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WHITEPAPER

Bridging the Quality Management Digital Divide

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If you haven't automated processes and digitized data, you've fallen behind. Why you need an enterprise quality management system (EQMS) to meet the demands of 2024 and beyond.

Today's market is complex, regulations increasingly stringent and competition intense. Manufacturers are operating in an environment of economic uncertainty, geopolitical turmoil, supply chain disruptions, rising costs, and scarce labor.

Companies with an exceptional level of quality control can pivot rapidly to mitigate risks, drive efficiency in their development and manufacturing processes, maintain compliance, and deliver high-quality products to market with speed and cost effectiveness.

The most high-performing manufacturers can do this in real-time, with immediate access to actionable insights from a single enterprise quality management system (EQMS) that seamlessly integrates with relevant systems (e.g., ERP, LIMS, MES, CRM), to digitize and automate core quality data and processes. Cloud-based EQMS opens the door to greater agility with the ability to leverage advanced digital technologies (AL, ML, NLP).

A manufacturer still reliant on disjointed legacy systems, data silos, and manual processes, simply can't keep up. While their quality team is spending countless hours and resources piecing together data to find the root cause of a problem, a competitor with a digital, fully automated EQMS has this information available in real-time with completeness, consistency, and accuracy.

Can your quality management team and its QMS deliver to meet these demands?

This paper presents:

- Market challenges and regulatory changes impacting manufacturer quality operations
- The top technology trends transforming manufacturing quality management
- Top 10 EQMS attributes for comprehensive control and rapid deployment

Market Challenges

The costs of developing, manufacturing, and delivering products to market are high. Supply chain disruptions continue to impact raw material and component availability and operational continuity. Manufacturers are increasingly being held responsible for sustainability in their supply chains. Amidst these challenges, quality failures present risks that no manufacturer can afford.

"Deloitte analysts predict 2024 will continue to present manufacturers with economic uncertainty, the ongoing shortage of skilled labor, and lingering and targeted supply chain disruptions, which will drive the need for strategies to scale up production and improve competitiveness." [1]

Costs

As Vizient reported, "The cost of raw materials, freight and labor are not expected to return to pre-pandemic levels and will continue placing pressure on supplier's manufacturing costs."[2]

Heading into 2024, manufacturers must find ways to operate more efficiently and cost effectively. Addressing cost of quality (COQ) factors - prevention cost, appraisal cost, internal failure, and external failure - can help alleviate expenses while driving quality improvements that get high quality products to market faster.[3]

Supply chain disruptions

"While there has been a notable improvement in the average lead time for production materials, it has not returned to pre-pandemic levels," reported Deloitte in its 2024 Manufacturing Industry Outlook.[4] The analyst firm cites ongoing shortages in components such as electrical, electronic, and semiconductor parts that "can complicate production and delivery for a variety of manufacturing subsectors."

Companies need greater visibility into their supply chains to identify potential disruptions, including raw material and component shortages, to avoid production delays. When a disruption or shortage is found, manufacturers must have the ability to quickly pivot to reliable alternative suppliers with levels of quality that match their own.

Sustainability

In its 2024 Predictions for Supply Chain, the American Productivity & Quality Center (APQC) reported how sustainability will emerge at the forefront of supply chain management (SCM) amidst new environmental, social, and governance (ESG) regulations – including those holding manufacturers responsible for the practices of their suppliers.[5]

The organization noted how the "U.S. Security and Exchange Commission (SEC) is expected to mandate ESG reporting as early as 2024, and public companies will soon be required to report their greenhouse gas emissions." It also pointed to the EU's Corporate Sustainability Reporting Directive (CSRD), which is "mandating sustainability reporting, with almost 50,000 organizations expected to start sustainability reporting in 2024."

> In a recent Deloitte survey, 76% of manufacturers said they are adopting digital tools to gain enhanced transparency into their supply chains.

APQC recommended top executives "prioritize building a sustainable supply chain and integrating ESG reporting into their business, which may require recrafting their procurement and logistics strategies with sustainability in focus."[6]

Regulatory Changes

The U.S. Food and Drug Administration's (FDA) recent activity aimed at amending or revising existing regulations around manufacturer quality management, transparency to information, and reporting signals significant changes ahead. Is your quality team equipped to deliver?

In its Summary of FY 2024 Legislative Proposals, the FDA expressed its desire to amend the Federal Food, Drug, and Cosmetic Act (FD&C Act) to enable enhanced and extended authorities over manufacturers of drugs, medical devices, and foods. Beyond these proposals, the agency has many other pending guidance and rules aimed at enhanced tracking and reporting.[7]

The following are elements of FDA regulation likely to impact a manufacturer's quality operations with regards to transparency, data sharing, and reporting.

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“Building a sustainable supply chain requires organizations to embed environmental, social, and governance (ESG) considerations in the sourcing of raw materials, conversion of raw materials into products, and delivery of those products to customers.”

Drug manufacturers

The FDA is seeking to expand notification requirements to include notifying the agency of an increase in demand for drugs that the manufacturer likely will be unable to meet. Currently, FDA generally does not receive notice or adequate information from drug manufacturers regarding increases in demand that would position the agency to assist in preventing or mitigating drug shortages driven by an increase in demand.

FDA is also seeking to enhance the manufacturing volume information required to be reported under Section 510(j)(3) of the FD&C Act to expressly require registrants to provide data identifying the suppliers they relied on to manufacture the listed drug and the extent of such reliance.

Additionally, the FDA seeks to explicitly require facilities at which human and animal drugs are manufactured to create, submit, and maintain Site Master Files (SMFs) that contain "specific information about the firm's quality management policies and activities and the production or quality control of manufacturing operations carried out at the named site and identify any closely integrated operations at adjacent and nearby buildings."

Currently, FDA has no authority to require drug manufacturing facilities to submit SMFs. The agency backs this amendment to the FD&C Act by stating how SMFs can assist it in "conducting risk identification for sites for surveillance and for-cause based inspections," and improve its understanding of quality management practices and supply chain management."

Medical device manufacturers

The FDA is requesting express authority for the agency to ensure that data supporting application and non-application medical products are reliable and verifiable for as long as the product may be legally marketed, including throughout the lifetime of the application or market authorization.

The FDA also seeks to continue the requirement for medical device manufacturers to notify the agency about interruptions or discontinuances in the manufacture of certain devices during or in advance of a public health emergency (PHE). Additionally, the FDA is requesting clear authority to review risk management plans (RMPs) to help ensure manufacturers have plans in place to ensure resiliency and mitigate future supply chain disruptions.

Outside of the FDA's FY 2024 legislative proposals, medical device manufacturers are awaiting publication of the agency's final rule to amend its medical device Quality System Regulation (QSR) at 21 CFR Part 820 to align with ISO 13485 (expected by the end of 2023). Among the proposed changes are additional record control requirements to "ensure that records are established and maintained in a consistent and concise manner that demonstrates their validity and authenticity. The proposed rule also provides clarification concerning manufacturers' obligations to make records available."[8]

Food manufacturers

The FDA seeks to expand its authority to request records or other information in advance of or in lieu of inspections to include all FDA-regulated products to explicitly include food, tobacco product, and cosmetic establishments.

The agency also seeks explicit authority to conduct remote regulatory assessments (RRAs) with manufacturers, which may include remote interactive evaluations such as livestreaming video of operations, teleconferences, and screen sharing, so FDA may virtually assess the establishment's compliance with applicable laws and regulations.

Additionally, the FDA is also seeking authority to require firms to provide shortage notification for FDA-designated categories of food during a declared public health emergency.

Outside of the FDA's FY 2024 legislative proposals, the FDA's Food Traceability Final Rule "establishes traceability recordkeeping requirements, beyond those in existing regulations, for persons who manufacture, process, pack, or hold foods included on the Food Traceability List (FTL)." The compliance deadline for recordkeeping requirements is January 20, 2026.

Manufacturers subject to the rule must "maintain and provide to their supply chain partners with key data elements (KDEs) for certain critical tracking events (CTEs) in the food's supply chain." Furthermore, "all records required under this rule, along with any information required to understand the records, must be made available to the FDA within 24 hours after a request is made (or within a reasonable time to which the FDA has agreed)."

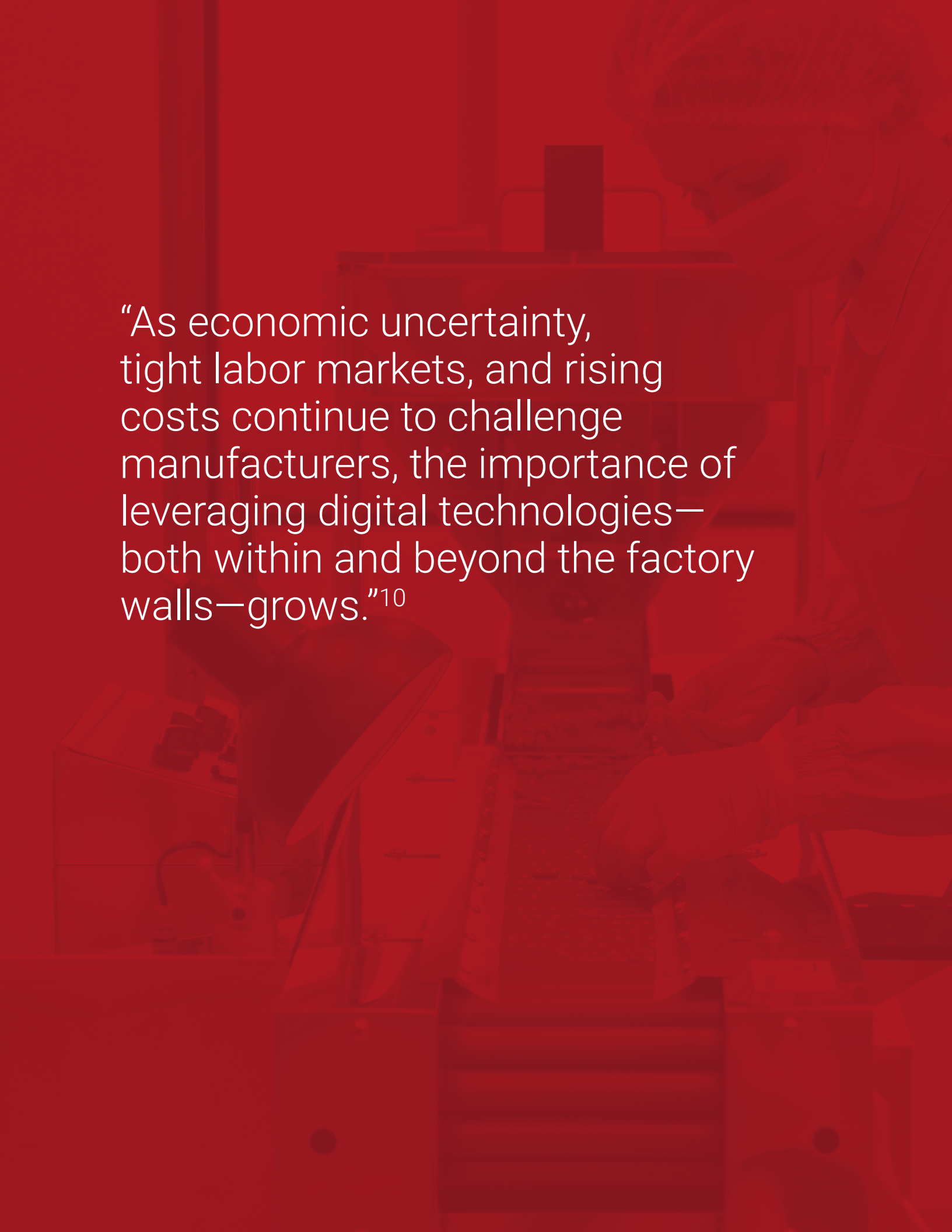
What This Means for Quality

Manufacturers must find ways to operate with greater speed, accuracy, and precision in the face of rising costs, threats to supply chain continuity, and regulatory demands for greater transparency and more comprehensive reporting.

Looking to 2024 and beyond, market conditions and more stringent regulations will push manufacturers to modernize their quality management systems. Critical areas of optimization include:

1. **Visibility:** Quality teams need visibility to all processes and data impacting quality throughout the enterprise, including internal relevant departments and functions (e.g., R&D, manufacturing, customer service) and the operations of external suppliers. The EQMS must seamlessly integrate with relevant systems (e.g., ERP, LIMS, MES, CRM), to harmonize information and documentation so it is accessible in one place.
2. **Control:** It is not enough to have transparency into quality operations; quality management teams must have the ability to control quality measures. Therefore, they require a EQMS that automates, and standardizes quality workflows so they are aligned with the manufacturer's standard operating procedures (SOP), industry guidance and best practices, and governing regulations. Furthermore, as regulators and other stakeholders require manufacturers to extend quality control out to their suppliers, quality teams need an EQMS with supplier management capabilities.
3. **Flexibility:** Change is coming at a faster pace and with all the uncertainties in today's market and regulatory environment, manufacturers need the ability to pivot quickly and act fast. Quality teams need an EQMS solution that is highly configurable so they can easily and efficiently adapt processes as required.
4. **Analytics:** The volume of quality data generated by manufacturers today far exceeds what a quality team can process manually. They require an EQMS with advanced analytics capabilities that automate the analysis process and present actionable insights. Regulators are increasingly requiring manufacturers to alert them to potential disruptions and shortages; therefore, the ability to perform predictive analytics is critical in today's environment.
5. **Reporting:** The FDA and other stakeholders are requiring manufacturers to report more comprehensive quality information with greater precision, accuracy, and speed. To meet these demands, quality teams must have the ability to centralize all data and documents for reporting within a single EQMS solution. Ideally, the solution should be configured to automatically generate the required reports on demand to prevent delays and potential compliance failures.

"Outdated data exchange practices, unstructured data submissions, and undue limitations on data sharing are just a few of the roadblocks to unlocking the value of data-driven insights."[9]



“As economic uncertainty, tight labor markets, and rising costs continue to challenge manufacturers, the importance of leveraging digital technologies—both within and beyond the factory walls—grows.”[10]

The Top Technology Trends Transforming Manufacturing Quality

Manufacturers that leverage advanced technologies to improve quality oversight and management throughout their operations – from research and development (R&D) through to post-market practices – can successfully navigate market challenges and identify and address risks before they result in costly quality and compliance failures.

As manufacturers face increased pressure to optimize their quality management processes, EQMS solutions providers are leveraging advanced technologies to meet these demands.

"The manufacturing industry is on the verge of a data driven revolution," The World Economic Forum recently stated. "Companies are collaborating in hyperconnected value networks, using data and analytics applications to drive productivity, develop new customer experiences and improve the societal and environmental impact of companies."[11]

Industry 4.0 technology (data, analytics, AI, ML) value potential in manufacturing[12]

15-30%
Labor productivity increase

15-20%
Inventory holding cost reduction

30-50%
Machine downtime reduction

10-20%
Cost-of-quality improvements

85%
Forecasting accuracy improvement

10-30%
Throughput increase

Here are three of the top 2024 technology trends supporting manufacturer EQMS optimization and regulatory compliance. They closely align with the FDA's digital transformation journey, as described in the agency's Information Technology Strategy for Fiscal Years 2024-2027[13]

> "In terms of quality control and quality assurance, digital technologies reduce the impact of human factors in the detection and prevention of errors and non-conformities."[14]

1 Process and data digitization

The complexity of manufacturing and quality management today exceeds the capacity of manual, paper-based processes. The level of sophistication required to identify and address quality issues throughout an ever-expanding enterprise necessitates visibility that can't be found in spreadsheets or PDF files.

Automating and integrating quality processes, data, and documentation through an electronic EQMS is a manufacturer's first step to achieving the benefits of digital transformation – greater efficiency and lower costs. It minimizes manual intervention, dramatically reducing staff hours dedicated to routine tasks, and makes it easier for quality teams to find the information and documents they need when responding to auditor and regulator requests.

2 Cloud technologies

The next step on the quality management transformation journey is the transition to cloud based EQMS. In her recent article, Forrester Linda VP, Research Director Ivy-Rosser noted how "organizations are now placing a critical focus on enterprise software's main challenges." This is driving enterprise software manufacturers to increasingly transition from on premise platforms (ERP, SCM, CRM and HCM) to software as a service (SaaS). She stated:

"In 2024, we expect that the late-adopter categories will diminish to 25% of new enterprise software purchases, tipping software-as-a-service investments to the majority, at 75%, as vendors and customers seek better innovation and collaboration."

Implementation of a cloud based EQMS alongside other key enterprise SaaS solutions opens the door to a level of quality process optimization impossible with on premise systems. System and data integration are effortless. Quality teams have real-time access to comprehensive insights throughout the end-to-end value chain, from R&D to manufacturing to supply chain. Manufacturers can effortlessly scale quality and compliance processes as they grow.

3 Artificial intelligence

Artificial intelligence (AI), in its many forms, will be the most important area of technology in 2024, according to the findings of The Impact of Technology in 2024 and Beyond: an IEEE Global Study.[15] AI tops most analysts' lists for 2024 technology trends. This includes predictive and generative AI, machine learning (ML) and natural language processing (NLP).

Manufacturers that have implemented a cloud based EQMS to establish a source of real-time, accurate and complete quality data are positioned to leveraged AI-enabled actionable analytics to drive data-driven quality improvements. The speed at which AI can analyze tremendous volumes of data far exceeds the ability of any human. Instead of quality teams searching for insights and answers to their questions, AI presents this information to them.

With AI-driven analytics, quality management teams can act rapidly with precision - identify anomalies, patterns, and trends (descriptive analytics); find the root causes of problems (diagnostic analytics) and make predictions about future quality events (predictive analytics).

Key Steps in the FDA's Digital Transformation Journey

In the FDA Information Technology Strategy for Fiscal Years 2024-2027, the agency describes how it plans to better leverage technology to enforce more robust governance, become more agile, and "think differently to narrow the gap between current IT capabilities and the rapid pace of innovation and technology advancements." Here are some of the cited key steps in FDA's digital transformation.

- Accelerate cloud adoption: Empower users with cloud offerings to meet their mission needs, e.g., scalability and agility. Provide best practice guidance on cloud models, e.g., hybrid and transition strategies based on the unique needs across Centers and Offices.
- Increase digital maturity: Maximize the use of technology (e.g., data, automation) in core business areas and enable processes to improve their ability to adapt to changes and scale.
- Enhance data governance: Implement AI-powered best practices for governance and enterprise data management that improve data quality, security, and the speed and accuracy of insights and decisions.
- Enable advanced data analytics: Ensure experts can easily combine and analyze information from various internal and external sources to gain comprehensive insights.

Top 10 EQMS Attributes for Comprehensive Control and Rapid Deployment

With an unprecedented level of challenge and change in manufacturing, there is tremendous pressure to rapidly transform quality management processes.

When evaluating EQMS solutions for these 10 design factors and capabilities that enable comprehensive control over end-to-end quality management, rapid and seamless deployment, the ability to leverage advanced technologies, and the flexibility to expand quality oversight in alignment with company growth and expansion.

1 A single solution

Select an EQMS that serves as a single solution to replace manual and legacy quality systems by consolidating of all core quality management and regulatory compliance management processes with the platform. This eliminates the need to budget for and install individual quality "modules."

Choose an end-to-end EQMS for a centralized source of truth that facilitates search and retrieval of documents. All users and stakeholders will go to only one place for all quality documents and tasks. Likewise, auditors and regulators will be able to find everything they need in one place.

2 Enterprise-wide integration

To drive quality enterprise-wide, choose an EQMS with an open integration interface that delivers robust, flexible interaction with existing information systems and databases to facilitate quality production. This includes integration with reporting tools, including Microsoft® BI, SAP® Crystal Reports, SAP® Business Objects, IBM Cognos® and Qlik®, enterprise business systems including ERP, PLM, LIMS, CRM, CMMS, and internally developed applications and databases.

3 Out of the box deployment

An EQMS with processes and workflows pre-configured to industry-specific standards and regulations, such as FDA CGMP, FDA 21 CFR Part 11and Part 820, EU GMP, electronic medical device reporting (eMDR/EU MDR), and ISO quality standards, means the solution is available for a manufacturer's quality management team to use from day one. They can start with the solutions they need to deploy first, and then seamlessly integrate new processes as required.

Because manufacturers vary in their level of quality management process and technology maturity, an EQMS that is available on-premise and in a multi-tenant cloud application, both with identical software, offers flexibility to deploy the model that fits the current needs of the company.

4 Dynamic and configurable

A highly configurable EQMS enables a manufacturer to shape the solution to support unique or complex applications and easily adapt and scale over time to meet evolving business needs. Point-and-click administration (forms design, signatures, escalation rules, etc.) eliminates the need for re-validation as the system is enhanced.

5 Standardized workflows

Variability increases the risk for errors and inefficiencies. The ability to standardize all documents-based processes within the EQMS drives consistency, accuracy, and efficiency. When the quality team need to create a new standard operating procedure (SOP) or launch a corrective and preventive action (CAPA), they can leverage standardized formats in the EQMS instead of having to start from scratch.

6 Full visibility and control

Choose an EQMS that facilitates end-to-end quality and compliance management visibility and control to help the quality management team make informed decisions to continually improve quality operations. The most comprehensive solutions feature dashboards, status reports, alerts, notifications, and escalations that keep teams and management aware of late tasks and review requests. If an issue is detected, users should be able to assign a corrective action through the solution and followed it to closure, with linkages to the task that the issue was initiated from.

7 Automation

When an EQMS automates routine tasks in quality processes, including document control, change control, training management, audit, CAPA, and nonconformance management, this improves efficiency, accuracy and can dramatically reduce the number of hours devoted to daily tasks.

8 Risk-based compliance

An advanced EQMS solution automatically coordinates, tracks, and assesses activities to ensure compliance with global regulations and ISO standards, and links findings, evidence, applicable policies and procedures, training, and electronic approvals to any task. It provides quality professionals with instant, detailed insight into compliance risk and status with graphical management dashboards.

9 A collaborative ecosystem

Connected processes and workflow integration and standardization creates a quality ecosystem where users, managers, regulatory bodies, and suppliers can collaborate on quality issue management, compliance requirements, reporting, training, and audits.

10 Advanced analytics and reporting

An EQMS with real-time key performance indicators (KPIs), powerful analytics, trending, and reporting tools present quality management teams with actionable insights to make informed, data-driven decisions. They can shift from reacting to quality issues as they arise to proactively identifying and addressing factors that can lead to poor quality to prevent downstream impacts.

Conclusion

To thrive in today's challenging and ever-changing environment, manufacturers need exceptional quality control capabilities that enable them to pivot rapidly, enhance efficiency, reduce risk, maintain compliance, and ultimately deliver high-quality products to market quickly and cost-effectively.

These factors are rapidly driving manufacturers, including those in highly regulated industries, to consolidate, digitize and automate quality management processes within an EQMS. While the benefits of EQMS solution implementation are wide-ranging and impactful, the move doesn't need to be complex, time-consuming, or costly.

To support a seamless and speedy transition, one that positions a quality management team for successfully navigating current and emerging market challenges and regulatory changes, select an out-of-the-box, configurable and scalable EQMS solution aligned with the technology innovations – digitization, automation, cloud integration - reshaping the manufacturing and compliance landscapes.

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