained. This is no longer an issue. "With MasterControl, there's a connection between production and the quality system that verifies and checks those parameters ... to make sure they're being done correctly by the correct people."

Even though they've just implemented MasterControl, Northeast Scientific is already reaping the benefits. Allmendinger explained how digitising has helped Northeast Scientific get their products to market faster, "Before, we did one 510(k) a year. Right now, we're doing four or five 510(k)s simultaneously." Digitising has placed the company in the perfect position to continue growing and adapting to the future.



4

The Future of Quality Is Predictive: Keys to Unlocking Your Data's Intelligence



4.1

Going beyond proactive.

Shifting from a reactive to proactive approach to quality and compliance has been a de facto mission statement for years, yet in such a highly competitive industry, the ability to leverage data for predictive — and not merely proactive — purposes is becoming a must-have competency of the quality function. Organisations that adopt a data-driven, platform-enabled quality model are augmenting their capacity to yield real-time quality intelligence and predictive insights.

When equipped with the ability to connect data within a common platform, every function within a medical device organisation — from the C-suite to the shop floor and every point in between — can have an appreciable impact on the transformation of product quality data into real-time intelligence.

Making analytics and product quality data management improvements can yield big returns.

McKinsey & Company has developed an approach they've dubbed "smart quality," which is a combination of improved processes, automation and digitisation, and advanced analytics. It's provided measurable benefits in the following areas:



1

Improved complaint management:

A medtech company closes more than 55% of complaints within 24 hours without human intervention.



2

Reducing recurring deviations and nonconformances:

By getting to the root cause of the issues, several companies have reduced the overall volume of issues by 65%.



3

Shortened investigations:

Along the same lines, investigation time for those deviations and nonconformances has been reduced by 90%.²¹

4.2

Mixing proven platforms with emerging technologies.

At a foundational level, quality and compliance professionals are looking to modernise their core QMS systems. Gartner recommends evaluating providers against a mix of current state and future state considerations:

- 1 Define QMS software requirements by thoroughly assessing the current state of the quality organisation coupled with future business needs.
- 2 Consider compatibility and integration through the availability of APIs for ERP, PLM, MES, LIMS, LMS, and others.
- 3 Evaluate providers' and their partners' industry depth, geographic reach, and product roadmap by asking detailed questions about each.
- 4 Consider the vendor's product roadmap, strategic direction, and how it is differentiated from its competitors.

Gartner also strongly advises that companies thoroughly analyse their quality organisation and processes before beginning the request for proposal (RFP) or request for information (RFI) process. Those in the market for a QMS are typically focused on "employee training, remote supplier audits, and the need for continuity with respect to handling [corrective action/preventive action] CAPA and nonconformance in a remote environment."

The need for remote work highlighted the dependency on the cloud and cutting-edge technology. Some of the specific capabilities that tech-savvy organisations are coming to expect from advanced QMS solutions include:

Improved access to essential data:

During COVID-19, access to data from anywhere at anytime was vital. Companies without this ability floundered when it came to quality processes. Gartner found that, "in the current environment, ... clients report significant challenges collaborating with colleagues in the quality organization, accessing data remotely, processing changes, and handling ongoing uncertainty."²² Software that provides remote access streamlines decision-making by giving the people who need timely quality and compliance data access to it quickly.

High-value uses for emerging technologies that advance quality goals:

Finding a way to convert product quality data into real-time intelligence and predictive insights was once just a fantasy. Thanks to the relentless advancement of technology, however, the predictive power of data has become the new reality — and it is gaining more relevance every day. Advanced analytics are more an expectation than a perk, and pretty soon AI will fall into that category as well. According to a survey from PwC, 88% of respondents in the life sciences said the pandemic accelerated AI adoption.²³

Ease of use:

Increased competition in the software industry means vendors are tripping over themselves trying to improve their user experience. This is wonderful for medical device developers that are looking for a QMS, or other enterprise software. If software is difficult to implement, use, validate, and update, there are plenty of other options that perform better.

4.3

Fuelling growth and innovation with connected data.

All medical device organisations should be making data-driven decisions. That reality is within reach with modernized software solutions that offer advanced analytics and AI in their platforms. AI-enabled solutions are becoming so prevalent that a recent Deloitte survey found that 75% of AI adopters believe all enterprise applications will have built-in AI by 2023.²⁴

MasterControl is on track to incorporate AI into our software. We already ensure your processes and data are connected. And with the added iPaaS integration options enabled by MasterControl's partnership with MuleSoft, your quality management competencies can be extended to other business-critical applications while still ensuring that data stays synchronised between systems. With MasterControl's extensive integration capabilities, you always have the assurance that your data has a single source of truth.

That data will be best used with our advanced research projects that ensure organisations can effectively and confidently capitalise on emerging technologies like ML and AI; natural language processing (NLP); and intelligent process automation (IPA). Recent advanced research projects have focused on using advanced NLP, ML/AI, and process automation technologies to:

- 1 Automate text extraction from unstructured documents, identify and contextualise relevant data, and auto-populate information into MasterControl to increase efficiency and accuracy.
- 2 Create Netflix-style contextual search and recommendation engines to improve search speed and pull relevant information and documents forward based on users' past searches and search language history to refine the recommendations it provides over time.
- 3 Streamline workflow creation and execution and allow users to effortlessly connect data sources, process steps, and systems.

To keep pace with the changing quality landscape, quality leaders can rely on proven MasterControl solutions that are engineered to help quality teams be more dynamic and work with MasterControl innovation teams to define the future of data-driven quality.



4.4

The importance of a digitally empowered quality workforce.

The COVID-19 pandemic changed a lot of things in the general workforce. One of those was a shift in power from the employers to employees. Another is the expectation that a role will either be entirely work from home or at least offer flexibility, with some days being in the office and others being work from home. Regardless of the industry, these expectations are taking hold. Employers were forced to allow remote work and employees discovered they liked it. So much so that some are determined to never return to the office.

How does this affect medical device quality departments? Some quality functions are difficult, but not impossible to complete remotely (e.g., inspections or audits), while others are very conducive to remote work if you have the right tools. For example, with a cloud-based document management system, quality professionals can create, collaborate on, and gain approval for new standard operating procedures (SOPs) without setting foot in the office.

When medical device companies use AI-enabled technologies, they make the quality department more effective regardless of where they're working from. With AI adoption increasing, it's important to note that the demand for quality professionals isn't going anywhere. AI will take on some of the work that quality does now, but it will mostly serve to enable decision-making and augment quality professionals.

The study from Cognizant makes this obvious. One of the questions asked of life sciences executives was to estimate what percentage of work would be done by machines by 2023. They were asked about eight categories, but interestingly in every case the executives expect less than 25% of the work to be done by intelligent machines.²⁵ The emphasis is increasingly on human-machine collaboration and getting the best of both worlds by letting the two complement each other.



Summary

Quality isn't exclusive to a single department. It's pervasive and integral to every function throughout the enterprise.

Despite the inherent challenges of connecting quality and compliance data in an industry defined by truncated timelines, greater product complexity and personalisation, and expanding supply chains and contract partner ecosystems, there are tools that can help you ensure quality's pervasiveness and connectivity.

Connected applications, advanced analytics, and AI are becoming

essential tools as the focus on data and predictive insights continues to mature in the medical device industry. They are empowering companies to simplify the adoption of a product life cycle approach to quality by converging data and processes within a system that provides true quality intelligence and enables real-time decision-making.

MasterControl is the foundation for connected quality data and complete product quality. It unifies applications, data, and documentation across your entire product development life cycle,

from concept to commercialisation. MasterControl enables organisations like yours to go beyond proactive quality management and unleash the intelligence and insights concealed in unstructured data.

Discover how MasterControl can make your vision of truly connected quality data a reality.

About MasterControl

MasterControl Inc. is a leading provider of cloud-based quality, compliance, and production management software for life sciences and other regulated industries. Our mission is the same as that of our customers – to bring life-changing products to more people sooner. The MasterControl Platform helps organisations digitise, automate, and connect critical processes across the regulated product development life cycle.

Learn more at mastercontrol.com



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