Dot Compliance

WHITEPAPER

Implement your QMS in Under 30 Days

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Implement your QMS in Under 30 Days

It's 2022: Should it still take months or years to implement a quality management system (QMS) solution?

Due to outdated technology and old deployment practices, many emerging life science companies still accept the idea they need a costly and complex QMS that cripples them financially, takes 6, 12, 18 months to configure and implement, and continuously surprises them with hidden fees for updates, upgrades and validation.

Don't buy into the myth. The technology barriers of the past are gone.

Processes in our world are rapidly shifting from manual to digital – from retail purchases to health records – thanks to the evolution of advanced technologies, including cloud computing, managed infrastructure platforms, and software as a service (SaaS). This is making it easier, faster, and more cost-effective to accomplish tasks and meet goals in a secure environment.

The same holds true for quality management, with recent cloud deals in life sciences becoming a significant share of the industry's IT investment.[1]

In 30 days, your company can be up and running with a cloud-based QMS solution that is fully validated and configured with best practices that meet U.S. FDA, ISO and GxP regulations.

After reading this paper, you will understand:

- Why it takes so much time, effort and money to deploy traditional enterprise quality management (eQMS) software
- How the evolution of regulations has shaped today's demanding quality requirements
- How digital technologies have shattered the quality management software status quo
- How a ready-to-use QMS cuts through the clutter for quality without the complexity
- How to implement a QMS in 30-days using a streamlined process based on industry best practices
- Why it is critical to build a future-ready digital strategy now to remain compliant and competitive still while meeting your growing needs

Dangers of Conventional QMS

Conventional QMS vendors will try to convince you that a fully customized QMS platform requiring months of configuration and validation is the only way to manage quality in today's complex business and regulatory environment. In reality, all the unnecessary work only serves to put more of your money into their pockets.

Let's take look at the conventional process for developing and deploying a traditional QMS platform and why it is so lengthy and costly.

Requirements gathering

The process starts with the QMS vendor gathering the life science manufacturer's requirements for even the most common and industry standard best practices. While most of the deployments mirror themselves from one company to the next, the vendor still gathers the same requirements over and over again. For each company and deployment, this process can take months.

Solution configuration and validation

Next the vendor configures its standard QMS solution to the requirements, validates it and presents it to the customer – at a heavy price tag for solution development and professional service fees.

Dangers of Conventional QMS

- Waterfall in nature
- Overly customized
- Time-consuming
- Costly to implement and maintain
- Resource intensive
- Typically, 6 to 12+ months in duration
- Technical challenges often take on a life of their own
- Validation becomes the focus
- Regulations change
- Knowledge becomes siloed
- Solution re-configuration and re-validation

Solution re-configuration and re-validation

If the customer decides they want a different configuration, the QMS provider must go back to the drawing board, conduct a redesign, and present it again and again until it is right.

What many life science companies don't know is that each time a change is made to a blank canvas QMS configuration, the vendor must revalidate it. These changes often result in months of professional services – raising costs significantly.

This process doesn't stop at system go-live. With a customized QMS solution, each time the customer asks the vendor to make a change to the implemented solution, such as adding a new capability to meet internal or industry requirements, the vendor must reconfigure and revalidate the solution – with the customer paying additional professional service fees.

The internal resource burden

The process of implementing a customized QMS solution is very resource intensive, not just for the vendor but also the customer. With a conventional approach such as the one just described, the customer's subject matter experts (SME) report they spend 50% of their time on the project, when most life science companies don't have these types of resources to spare.

Another major challenge with the conventional approach is the deep-set knowledge that is embedded in the SMEs and others who led the implementation work. With a highly customized solution, knowledge of the QMS and why it was configured in a certain way resides in the heads of a select few. When they leave the company that knowledge leaves with them.

Less than optimal on-premise and home-grown QMS

Until recently, an on-premise platform was the only option for an electronic QMS and many life science manufacturers still rely on this model today. Because of hardware, software and database complexities, these solutions take months or even years to implement.

The life science manufacturer's infrastructure team must scope out the hardware and then work with internal database teams to scope out the various data sources required for QMS implementation.

Because quality impacts all aspect of a manufacturer's operations, this means collaborating with a broad range of stakeholders (e.g., R&D, manufacturing, customer service, etc.) all with their own separate IT systems and data sets.

With a highly configured QMS platform, inevitably something goes wrong along the way. It can take weeks for investigators to come to a conclusion as to the cause – was it a hardware, software or database issue? – with finger pointing among groups.

A life science manufacturer that builds its own home-grown solution versus implementing a custom QMS faces even greater challenges with solution development, validation and maintenance, while one that still relies on paper trades technology for labor-intensive, error-prone manual processes.

The Evolution of Quality and Safety Regulations

When you take a step back and consider the long and complex journey of quality management in the life sciences, spanning 100+ years of shifting priorities and regulations, it is easy to understand why traditional QMS solutions and processes became so complicated and cluttered.[2]

The foundation of many of today's U.S. Food and Drug Administration (FDA) drug and medical device regulations were laid in the 20th century, including provisions governing labeling, claims, pre-market approval, manufacturing inspections, and risk-based device classification, with continuous change driven by the need for quality and safety improvements.

Over the decades, life science regulation and guidance has evolved to address the changing landscape. As devices and drugs have become more complex, alongside patient care advancements, the laws governing manufacturers' operations are shifting more rapidly to the point where quality teams are faced with a constant stream of proposed and emerging requirements.

Late 19th century: Drugs regulated at state level

U.S. states exercised principal control over domestically produced and distributed foods and drugs, resulting in vast inconsistency from state-to-state.

1906: Federal oversight of drug quality begins

President Teddy Roosevelt signs the Federal Food and Drugs Act mandating drug sales defined in accordance with the U.S. Pharmacopoeia and the National Formulary standards of strength, quality, and purity.

Drugs could only be sold in any other condition if specific variations from the applicable standards were plainly stated on the label. Furthermore, the food or drug label could not be false or misleading, and the presence and amount of eleven dangerous ingredients, including alcohol, heroin and cocaine, had to be listed.

1930s: FDA formalizes drug quality and safety regulations

This decade marks the beginning of widespread government and public scrutiny of drug product quality and safety.

1937

100 people die, many of whom were children, after taking an untested product that a Tennessee drug company marketed as "new sulfa wonder drug" containing a highly toxic chemical analogue of antifreeze.

1938

Passage of the Food, Drug, and Cosmetic Act in response to the 1937 deaths, which reshapes the provisions of the 1906 Federal Food and Drugs Act to mandate:

- Drugs be labeled with adequate directions for safe use
- FDA's pre-market approval of all new drugs to prove they were safe before being sold (medical devices were equated to drugs for regulatory purposes)
- Prohibited false therapeutic claims for drugs
- Formally authorized factory inspections, and it added injunctions to the enforcement tools at the agency's disposal

1950s and 1960s: Stricter agency controls and good manufacturing practices

After nearly averting disaster in the U.S. related to a harmful drug product, the FDA takes steps to strengthen its oversight of all pharmaceuticals, both newly introduced and already marketed. The 1950s and 1960s also mark the establishment of good manufacturing practices for pharma companies.

1951

The debate by the FDA, industry, and health practitioners over what constituted a prescription versus an over-the-counter drug is resolved with passage of the Durham-Humphrey Amendment.

1962

The Thalidomide crisis, with the sedative producing thousands of deformed newborns outside of the United States, drives passage of the Kefauver–Harris Amendments to the Federal Food, Drug, and Cosmetic Act. This significantly strengthens the FDA's control over drug products to help protect patient safety:

- Requires FDA to assess the efficacy of all drugs introduced since 1938
- Mandates efficacy as well as safety before a drug could be marketed
- Institutes stricter agency control over drug trials, including a requirement that patients involved must give their informed consent
- Transfers from the Federal Trade Commission to the FDA regulation of prescription drug advertising
- Establishes good manufacturing practices by the drug industry
- Grants the FDA greater powers to access company production and control records to verify those practices

1965

Congress gives the FDA enhanced control over amphetamines, barbiturates, hallucinogens, and other drugs of considerable abuse potential in the Drug Abuse Control Amendments.

1970s: Quality systems and control procedures defined

The FDA turns its sights on the expanding development of medical devices for patient care and establishing quality systems requirements for both drugs and devices.

1970

The U.S. Secretary of Health and Human Services commissions the Study Group on Medical Devices, which recommends medical devices be classified according to their comparative risk and regulated accordingly.

1976

After thousands of women were injured by the Dalkon Shield intrauterine device, Congress passes the Medical Device Amendments, which requires manufacturers to register with FDA and follow quality control procedures. Some products must have pre-market approval by FDA; others must meet performance standards before marketing.

1978

The final rule is issued for Current Good Manufacturing Practice (CGMP) requirements for both devices and drugs (21 CFR 210–211 and 820), under which manufacturers must establish and follow quality systems to help ensure that their products consistently meet applicable requirements and specifications.

1980s: Patient advocacy paves the way for enhanced quality and safety

There is a renewed interest in patient safety to both protect individuals from harm and improve treatment for medical conditions.

1982

Following deaths from cyanide placed in Tylenol capsules, the FDA issued Tamper-resistant Packing Regulations to prevent future poisonings. This was followed in 1983 by passing of the Federal Anti-Tampering Act, which made it a crime to tamper with packaged consumer products.

1983

Passage of the Orphan Drug Act offers incentives to manufacturers to develop drugs for the treatment or rare diseases.

1984

Increased regulatory scrutiny over medical device safety comes into play, with passage of FDA Medical Device Reporting (MDR) regulations, which require manufacturers who have received complaints of device malfunctions, serious injuries or deaths associated with medical devices to notify FDA of the incident.

1987

The International Organization for Standardization (ISO) publishes its first quality management and quality assurance standards (ISO 9000:1987), marking the foundation of the first common standard for quality management.

1988

The Prescription Drug Marketing Act bans the diversion of prescription drugs from legitimate commercial channels, requiring drug wholesalers to be licensed by the states; restricting reimportation from other countries; banning sale, trade or purchase of drug samples, and trafficking or counterfeiting of redeemable drug coupons.

1990s: The decade of reporting and quality system reforms

As unsafe medical devices are linked to patient harm and death, the federal government launches new regulations requiring device manufacturers to perform post-market surveillance, the establishment of systems and processes for the tracking and reporting of adverse events, and guidance around electronic records.

1990

The Safe Medical Devices Act (SMDA) requires manufacturers to conduct post-market surveillance on permanently implanted devices whose failure might cause serious harm or death, and to establish methods for tracing and locating patients depending on such devices. The act also authorizes FDA to order device product recalls and other actions.

1993

MedWatch is launched for voluntary reporting of problems associated with medical products to be filed with FDA by health professionals.

1996

The Medical Devices; Current Good Manufacturing Practice (CGMP) Final Rule; Quality System Regulation includes requirements related to the methods, facilities and controls used for designing, manufacturing, packaging, labeling, storing, installing, and servicing of medical devices intended for human use (21 CFR Parts 808, 812, and 820).

The Medical Device Reporting (MDR) regulation becomes effective for user facilities and device manufacturers, providing a mechanism to identify and monitor significant adverse events involving medical devices.

1997

The most wide-ranging reforms in agency practices since 1938 are enacted with the FDA Modernization Act, which includes measures to accelerate review of devices and regulate advertising of unapproved uses of approved drugs and devices.

The FDA's Electronic Records Final Rule (21 CFR 11), which provide criteria for acceptance by FDA of electronic records, electronic signatures, and handwritten signatures executed to electronic records as equivalent to paper records and handwritten signatures executed on paper.

The 21st Century: 20+ years of quality system and process revisions

Regulatory change has been fast and furious over the past 20+ years, requiring life science manufacturers to keep a pulse on shifting requirements and regulations, and updating their quality management systems and processes accordingly. Here is a partial list of recent changes, with the majority introduced in the past 5-10 years.

2002

The FDA launches the Pharmaceutical CGMP Initiative for the 21stCentury – a Risk Based Approach initiative to enhance and update the regulation of manufacturing processes and end-product quality of drugs and biological medicines.

Passage of the Medical Device User Fee and Modernization Act (MDUFMA), which includes performance goals for many types of premarket reviews; provisions for device establishment inspections by accredited third parties; and new requirements for reprocessed single-use devices.

2006

FDA's Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations to help manufacturers implementing modern quality systems and risk management approaches meet the requirements of the agency's CGMP regulations (21 CFR parts 210 and 211).

2007

The FDA Amendments Act (FDAAA) is signed into law, reauthorizing and expanding PDUFA and MDUFMA and ensuring that FDA staff have the additional resources needed to conduct the complex and comprehensive reviews necessary to new drugs and devices.

2008

In response to FDAAA, the FDA launches its Sentinel Initiative to establish a national electronic system, which has since become the largest multisite distributed database in the world dedicated to medical product safety.

2009

The FDA issues Q10 Pharmaceutical Quality System, an internationally harmonized guidance intended to assist pharmaceutical manufacturers by describing a model for an effective quality management system for the pharmaceutical industry.

2011

Following an in-depth review of device quality data that flagged widespread or common manufacturing risks that impact product quality, the FDA launches the Case for Quality to help manufacturers understand and sustain the link between a quality improvement approach and the benefits such approach provides.

2012

The FDA Safety and Innovation Act (FDASIA) expands the agency's authority to collect user fees from industry to fund reviews of innovator drugs, medical devices, generic drugs and biosimilar biological products; promotes innovation to speed patient access to safe and effective products; increases stakeholder involvement in FDA processes, and enhances the safety of the drug supply chain.

The FDA Adverse Event Reporting System (FAERS) launched to support the agency's post-marketing safety surveillance program for all marketed drug and therapeutic biologic products. It contains adverse event reports FDA has received from manufacturers as required by regulation and reports received directly from consumers and healthcare professionals.

The Signal Management Program is established to ensure consistency, efficiency, accountability, and transparency in how CDRH evaluates and addresses signals related to marketed medical devices.

2013

Prompted by an outbreak in 2012 of an epidemic of fungal meningitis linked to a compounded steroid, Congress enacts the Drug Quality Safety and Security Act (DQSA), which outlines steps for an electronic and interoperable system to identify and trace certain prescription drugs throughout the U.S.

The FDA issues the Mobile Medical Applications guidance to inform manufacturers, distributors, and other entities about how the agency intends to apply its regulatory authorities to select software applications intended for use on mobile platforms (mobile applications or "mobile apps").

FDA issues its final rule requiring the label of medical devices to include a unique device identifier (UDI) and the labeler to submit product information concerning devices to FDA's Global Unique Device Identification Database (GUDID).

2014

The FDA publishes its final rule on Electronic Medical Device Reporting (eMDR) that requires manufacturers and importers to submit MDRs to the FDA in an electronic format that the FDA can process, review and archive.

The FDA's Content of Premarket Submissions for Management of Cybersecurity in Medical Devices identifies issues related to cybersecurity that manufacturers should consider in the design and development of their medical devices as well as in preparing premarket submissions for those devices.

2016

ISO publishes its Medical devices — Quality management systems — Requirements for regulatory purposes (ISO 13485:2016), specifying requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements.

Passage of the 21st Century Cures Act (Cures Act), which is designed to help accelerate medical product development and bring new innovations and advances to patients who need them faster and more efficiently.

2017

FDA issues its final rule on Current Good Manufacturing Practice Requirements for Combination Products to provide clarification and specify how compliance with applicable CGMP requirements may be demonstrated with this category of products.

FDA publishes Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices guidance to clarify how the agency evaluates real-world data to determine whether they are sufficient for generating the types of real-world evidence that can be used in FDA regulatory decision-making for medical devices.

FDA issues the Software as a Medical Device (SAMD): Clinical Evaluation guidance, adopting the internationally converged principles agreed upon by the IMDRF to communicate how clinical evaluation should be an iterative and continuous process as part of the quality management system for SAMDs to make them clinically relevant to users.

2018

FDA releases the Medical Device Safety Action Plan: Protecting Patients, Promoting Public Health, outlining a vision for how the agency can continue to enhance programs and processes to assure the safety of medical devices throughout the total product lifecycle (TPLC).

2019

FDA publishes the Safety and Performance Based Pathway guidance, providing the agency's current thinking on expanding the concept of the Abbreviated 510(k) Program for demonstrating substantial equivalence for premarket notification (510(k)) submissions.

The FDA's Harmonizing and Modernizing Regulation of Medical Device Quality Systems describes how the agency intends to harmonize and modernize the Quality System regulation for medical devices.

2020

The Center for Devices and Radiological Health's (CDRH) Standards and Conformity Assessment Program (S-CAP) encourages medical device sponsors to use FDA-recognized voluntary consensus standards in their product submissions, as conformity to relevant standards both reduces regulatory burden and fosters quality.

2021

In response to unacceptable levels of nitrosamine2 impurities in pharmaceutical products, the FDA issues a Pharmaceutical Quality/ Manufacturing Standards/ Current Good Manufacturing Practice (CGMP) Guidance for Industry, reiterating how the manufacturer's pharmaceutical quality system extends to control of the quality of purchased materials and emphasizing how awareness of the supply chain of raw materials is an important factor in preventing contamination.

FDA introduces the Safer Technologies Program for Medical Devices, a voluntary program for devices and device-led combination products that are subject to review under a premarket approval application (PMA), De Novo classification request ("De Novo request"), or premarket notification (510(k)).

FDA reorganizes its information technology (IT), data management and cybersecurity functions into the new Office of Digital Transformation (ODT).

2022

The FDA's draft guidance on Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions, an updated, iterative approach to device cybersecurity in response to the rapidly evolving landscape, an increased understanding of emerging threats, and the need for capable deployment of mitigations throughout the TPLC.

Under the Quality System (QS) Regulation/Medical Device Good Manufacturing Practices, the FDA seeks to harmonize its requirements for a Quality Management System (QMS) with internationally recognized regulatory requirements for QMS for devices, ISO 13485, which is used by many other regulatory authorities.

Infographic

The Evolution of Quality & Safety Regulations

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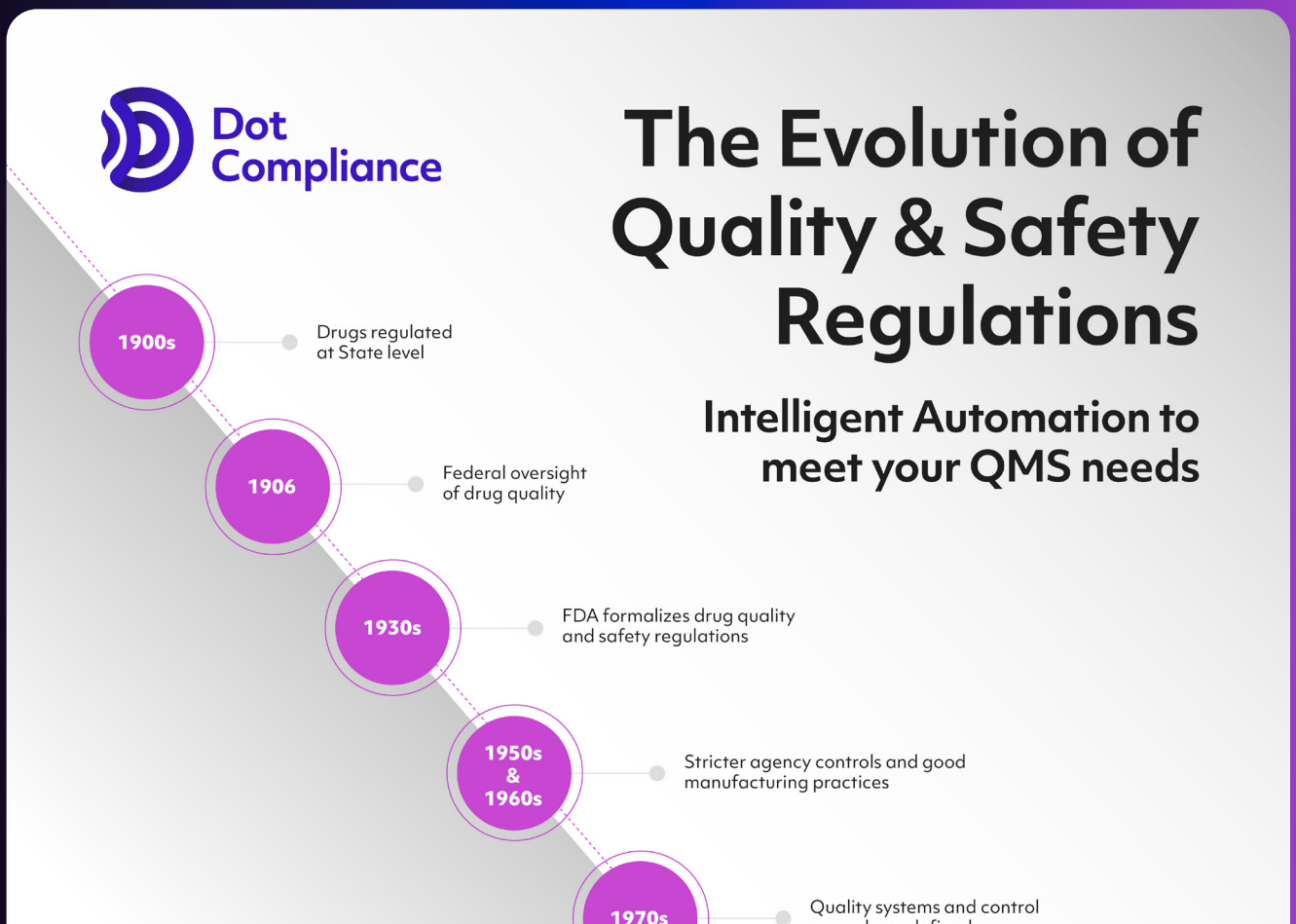

Recent updates to European Union guidances and regulations[3]

The life sciences is a global industry with manufacturers developing and marketing drug and device products across different countries, each with their own regulations. Here are a few recent changes in the European Union (EU) impacting life science manufacturing operating in EU countries.

2017

The Medical Device Regulation (MDR) is adopted in April 2017, changing the European legal framework for medical devices and introducing new principal and supportive responsibilities for the European Medicines Agency (EMA) and for national competent authorities in the assessment of certain categories of products. The Regulation enters into force in May 2017 and has a staggered transitional period.

2020

The European Commission proposes a new patient-centered pharmaceutical strategy for Europe that aims to ensure the quality and safety of medicines, while boosting the sector's global competitiveness. It proposes to revise the manufacturing and supply provisions in the pharmaceutical legislation to improve the transparency and reinforce oversight of the supply chain and clarify responsibilities to ensure overall environmental sustainability, safeguard the quality of medicines and ensure preparedness for new manufacturing technologies.

2021

Regulation 2017/745 on medical devices (MDR) became effective in the European Union on May 26, 2021, introducing new or revised responsibilities for EMA for specific types of devices: Medicines with an integral device; medical devices containing an ancillary medicinal substance to support the proper functioning of the device; medical devices made from substances that are absorbed by the human body to achieve their intended purpose; and borderline products for which there is uncertainty over which regulatory framework applies.

2022

Regulation 2017/746 on in vitro diagnostic medical devices (IVDR) became effective in the European Union on May 26, 2022, introduces a new classification system for companion diagnostics and the obligation to undergo a conformity assessment by a notified body.

Shattering the QMS Status Quo

It has been over 40 years since the final rule was issued for device and drug CGMP requirements (21 CFR 210–211 and 820) and manufacturers were first required to establish and follow quality systems. Over the decades, quality compliance and management has grown increasingly challenging as the FDA and global regulators update and/or replace requirements to protect patients from emerging risks.

Vendors of conventional QMS keep adding onto their platforms to accommodate new demands. Each time they bolt on new capabilities, their customers face the challenges and costs of system re-configuration and re-validation.

Take for instance recent and emerging regulations by the FDA and European Commission around life science manufacturers' increasing reliance on third party suppliers, and their responsibility for managing risks up and down their supply chains. Extending a conventional QMS to provide visibility into and control over supplier quality is no simple task.

Some vendors claim they have solved for the issue of solution expansion and enhancements by redeploying their on-premise QMS models in the cloud. The problem with this approach is that they are offering the same clunky, overly configured processes from the past 10-20 years in a different way. And they still insist on the same long, drawn out, costly development, implementation and re-validation processes, meaning even a cloud based QMS of this nature can still take up to a year to deploy.

Are you willing to wait a year for a capability your quality team needs now?

The technology barriers of the past are no longer our reality today, so we need to think differently moving forward.

Instead of continuously adding onto outdated QMS technologies and processes that are insufficient in meeting today's demands, why not create a new model from the ground up that leverages digital innovation to cut through the clutter and deliver exactly what you need?

Welcome to ready-to-use QMS in the cloud

We are in an age of digital transformation where practically every industry has leveraged digital technology to streamline processes, reduce costs and work more efficiently. Even taking into consideration the complexities of working within the highly regulated life science industry, there is still no longer a need to choose between a comprehensive solution and a speedy implementation.

Whether you are an established life science manufacturer with broad quality management needs or an emerging company that just needs the basics for now, you can deploy a robust, compliant, ready-to-use cloud-based QMS in just 30 days.

Technological innovation, powered by Salesforce.com, the leading platform for enterprise SaaS applications in the life-sciences industry, coupled with decades of knowledge and experience in life science quality and compliance, has resulted in a secure QMS solution that is fully validated and configured with best practices that meet FDA, ISO and GxP regulations.

Look for a QMS with the following key attributes:

- Industry-standard, pre-configured and integrated, core QMS processes
- End-to-end process visibility
- Ability to expand beyond core quality processes
- Built on a secure and trusted SaaS platform
- Predefined user profiles
- Connectors to ERP, HR, and other key systems
- Full and transparent validation package including process PQs
- Access to analytics and insights
- Compliance with 21 CFR part 11, EU-Annex 11 and support ISO 9001, 13485, 14971, 27001 and other relevant GxP regulations

“Dot Compliance has helped us be more efficient in our processes, while also maintaining a high level of compliance in a highly regulated industry. I have no doubt that moving more QMS processes into Dot Compliance will allow the company to focus even more on technological innovations.”

- Adam Miller, Quality Manager, Stereotaxis, a pioneer in surgical robotics

Imagine a quality management workflow where users don't have to determine the next step – they are literally defined within the system and visually available for them to follow. With end-to-end visibility, users can visually navigate between processes, associated data, and related documentation, follow built in procedures, drill down to the sources of each process or quality event, and take appropriate corrective action when required.

Based on user's security permissions, they can see the full picture ***in just a few clicks.***

Automated QMS workflow in action

1. In-take a customer complaint
2. Launch an investigation for the root cause
3. Launch corrective action, if necessary
4. Submit a change control with action items
5. As part of change control, identify affected documents that require revision to correct that root cause (assuming it was related to training and documents)
6. Route affected document through training cycle for all employees who need to be trained

Unipharm, a leading EU-GMP certified generic pharma manufacturer with vast first-to-market record, reduced process time for document control and training by 30% with deployment of Dot Compliance QMS automated workflows for document review, approval, content distribution, and training compliance.

The solution's comprehensive set of ready-to-use modules integrate with not only your legacy QMS but also multiple other systems (e.g., DMS, LMS, electronic forms, SQM, audit management, EBR, PLM, ALM/ design control, LIMS, ELN, RA, RIM, CTMS, maintenance, calibration, ITC, etc.). Another benefit of having a one stop shop where all quality processes are handled under a single roof is that it allows you to run metrics across processes as well.

As life science regulations and requirements continue to evolve, new applications for the QMS are built on the secure and trusted multi tenet Salesforce.com platform with straightforward installation processes. This means your company can immediately benefit from new functionality and features as soon as they are introduced with no additional configuration or validation required.

Leave the validation to the vendor

Validating a QMS requires the creation of documentation following a standard validation model.

With a conventional implementation process, you as the customer are responsible for developing this documentation, including user and functional requirements and risk and impact assessments, along with many more, all bundled up with a traceability and summary report.

With a ready-to-use QMS, the vendor provides up to 100% of this documentation right out of the box, written based on medical device or pharmaceutical industry standards, depending upon the customer's operations.

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How to Deploy a Ready-to-Use QMS in 30-days

A ready-to-use QMS means the solution is literally ready-to-use in 30 days. It doesn't mean your company must adopt every process out of the box immediately, that is still your choice. For example, you adopt document management and training modules initially upon go-live, then add complaint handling when you need it.

The difference between "adoption" and "implementation" is important here. With a conventional QMS, the vendor must implement a new capability, but with a ready-to-use QMS, the software has already been implemented so the life science manufacturer can simply adopt additional capabilities at any time.

Steps in a 30-day adoption process

Here are the steps required to implement a QMS in weeks using a streamlined process based on industry best practices.

The "primary" steps are those any life science manufacturer would need to take to adopt a ready-to-use QMS (either don't have system or have paper-based system), while the "secondary" steps are those one would need to take if they are transitioning from an electronic legacy system (whether home-grown, on-premise or cloud).

EXPERT TIP

Look for a QMS vendor that includes its "try and buy" process.

Week 1

Primary

Initiation: Assign project team, map stakeholders and sponsors, hold kick-off meeting, schedule recurring team meetings.

Secondary

Design: Development environment, migration, and interface strategies (if migrating data from legacy system and/or integrating QMS with other systems (e.g., ERP, MES, etc.)

Weeks 2, 3

Primary

System Adoption and Review: Customer begins using QMS with its own data based on standard operating procedures (SOP) provided by the vendor. During this process, the customer defines what permissions are required for different users within the organization, using the system's reports and dashboards along the way.

Week 4

Primary

Deployment: Deployment from the perspective of adoption. This includes administrator and user training, defining the system roll out plan, going live with the QMS, then transitioning to post go-live support.

Week 5

Secondary

Documentation: If customer chooses to make changes to the system, the vendor performs core team testing, updates the performance qualifications (PQ), SOPs and work instructions and provides a validation summary report. Because these are considered minor updates, versus major high-risk changes, the process is simple and short.

Ongoing

Primary

Optimization: Vendor collects requests for enhancements from customers on an ongoing basis and performs periodic system health checks.

Building a Future Ready Strategy

Trends in digital transformation

Only 18% of life science quality professionals in a May 2022 poll say their organization has a digital transformation task force; 59% said they don't and 23% did not know.

Disparate systems used for different processes was named the biggest challenge to quality and compliance among life science manufacturers polled during a Quality Digest May 2022 webinar.

Looking at the evolution of quality over the past few decades from a regulatory and life science industry perspective, it's clear processes must become more digital and streamlined to meet compliance and safety demands.

Regulators, clinicians and patients demand that drug and device manufacturers instill quality throughout their product life cycles, across their organizations and out to third party suppliers. They call for improved post-market surveillance to protect patients and keep them safe from poor quality products. The pressure on life science manufacturers to improve quality has grown exponentially since the early days of the FDA, and emerging regulations show there is no sign of this accountability slowing or stopping.

The shift from manual to digital quality management processes must accelerate for manufacturers and the industry to meet these demands. But all life science companies face the same dilemma - How do I build a strategy for the future when my immediate needs are so pressing (e.g., clinical trial submissions, audits, product launch, etc.)?

A drug or device manufacturer that ignores the big picture of the digital quality evolution and embarks on a short-sighted strategy that only meets its needs today risks falling behind. Automating processes in a digital environment not only supports compliance, but it also enables a manufacturer to innovate quicker, adapt to regulatory and market changes faster, and get high quality products out the door sooner.

Here are five barriers to enacting a future-ready digital strategy and best practices to overcome them.

1. Leadership

Initiatives without executive leadership support are doomed to fail. Identify a leader within your organization who has a clear vision for quality management transformation and a strategy focused on high-value outcomes. This individual will need to be 100% on board with investing in people, processes and technology to meet that vision.

2. People

The people in your organization can also be a barrier, in terms of fear or resistance to change. Another issue is gaps in experience and skills as roles change. For example, when you take away the challenges that come with traditional quality systems and processes (e.g., manual data entry, documentation, reporting, etc.), you will free up your quality team to become more analytical and proactive, performing value-added tasks such as finding root causes to issues.

If you find the members of your quality team lack the knowledge/ability to perform these higher-level activities, you may need to consider reskilling or perhaps other changes to deal with human capital deficit.

3. Processes

Disparate systems and processes have long plagued life science quality management teams and can hold companies back from pursuing digital initiatives. Through adoption of a ready-to-use QMS built on industry standards, a company can replace redundant systems, standardize processes, and harmonize its data, enabling a quick and seamless transition from manual to digital and automated quality management workflows.

4. Data and technology

Life science manufacturers that transition from a home-grown system will likely face an experience deficit with new QMS platforms featuring advanced technologies. However, those adopting a SaaS, ready-to-use QMS will have an easier transition because much of that technology is transparent in the background while users are presented with an intuitive, easy to use interface.

Cybersecurity is another concern for manufacturers considering a transition from on-premise to SaaS, cloud QMS. A company should be 100% sure its QMS vendor has the proper procedures and technology in place to alleviate those concerns. A QMS built on a SaaS platform trusted by leading companies across many industries, such as Salesforce.com, is the right place to start for security, compliance and data protection.

Executives recognize technology's strategic importance as a critical component of the business, not just a source of cost efficiencies, a McKinsey & Company survey revealed.

5. Quality and compliance

Keeping up with new regulations and guidance from the FDA and other authorities is another barrier. Selecting a QMS vendor with a ready-to-use, cloud-based solution alleviates some of the concern because the vendor is taking on the responsibility for maintaining the software's compliance.

The digital culture shift and roadmap

Historically, QMS implementations were overly focused on technology, with IT leading the charge without buy-in from the business side of operations. As the life science industry recognizes how digital transformation can improve product quality and financial performance, there is a cultural shift occurring with QMS initiatives led by business and delivered by IT.

Enterprise initiatives driven solely by technology typically miss the mark. Therefore, IT initiatives must work toward the same metrics as the business going forward.

Here is a simple five-step process based on a business-led approach to guide your digital roadmap.

1. Vision: Start with the vision provided by your company's executive management. The vision can be thought of as the "What we want as a company" statement, for example, "We want customers to know we put safety first."
2. Business Objectives: Business objectives are specific measurable results by which you will ultimately determine success. Establish one or more tied to your vision.
3. Business Capabilities: Assess current people, processes and software to identify any gaps needed to meet objectives.
4. Technical Capabilities: Map existing software solutions to the needed business capabilities and identify any gaps. If you already have technology in place to address the business capability, use it. However, you will likely find technology gaps that need to be filled.
5. IT Initiatives: IT can then begin mapping out initiatives to deliver solutions.

The Challenges Today

Overly Focused on Tech

Technically sound solution that does not meet the underlyning business needs.

Lack of buy-in

Inadequate involvement from stakeholders resulting in a lack of buy-in and ownership.

Unclear Communication

Unclear communication resulting in confusion, mixed messages about the effort, damaging organizational support and momentum.

The IT Transformation

Focus On Outcomes

Define clear lines of ownership between IT and business to illustrate how/when collaboration must occur.

Buy-in

Established formal governance roles and responsibilities to achieve the organization's vision with clear escalation paths.

Communication

Multidisciplined change agents who are passionate about the objectives and plan to communicate early and often about expectations and value to avoid resistance.

Conclusion

Quality in the life sciences is complex, but thanks to today's digital technologies, your quality management system and processes don't have to be.

Life science manufacturers who are strategically focused on digital transformation can gain a competitive edge, while those stuck in a conventional quality management approach struggle unnecessarily with complexity and high costs.

A ready-to-use cloud QMS built based on best practices (FDA, ISO, and GxP) enables your company to meet industry and internal quality standards and comply with ever-changing regulations all while accessing data and analytics to drive improved operational and financial performance - in as little as 30 days, without hassles or hidden costs and with ongoing support and solution enhancements.

Don't wait - start your digital transformation today by aligning quality management with your company's broader vision and objectives.

References

1 The case for cloud in life sciences, McKinsey, October 28, 2021, https://www.mckinsey.com/industries/life-sciences/our-insights/the-case-for-cloud-in-life-sciences

2 The evolution of quality and safety regulations compiled from information on FDA's website, FDA.gov, and ISO's website, ISO.org.

3 The Recent Updates to European Union Guidance and Regulations compiled from the European Commission website, https://ec.europa.eu, and the European Medical Agency's website, https://www.ema.europa.eu/