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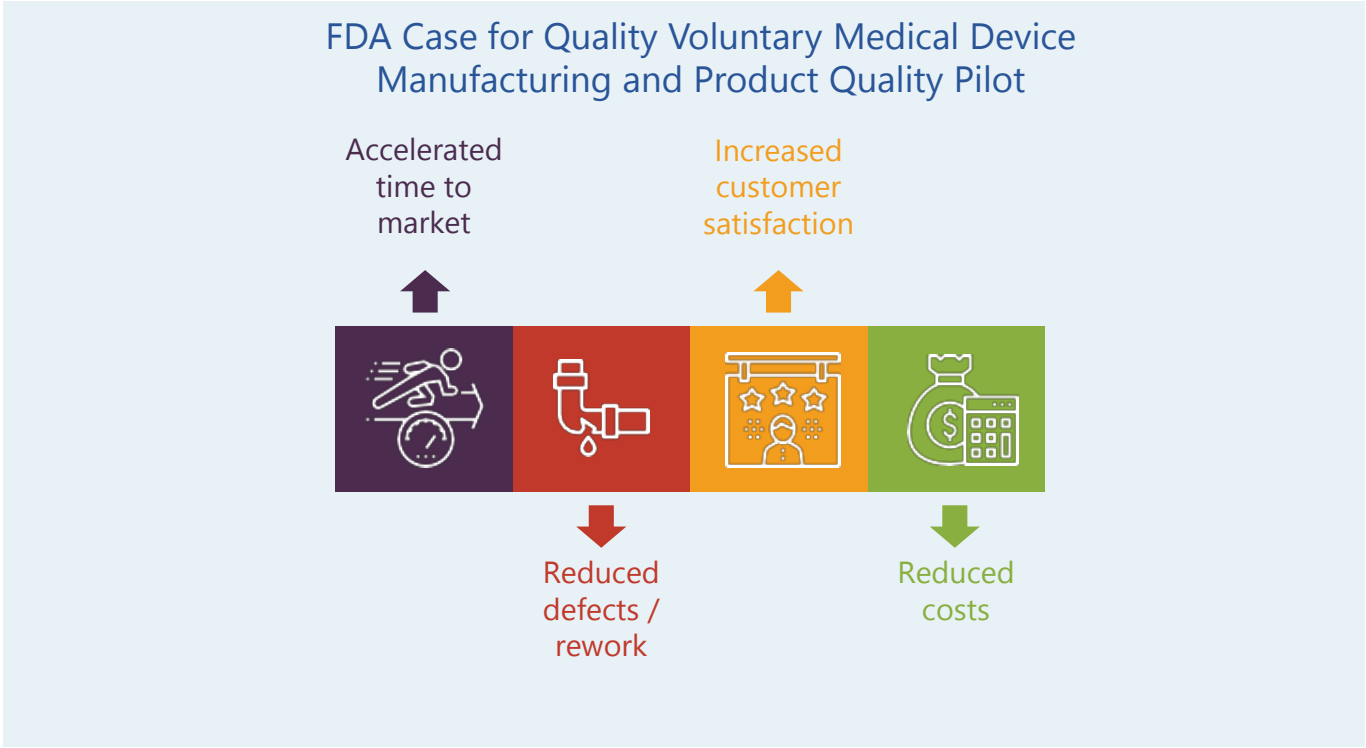
How Next Generation Electronic Quality Management Systems Equip Medical Device Companies to Handle FDA's New Approach to Quality Regulations

Introduction

Compliance managers at prominent medical device companies are collaborating with the U.S. Food and Drug Administration to reinvent the methods for meeting quality regulatory standards. Supporting this vision, the next generation of cloud-based quality management systems brings modern, collaborative, web- and mobile-friendly productivity to help compliance professionals prepare for this new world.

A growing number of companies have joined the FDA Case for Quality Voluntary Medical Device Manufacturing and Product Quality Pilot. Officially launched in December 2017, the initiative now includes 24 facilities at 16 leading organizations such as Siemens, Medtronic, Baxter Healthcare, and Boston Scientific.[1]



This pilot program leverages a maturity model by which medical device organizations may measure their capability to produce high quality devices and increase patient safety.[1] *FDA will adjust their engagement activities and submission requirements as a recognition of this independent assessment of quality maturity.*

In this pilot, FDA is adjusting engagement activities and submission requirements in recognition of independent quality appraisals.[2] The goal is to move the medical device industry from a single-minded focus on compliance to a mindset that blends continuous improvement and product quality with improved patient safety as the ultimate outcome.

Medical device standards 21 CFR Part 820, ISO 13485, and others are not impacted by this FDA Case for Quality initiative. Instead, the program is attempting to change the process for meeting these requirements. The original motivation for creating this program came about years ago when FDA noticed little difference in the number of medical device product issues at companies with excellent compliance records versus those with average or poor compliance. Surprised by this result, regulators, industry stakeholders and other groups responded by looking for new ways to produce both good compliance and higher levels of product safety.

Collaborative, Integrated EQMS Position Firms for New Regulatory Compliance Approach

It won't be easy to change years or decades of compliance conformity into a culture that integrates product quality and continuous improvement. However, those firms that employ new cloud-based electronic quality management systems (EQMS) are well positioned to adapt to this changing regulatory approach with the latest in flexible, secure, and scalable compliance management tools that are fully integrated with other enterprise applications.

Moving away from a traditional understanding of compliance to prepare for FDA's approach requires new thinking, says Elizabeth Zybczynski, Senior Principal Engineer at Baxter Healthcare.[1] She offered a few examples based on her company's experience noted in the table below.

Old Paradigm	New Paradigm
Quality Requirements increase the cost of our products	Quality is free
The Quality Organization is the police	The Quality Organization helps ensure predictable outcomes
Compliance is a goal in and of itself	Compliance happens naturally when we operate in State of Control
State of Control only applies to items in the Quality System	State of Control is a concept that applies to everything we do

Too often, the traditional approach to compliance included reactive adoption of quality solutions, resulting in a collection of disparate systems with little visibility across the enterprise. In the new paradigm, the emphasis on collaboration with internal and external stakeholders, plus integration across business functions in support of continuous improvement, supports implementation of modern 100% cloud-based EQMS to help medical device companies evolve. [3]

As Zybczynski of Baxter put it, an archaic approach to quality means:

- Failure to adopt new approaches to quality for fear of creating a compliance risk.
- Failure to adopt new technologies for fear of creating more validation work and compliance risk.
- Segregating processes into "inside the quality system" and "outside the quality system." [1]

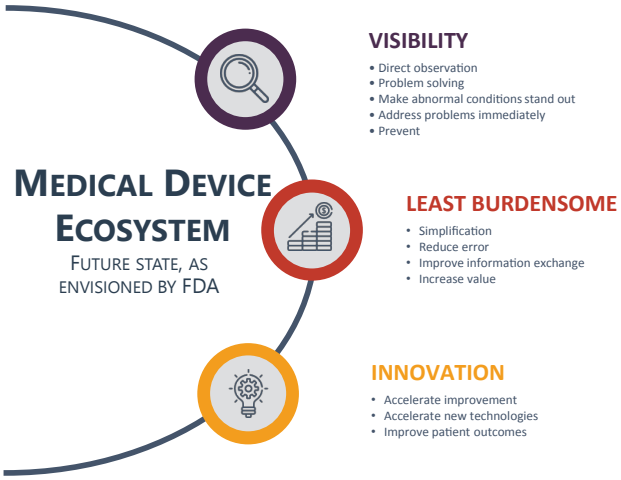
Following tradition has caused the medical device industry to fall decades behind in its approach to quality, resulting in capabilities which are significantly lower than other industries. As proof, consider the six-sigma defects-per-million evaluation comparing airline baggage handling and medical device manufacturing. Airlines achieve a score of more than 4 sigma while medical device companies lag behind, scoring less than 4 sigma. [1]

"I welcome where the FDA is going," said one Medtronic participant

In the new Case for Quality initiative, all 16 participating medical device companies report they would recommend participation to other organizations, according to program effectiveness metrics published by the Capability Maturity Model Integration (CMMI) Institute, which plays a key role in the new regulatory overhaul.

Positive responses to the Case for Quality are coming from individuals too. "I have both led and participated in FDA inspections and this experience, in comparison, was very positive," said one Medtronic employee quoted by Kathryn Merrill, Senior Lead Six Sigma Manager at Medtronic. "I welcome where the FDA is going and will do everything I can to endorse this program," the employee said. [1]

FDA and other supporting organizations such as the Medical Device Innovation Consortium are also encouraged by the results to date. Officials expect a total of 30 companies to join the program by the end of 2018 and say



FDA envisions a future state in which the medical device industry achieves a mindset that blends continuous improvement and product quality with improved patient safety as the ultimate outcome.

they will expand it more fully in years to come.

Current program metrics also show that 89.4% of the participants found the medical device facility appraisals helpful in identifying areas or processes that could improve how work is performed to increase product quality. This metric reflects progress in meeting the program's continuous improvement goals.

Medical device companies both inside and outside the program that are using EQMS get an integrated picture of quality across the organization, which enhances their ability to focus on continuous improvement. And those organizations using EQMS that are 100% cloud based can realize continuous improvement benefits through improved collaboration, better risk management, easy data access, analytics and artificial intelligence and more effective overall compliance management.

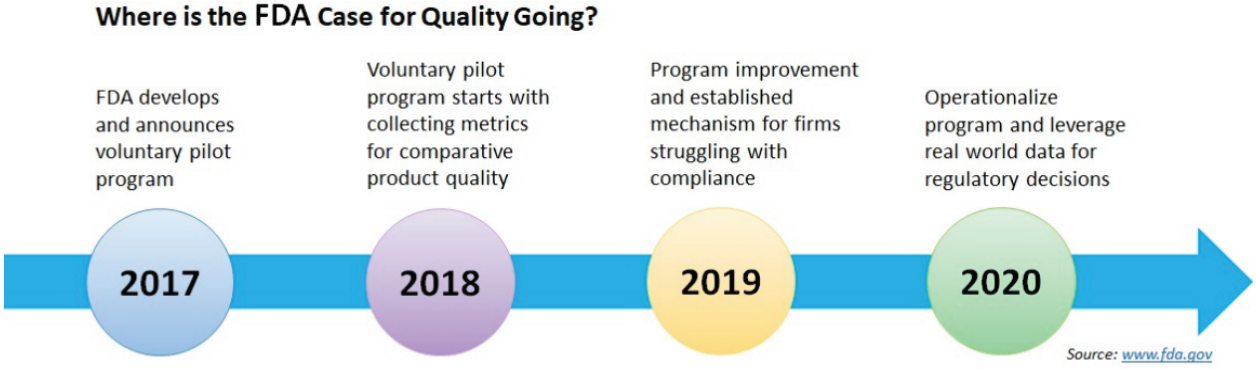
There are "always benefits to adopting any type of automation"

Compliance managers using EQMS are understandably concerned about how legacy systems will stand up to the changes introduced by FDA's Case for Quality.

At a recent webinar about the FDA initiative, an audience member asked, "For EQMS, how does this appraisal approach impact what companies can expect in the future?" [4]

While not endorsing any brand name or system, FDA Case for Quality Program Manager Francisco (Cisco) Vicenty replied, "From an FDA standpoint there are always benefits to adopting any type of automation. It does improve the capability to connect and get to some of that information faster in a more reliable and traceable format."

Speed, reliability, connectivity, audit readiness — these are the hallmarks of EQMS. And they have been advanced to higher levels by today's modern cloud-based systems. The EQMS that best deliver these hallmark qualities promise to play a critical role in helping companies adapt to FDA's new approach to medical device regulation.



Modern EQMS Keeps Pace with Evolving Standards

The FDA Case for Quality initiative uses the CMMI maturity model to measure a company's capability to produce medical devices that are high quality and highly safe. Customized for the medical device industry, this model involves 11 appraisal metrics such as configuration management, requirements development and maintenance, and governance. To provide meaning, each of these measures is supported by large quantities of data pulled from across the device manufacturing organization.

Of the 11-appraisal metrics used in the FDA initiative, some are proving to be more valuable than others, participants say. Since the pilot program is only in its first year of implementation, these medical device quality metrics are likely to change over time as regulators and manufacturers work together to make this new approach more permanent.

A modern EQMS will become an asset in this evolving relationship between producers and regulators when it is built on reliable cloud-based architecture such as the Salesforce® platform, which offers the flexibility to integrate new applications and features in a rapid manner.

As background, Salesforce is the world's most trusted cloud platform for business. Initially designed to provide cloud-based applications for sales, service, marketing and more, the company has grown into a platform service for tailoring any application such as EQMS. Salesforce provides an advantage over cloud platforms from Amazon®, Microsoft®, Oracle® and others because it provides business application developers the configuration tools for a consistent approach to building the user interface, workflows, social collaboration, community portals, mobility, language, integration and reporting and analytics.

Benefits of 100% cloud-based EQMS

Mobile.

- With a 100% cloud-based EQMS, the compliance function can be run from a phone. Built mobile-first, the Salesforce Platform lets compliance managers do everything on the go – anywhere, anytime.

Integrated Business Community.

- Companies with 100% cloud-based EQMS can leverage Salesforce AppExchange, an ecosystem of more than 4,000 solutions from the Salesforce store.

Security.

- Trusted by companies worldwide, the robust and flexible security architecture gives compliance manager peace of mind.

Integration Services.

- Compliance organizations transitioning to the new regulatory paradigm can bring any kind of data — even legacy data from Oracle and SAP — together for a complete view of the business.

Analytics.

- Everyone in the organization can get insights into compliance data on any device.

Internet of Things.

- Connect compliance data generated from devices, apps, and products.

Collaboration.

- Drives productivity throughout the organization (see detail below).

Build.

- Give developers the power and flexibility to build, scale, and manage compliance apps on Salesforce using new configurations rather than customizations.

Protected Client Configurations.

- All configurations are specified as metadata, so automatic upgrades don't disrupt the applications or compliance workflow.

Managed Infrastructure.

- Unlike proprietary architecture, Salesforce enables companies to focus on compliance and continuous improvement, not technology infrastructure.

As this last point emphasizes, developing EQMS on the managed infrastructure of Salesforce.com rather than a proprietary cloud enables exclusive focus on applications, expanding the number and depth of medical device compliance solutions in response to fresh needs triggered by FDA's changing approach. Salesforce keeps the underlying platform robust, secure, and innovative to support existing and new EQMS applications.

For their part, compliance managers using a cloud-based EQMS built on Salesforce.com can maintain the entire system using internal resources or 3rd party experts — meaning there's no ongoing dependence on the EQMS vendor. This keeps expenses low compared with other EQMS solutions.

In a future shaped by data and connectivity, modern EQMS stands out

While not required to participate in FDA's Case for Quality pilot, EQMS makes collecting, processing, and analyzing the required data faster and more reliable compared with disparate or legacy QMS systems, spread sheets, or paper documentation.

The value of automation within a centralized EQMS can only increase as the volume and types of medical device manufacturing data continue to expand. As the Case for Quality process spreads widely across the medical device industry, there will be more pressure on compliance managers to pull key data from records, slice it and dice it to provide meaningful analysis, and report it in a comprehensive form to the experts who conduct facility appraisals.

Of course, data volumes have grown exponentially in recent years and will continue to do so, but so have the innovative ways to utilize data. Artificial intelligence, the internet of things, smart machines, and other innovations are creating huge leaps of progress — all enabled by improvements in data management and analytics. Legacy EQMS systems are not architected to work in this new data ecosystem.

By contrast, the modern EQMS built on Salesforce.com provides a 100% cloud-based platform for connecting data from multiple sources, creating interactive views of that data, and sharing those views in apps. Compared with legacy systems, 100% cloud-based EQMS provides more intelligent ways to distribute insight to business users so they can understand and act on changing compliance information. This offers distinct advantages to companies as they move toward the new FDA regulatory model.

In a future shaped by data, where FDA's regulatory paradigm for medical devices has shifted from an audit mindset to an appraisal model, modern EQMS systems are best positioned to deliver value for medical device manufacturers. They perform at scale and scale up to help medical device compliance managers stay on top of this data revolution now and in the future.

Modern EQMS Supports New Regulatory Approach for Device Firms of All Sizes

Not surprisingly, FDA launched its Case for Quality initiative in partnership with large, prominent, medical device companies. Yet in coming years the new approach is expected to be applied to all organizations no matter what the size. With this future state in mind, it's helpful to note that a modern EQMS built on Salesforce.com can scale from 5 to 10,000+ users easily and with no further intervention from medical device compliance managers.

Not only does modern cloud-based EQMS support organizations as they scale up in number of users, it also helps them move up

the maturity scale. As mentioned, the FDA Case for Quality initiative detailed here utilizes Capability Maturity Model Integration during medical device facility appraisals.

Below are the five maturity levels used in the program, starting with the most mature, as presented by Baxter's Elizabeth Zybczynski.

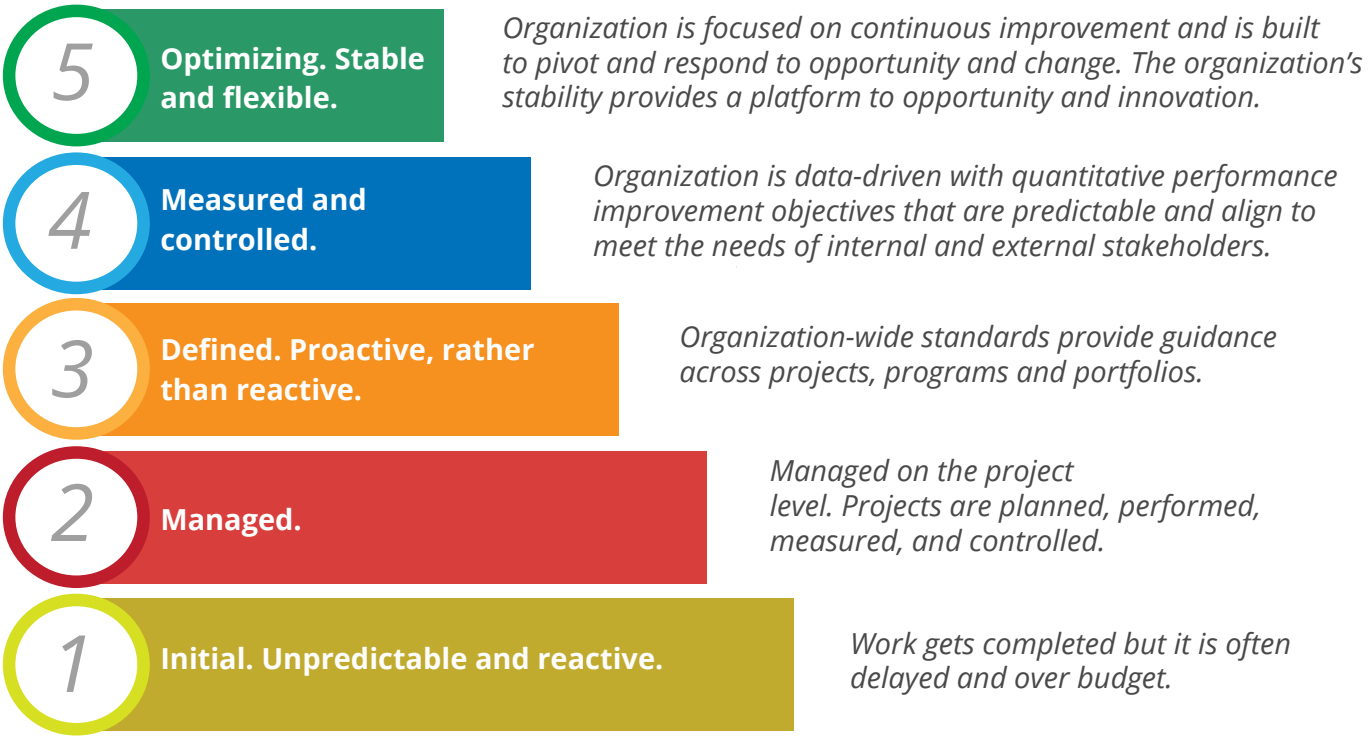
Moving up this maturity scale can be accelerated by modern 100% cloud-based EQMS. Its inherent flexibility and data-driven approaches make the systems ideal for evolving rapidly into FDA's new regulatory approach.

Connectivity Provided by Cloud-Based EQMS Supports New Appraisal Model

Supporting this journey up the maturity scale, EQMS applications built on Salesforce.com bring high levels of connectivity, a vital feature when the appraisal model is applied within a medical device organization.

Unlike the traditional audit approach where employees are instructed to address only questions asked and refrain from volunteering any extraneous details, the new FDA appraisal model relies on collaboration with employees to discover what's happening inside the organization relative to best practices. The interactions take place between the appraisal team and "doers" who are responsible for work products. These are simple and direct conversations with no artifacts to review.

Again, the goal of FDA's Case for Quality Pilot is continuous improvement that goes above and beyond compliance.[4] In a facility appraisal, employees are asked to be transparent and descriptive about how their work is done. The outcome of an appraisal is to identify improvement opportunities using



The 5 Maturity Models Used in FDA's Case for Quality Pilot Program

best practices as a guide. It's all designed to make a positive impact on the business. This differs substantially from the outcome of a traditional medical device facility inspection, which is the identification of FDA Form 483 findings with negative business impact.

FDA's changing regulatory approach prompted one program participant from Medtronic to remark, "This feels like a parallel universe."

In the table below is a comparison of the new and old compliance models presented by Quality Director Joe Friedrich of Boston Scientific. [4]

Comparison of Resource Allocation: CMMI vs. FDA Inspection

CMMI Appraisal	FDA Inspection
Capability maturity model appraisal of business practices and processes.	Inspection of quality system procedures and records.
Focused on eleven (11) CMMI Model practice areas.	Focused on 21 CFR Part 820 (or other) requirements.
Appraisers conduct group interviews of 'doers' responsible for work products.	Inspectors interrogate Quality leaders, process experts, and record owners.
Appraisers engage in discussions to truly understand how the business operates relative to best practices.	Inspectors review procedures, records, storyboards looking for evidence of noncompliance to regulations.
Many participants outside of QA	Few participants outside QA
Minimal disruption to site resources and no need for Back Room / Front Room.	Large support team with Back Room / Front Room, streams, scribes, etc.
Weaknesses are opportunities to improve business process	483s require escalation to CAPA and formal agency response.
Be open in answering questions and it's ok if you're not 100% sure.	Only answer questions asked. If you don't know the answer, don't guess.
It's OK to volunteer information that may be tangentially related to the question.	Don't volunteer information that doesn't pertain to question asked.
Highlight improvements made over time, as well as plans, if appropriate.	Don't discuss improvement opportunities or future plans.
Explain other systems and tools used to do your work. For example, PLCP, Business Essentials, VIPs, CI Boards, etc.	Don't deviate from what is documented the quality system, i.e. policies, procedures, records, etc.
No need to prepare for questions. Just respond as best you know based on you experience and perspective.	Be prepared to speak to any pertinent documentation. Facilitators will ensure the right people answer questions.
Do not bring your laptop, exhibits, or documentation to your interview. Is it just an open discussion.	Bring in procedures and records as appropriate. A laptop may be needed to view certain electronic files.

In the tables below are Boston Scientific's comparison of resource allocation, showing a maturity model appraisal takes 340 hours, 25% of the 1,370 hours it takes for a traditional FDA inspection. [4]

highly likely. That's why using Salesforce as a stable foundation to deliver more efficient upgrades of current applications and faster deployment of new solutions will be an advantage. The focus on rapid development

Comparison of Resource Allocation: CMMI vs. FDA Inspection

CMMI Appraisal – 5 Days			
	Prep	**Appraisal**	**Total**
Site Coordinator	80 hours	20 hours	100 hours
Participants	60 hours	180 hours	240 hours
Total	140 hours	200 hours	**340 hours**

2-day FDA Inspection	1370 Hours

EQMS built on the Salesforce.com platform can enhance this new appraisal process because it brings the power of social networks into medical device quality organizations, improving connections and knowledge among coworkers.

Salesforce Chatter is a private and secure social network for businesses. Everything that matters — from the status of a specific non-conformance, to corrective and preventive actions or change in customer information — gets delivered to all relevant stakeholders through their Chatter feed. With the connectivity provided by the Salesforce Chatter functions employees will be more informed and better able to participate in an appraisal.

EQMS Built on Salesforce Offers a Bridge to Quality 4.0

Considering the radical change ushered in by FDA's new regulatory environment for medical device organizations, a 100% cloud-based EQMS built on the Salesforce platform may deliver increased benefits over the long term. It is still the early days of this new regulatory paradigm and more change is is essential as need grows for compliance solutions not yet envisioned.

In addition to preparing for the new regulatory paradigm, 100% modern cloud EQMS can help the medical device industry move into the future world of operating known as Quality 4.0, which includes the digitization of quality but also examines the impact of this digitization on quality technology, processes and people. [7]

Leading the way are companies like ComplianceQuest, the fastest growing, 100% modern cloud (EQMS) natively built and run on the Salesforce platform. Delivering best-in-class out-of-the-box solutions, Compliance Quest fast-tracks an organization's efficiency, safety, and overall performance by combining enterprise quality, compliance, collaboration and communication across the product value chain. Suitable for emerging growth companies and scalable and flexible to meet the needs of medium and global enterprises, ComplianceQuest is easy to implement, validate, and use. Its team of domain experts is committed to innovation, product excellence and to the success of its customers especially those embracing transformation as part of FDA's Case for Quality.

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About ComplianceQuest

The vision at ComplianceQuest is to transform quality and compliance into a strategic advantage for our customers through experience, expertise and passion. ComplianceQuest is an innovative, 100% cloud based Enterprise Quality Management System solution company. We provide an enterprise grade solution that streamlines quality, compliance, content and collaboration management initiatives and strategies across diverse, globally based supply chain networks.

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