

White paper

# The way forward: Innovation in life sciences quality management

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Life sciences companies are accelerating their move to digital technologies—and quality assurance organizations have much to gain. This paper describes how automation can address the key factors driving change in quality management, such as compliance, collaboration and user experience, while reducing operational complexity and supporting innovation to create an Intelligent and Connected Enterprise.

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## The move toward automation—leaving operational complexity behind

### Executive summary

Digital technology offers enormous opportunities for life sciences companies to improve operational efficiency and support scientific innovation. In regulated environments, particularly manufacturing, where compliance is a constant concern, digital technology can dramatically reduce the complexity of meeting regulatory mandates. Digital technology can ensure simplified, secure collaboration among stakeholders across organizational boundaries. Faced with user demands for reduced complexity in their everyday work, today's companies need easy-to-use, mobile-enabled and secure interfaces.

Solutions designed for life sciences companies begin with implementing a single authoritative source for regulated content. This is key to streamlining processes with full compliance, secure and seamless content sharing and enabling a modern and intuitive user experience.

These tactical improvements lead to streamlined processes and dramatically improved productivity, enhanced customer service, faster time to market and, ultimately, vital strategic advantages that offer a big jump on the competition.

### Time to market: Intensifying demands

Being the first to offer innovative services is critical to strengthening existing relationships and attracting new customers. As such, companies need to shorten each step of the process to succeed. If accelerating time-to-market is indeed the driving force in business today, the pressure is even greater in the life sciences realm. Few other highly-regulated industries operate amid an environment of such strict quality standards and increasingly complex regulations.

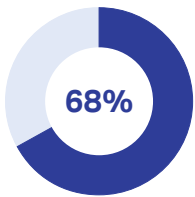
Technology continues to evolve against this backdrop. Newly agile enterprises worldwide are embracing technology breakthroughs that can speed up and streamline processes, enhance customer service and propel them ahead of the competition. Most biopharmaceutical and medical device manufacturers are poised to begin the journey to becoming Intelligent and Connected Enterprises and take advantage of innovations that are purpose-built for the industry. Enterprises are embracing cloud computing and its potential to support secure collaboration, enable a fast response to changing business requirements and achieve cost control.

### The compelling need to embrace digital technology

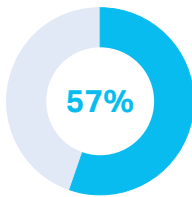
According to a 2017 executive survey report from Accenture, "74% of life sciences executives believe their organizations are entering entirely new digital industries, and that these innovations are moving them into regulatory gray areas." For quality organizations specifically, the major success factors in embracing digital technology are those of compliance, collaboration and user experience.

**Compliance:** Quality groups are under strict directives to comply with the electronic records and document control provisions. These records are often managed in disparate information silos. It is therefore not surprising that poor documentation procedures are the most cited reason for receiving a 483 Warning Letter from the FDA. [The FDA reported a 10% increase of observations](#) during local and foreign QS surveillance inspections in 2017. Further, 10% of all observations were related to document management deficiencies, most notably in the document controls and device master and history records requirements.

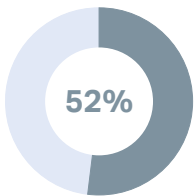
OpenText surveyed quality assurance professionals in pharmaceuticals, biotechnology and medical device organizations to determine which areas are most commonly automated using an electronic quality management system. The responses:



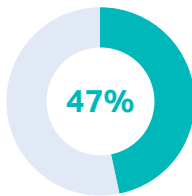
Document management



Training

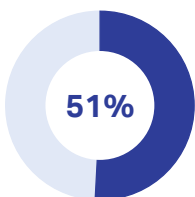


Non-conformance and/or CAPA

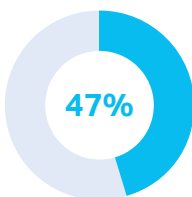


Change management

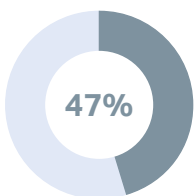
The survey also asked about the main challenges in CAPA management. The responses:



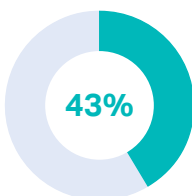
CAPA process know-how among non-conformance/CAPA record owners



Root cause determination



Generating reliable trends and metrics



Ease-of-use

i 128 respondents

ii 75 respondents

**Collaboration:** This fractured approach to document management impacts the full product lifecycle, from clinical to commercialization. The virtualization of supply networks across internal and external barriers has dramatically magnified the need for seamless collaboration. Both sponsors and contract manufacturing organizations must be able to exchange documents across organizational boundaries and geographies. Controlled documents must flow quickly through the supply chain. But, no matter how complex the operation, regulatory requirements that necessitate secure and tightly controlled electronic communications should not be overlooked. Easy user access must therefore be balanced with security and the protection of high-value intellectual property.

**User experience:** Previously, compliance was often cited to excuse a lackluster, complex UI. Now, business users are demanding a simple, consumer-like user experience regardless of compliance requirements. Occasional consumers of quality documentation are the norm, making a streamlined, intuitive experience with minimal training essential. Mobile accessibility is equally vital, as executives and employees must be able to complete assigned activities anywhere, anytime, from any device, in order to keep the workflow moving.

If IT is unable to deliver a satisfactory consumer experience, businesses may well avoid IT and focus on out-of-the-box solutions that focus on usability and configurability.

## The way forward

In the quality assurance realm, all aspects of the quality system generate regulated documents, such as standard operation procedures (SOPs), work instructions, validation documentation, reports and more. These documents are required in order to adhere to established quality processes, support training and pass inspections. To maintain compliance, operations must implement the following:

- Adaptable quality manufacturing processes in line with current Good Manufacturing Process (cGMP)
- A documentation control process that describes, specifies and records manufacturing and quality activities with requirements, such as GAMP-5 (FDA 21 CFR Part 11) and EU Annex 11
- Electronic records capabilities that meet the provisions of (FDA 21 CFR Part 11) while addressing the need for Pharmaceutical Best Practice (FDA 21 CFR 210 and 211), Biologics Best Practice (FDA 21 CFR 600-680) and Medical Device Best Practice (FDA 21 CFR 820)

Today's sophisticated solutions that are designed specifically for quality management can support all the above compliance processes. Listed below are the key features:

### Streamline: Efficient processes with full control

The best solutions streamline the document creation, review and approval processes while ensuring audit, version and print control.

**Document creation:** Companies need to ensure consistency and maintain control over documents from the moment they are created or entered into the content management system. Using standard terminology and vocabularies across the enterprise can provide consistency and minimize training when creating or uploading documents. The use of templates to create new content promotes a unified author experience, while metadata auto-population streamlines the authoring process, reducing errors and rework.

Certainly, authoring applications are evolving. OpenText Office® 365® offers tremendous potential for effective document creation and upload. When adopting a newer technology, however, companies should be mindful of GxP compliance and ensure proper controls within the electronic system.

**Review and approval:** To expedite document readiness, review and approval processes need to be effective and streamlined. Easy access to assigned work is therefore essential. In order to allow multiple reviewers to undertake simultaneous, realtime edits, quickly update content and review changes, companies should seek solutions that provide collaborative capabilities. Once a document is ready to be finalized, the solution should support a single, streamlined workflow for all contributors to perform a final review, rather than multiple, serial workflows.

**Change control:** As changes to content occur, such as new versions, edits or deletions, the solution should log all actions in an audit trail to maintain accountability across the content management system. Creation and revisions are typically controlled processes that require built-in change-control functionality or readily available integration with the quality management system. When a change to documentation is required, for example, during a scheduled periodic review, the entire process must be automated and tracked.

**Print and export control:** To ensure proper use of printed or exported hard copies of electronic records, preconfigured, dynamic watermarking and overlays should be used. For example, issued printing, a form of controlled print, assigns a unique print number when copies of master batch records to specific production orders are printed or reprinted. This capability should support partial or full reconciliation of the executable documents to provide full visibility into the use of hard copies, supporting established quality processes and agency inspections.

#### **Unify: Seamless content-sharing, reporting and archived records**

A content management system that ensures a single source of truth across the extended organization is essential to sharing information securely and reliably. This solution enables teams to shift from error-prone, paper-based systems to automated manual review and approval methods, ensuring accurate, consistent and efficient processes across multiple manufacturing locations.

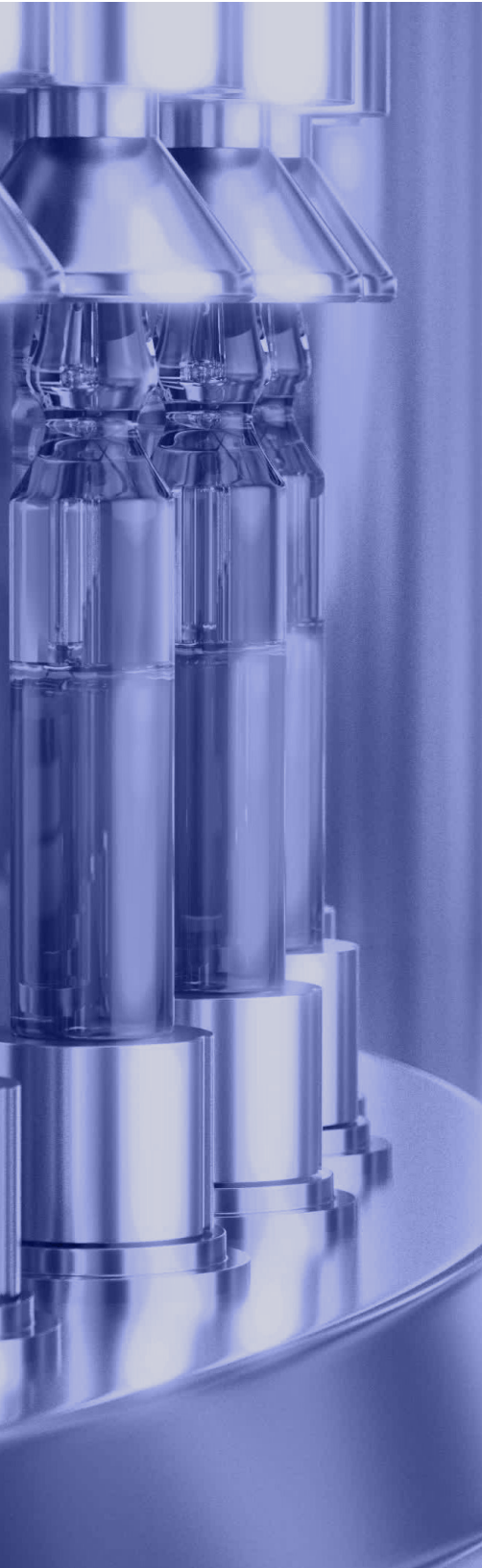
In a single shared content management system, documents can and should support tech-transfer processes to ensure content consistency. When a change is required, standard data between regulatory and commercial areas enables stakeholders to conduct quick impact assessments. Standardization means that internal and external partners are all using the same versions and, by extension, enables a natural collaboration across the extended organization.

In addition, a unified content management system can feed information from multiple sources into reports and dashboards supported by an analytics platform, transforming data into meaningful insights with relevant visualizations for more informed, faster decisions.

Finally, a shared content management system supports compliance with long-term records management. At the completion of the quality process, all information must be stored in a repository, where it is indexed and fully searchable, and quality records must be easily retrieved and viewed online. The right solution enables companies to apply appropriate retentions and automatically apply policies.

#### **Simplify: Easy user access, low-risk migration and validation**

Best practices for a quality management solution include a simple, role-based experience delivered on users' phones and tablets. If a quality manager needs to distribute SOPs, the manager should receive only relevant tasks and specific content with built-in workflows and the ability to take immediate action. By tailoring the experience to the user and ensuring anywhere, anytime access, work is done in a productive, efficient and compliant manner. Watermarks and access control capabilities support proper distribution and use of the content.



Given the mergers and acquisitions so prevalent in the industry today, many organizations try to maintain multiple content management systems that are often highly customized and function as silos, impeding efforts to simplify and unify regulatory processes. It is therefore imperative to break down these information silos and seamlessly share quality information across both internal and external teams. As companies turn to configurable, user-friendly solutions, they can also take advantage of the tools and services offered by an expert solution provider to ensure a low-risk migration, validation and comprehensive training.

Using documentation templates that support the validation efforts of a computerized system, based on Good Automated Manufacturing Practice (GAMP) compliance, companies can jump-start validation activities and reduce overall validation effort. Cloud deployments require qualified environments that are compliant with regulatory requirements and can be easily validated.

## **The move toward automation—leaving operational complexity behind**

The way forward is clear. To begin, companies can implement a single authoritative source for regulated content, enabling them to:

- Increase visibility into all quality process in realtime
- Streamline the creation, review, approval and change management of documents across the extended enterprise
- Use an industry-standard, document taxonomy to quickly create, search, retrieve and navigate documents for pharmaceutical and medical device products
- Leverage flexible lifecycle support for multiple control levels within a single repository
- Streamline the periodic review and change request processes and balance flexibility and control
- Automate the distribution of new, effective documentation internally, externally and on mobile devices
- Support the technical transfer process by ensuring document traceability and visibility
- Understand controlled document compliance using detailed, graphical reporting
- Leverage a proven, trusted and scalable platform on-premises or in the cloud

The result is unprecedented usability, efficiency, agility, document control and compliance—critical factors when it comes to getting products to market ahead of the competition.

As the pace of technological innovation accelerates, business pressures intensify in tandem. Transforming business processes should be an essential part of any digital reinvention program—and planned accordingly. By becoming an Intelligent and Connected Enterprise, organizations will be able to more easily adopt emerging technologies, such as artificial intelligence, and take advantage of the enormous potential for improving operational efficiency.