



# Shaping the Next Normal for Quality and Compliance

## 2021 Quality Management Trends

Let's just say what we're all thinking: 2020 was rough. It threw every element of our lives into disarray. We suddenly had to become experts at navigating a new way of working, schooling and socializing. It was disruptive and it was challenging, but it was also transformative. And while the past 12 months might have felt like 12 years, it's time to look forward to what the future holds. If 2020 was the year of disruption, 2021 will be the year of mastering change.

Pursuing innovation and breakthrough discoveries is part of the natural evolution of every industry. It's a given that to remain competitive, companies need to adopt new technologies in order to keep up with the advances in the marketplace. The circumstances surrounding the global pandemic highlighted the need for reliable connectivity and integration, which forced many companies to move up their plans for implementing digital technologies.

COVID-19 thrust the life sciences industry into the spotlight. That said, the trends shaping quality and compliance management in 2021 will be driven by the value and necessity of connected quality



## 1

# Connected Ecosystems Are Critical to Success

**Not long into 2020, the traditional workplace scenario began to unravel in order to abide by the social distancing mandates. Employees needed to turn basements and dining tables into makeshift offices and work remotely. Because quality management is not confined to a single department or role, companies using paper-based or hybrid quality management systems soon discovered the limitations of these systems. With a dispersed workforce, organizations lacked connectivity and continuity, making the assurance of consistent quality extremely difficult.**

Operating with a mostly remote workforce will likely continue into 2021 — for many companies, it may become the new norm. In this scenario, ensuring a high level of quality and maintaining compliance throughout a product's life cycle will rely heavily on digitized technology and connected quality. Global pharmaceutical compounding company Fagron is a prime example. The company processes the common steroid dexamethasone, which has proven to be effective in fighting the novel coronavirus in seriously ill patients.<sup>1</sup> Having a single, accessible quality system helps the company maintain maximum productivity while ensuring quality throughout the product's life cycle.

## Elements of a Connected Technology Approach



### Holistic Approach

Consider the entire life cycle when implementing technology solutions.



### Technology Platform

Seamless infrastructure to house the technology solutions.



### Continuity

Ensure any added and new technology can be integrated.



### Organizational Collaboration

Have IT ownership with cross-functional input.

“ [Companies can] seize powerful first-mover advantages that accrue in digitizing markets. These advantages include unlocking data for better decision making, creating solutions that complement commercial offerings, engaging with customers, and reimagining internal processes.”

—McKinsey & Company<sup>2</sup>

## Theoretical to practical: Recognize the Value of a Platform Infrastructure

- 1 Cloud Adoption:**  
Eliminate silos by harmonizing technology systems. Improve real-time communication, collaboration and data sharing across all business units.
- 2 Agile Ecosystem:**  
Maximize system uptime and expand bandwidth on demand to efficiently collaborate and keep up with increasing workloads.
- 3 Connected Platforms:**  
Ensure seamless integration and connectivity. In the cloud, multiple systems are connected by application programming interfaces (APIs) or integration platform as a service (iPaaS) solutions. Embed quality into the organization's culture while streamlining the productivity of systems you already own.

# 67%

of business leaders see digitalization as highly relevant to their long-term viability.<sup>3</sup>



## 2

# Creating Business Value With Data-Driven Platforms

**Whether six feet or six continents apart, colleagues need to interact, data needs to be exchanged and decisions need to be made in real time. With ongoing advancements in technology, enterprises have abundant amounts of data at their disposal. However, because data comes from a variety of sources and in different formats, companies are not able to use all the available data to its full potential.**

**“By 2023, data literacy will become an explicit and necessary driver of business value, demonstrated by its formal inclusion in over 80% of data and analytics strategies and change management programs.”**

—Gartner<sup>4</sup>

Legacy quality management systems require more time and effort than is necessary. Quality managers commonly spend an extensive amount of time double checking spreadsheets and documents, and quality deficiencies are often discovered late, putting delivery timelines at risk.

Working with unstructured data (word processing or spreadsheet documents, emails, transcripts, online forms, etc.) is particularly challenging. This type of data is often stored in multiple locations, making it difficult to disseminate to everyone who needs it. In a regulatory environment, quality evidence that cannot be substantiated upon request may as well not exist. Out of necessity, companies in all industries are modernizing their operations to better leverage data.

Organizations that adopt a data-driven, platform-enabled quality model will augment their capacity to yield real-time quality intelligence and predictive insights. When equipped with the ability to connect data within a common platform, every function within an organization can have an appreciable impact on the transformation of the product's quality data into real-time intelligence.



## Theoretical to practical: Use All Your Data

- 1 Bring Intelligence to Unstructured Data:**  
Automate text extraction from unstructured documents and contextualize relevant data into the QMS for better accuracy and efficiency.
- 2 Improve Search Capabilities:** Incorporate contextual search and recommendation engines to improve search speed. Pull relevant information and documents forward based on past searches and search language history to refine the recommendations provided over time.
- 3 Connect Data Throughout the Product Life Cycle:**  
Streamline workflow creation and execution, and allow users to improve data integrity with connected data sources, process steps and systems.
- 4 Employ Real-Time Data Analysis:**  
Stay informed and up to date on your operational trends by gathering, processing and analyzing complex data sets in a fraction of the time it would take in an on-premise infrastructure

“ The life sciences industry is at an inflection point. Companies throughout the industry now recognize that to remain competitive they need to make better use of all their data assets. To be a leader in this new data-driven world, life sciences companies must fundamentally transform how they create, manage, and effectively use all [their] data.”

– Accenture<sup>5</sup>



## 3

## Artificial Intelligence and Advanced Analytics Go Mainstream

Data analytics can be cumbersome and not always yield needed insight in a timely manner. Modernized technologies such as artificial intelligence (AI) and its associated technologies, machine learning (ML) and natural language processing (NLP), are redefining the parameters of what is possible in life sciences product development. Using historical and new data, analytical queries and ML algorithms, companies can forecast quality events, behavior and trends.

The objective of AI and predictive analytics is to help make more accurate predictions about future or otherwise unknown events. This is beneficial due to the technology's ability to quickly find data that directly relates to a behavior or issue. Life sciences companies are using these technologies as a tactical advantage in achieving compliance. By accurately identifying and mitigating new or potential compliance risks, quality is assured at each phase of product design, development and manufacturing.

**Accenture predicts that by 2022 strategic scaling will be imperative to success<sup>6</sup>**

**40%** of industrial organizations will implement internet of things (IoT)- and AI-enabled predictive maintenance.

**83%** of executives say they won't achieve their growth objectives without scaling to AI.

**75%** of companies believe they risk going out of business in five years if they don't scale to AI.

## Theoretical to practical: Reach New Heights in Operational Efficiency

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- 1 Optimize and Advance Staff Expertise:**  
Identify repetitive tasks that can be completed using AI or ML. Advancing employee skill sets to include deep learning, data analytics and working with complex data-driven systems increases their ability to contribute to more business-critical projects.

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- 2 Streamline Change Control Processes:**  
Evaluate current processes to identify gaps and inefficiencies. By implementing automated processes for effecting, controlling and systematically adapting to changes, it's easy to see and mitigate recurring quality issues before they become costly defects.

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- 3 Reduce Equipment Downtime:**  
Use AI-enabled predictive analytics to accurately foresee potential equipment calibration issues and mechanical failures. Ensure consistent quality by maximizing equipment efficiency and uptime.

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- 4 Streamline Batch Record Processes:**  
Use connected production records to seamlessly share information and alert users about patterns and issues, so operators can mitigate quality events before they occur.

“Cutting-edge analytics techniques such as deep learning, transfer learning and reinforcement learning will disrupt areas that have already been transformed by advanced analytics. And cognitive computing and natural language generation can drive further productivity advances in business processes... The companies that get ahead will therefore be those that seek opportunities to advance their platform plays and find the next generation of solutions before others do.”

– McKinsey & Company.<sup>7</sup>



# Modernized Risk Management Elevates Quality

**Controlling risk is an important requirement in the design, development and manufacture of health care-related products. Standards and regulations such as the International Organization for Standardization (ISO) 14971, International Conference on Harmonization (ICH) Q9 and the European Union's Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR) were instituted for the express purpose of enforcing heightened safety measures and risk management processes.**

On average, about 4,500 drugs and medical devices are pulled from U.S. shelves each year, so risk mitigation will continue to be strongly emphasized by global regulatory bodies. However, simply meeting compliance obligations does not equal effective risk management. That said, life sciences companies need to integrate risk-based thinking into the entire quality ecosystem by effectively aligning people, processes and technology. As a result, companies will be more prepared for current and future challenges. U.S. Food and Drug Administration (FDA) Commissioner Stephen Hahn has repeatedly stressed the importance of modernized technology for improving product quality and safety.

**“Has deployment of advanced safety technology or process capabilities provided improvement in financial or operational performance? Respondents overwhelmingly said yes, with 75% reporting operational improvements and 60% claiming financial improvements.”**

– LNS Research<sup>8</sup>



## Theoretical to practical: Accelerate Compliance and Time to Market

- 1 Embed a Culture of Vigilance:** Help employees become more aware of risks throughout the supply chain, so associates at all levels can raise awareness if supply chain issues arise.
- 2 Manage Risk With More Precision:** Using a connected, data-driven quality platform allows you to manage all quality processes from anywhere, creating a unified risk management framework.
- 3 Embrace a Quality by Design Approach:** Understand the true nature of quality and implement it during product design, development and manufacturing. This facilitates more informed and proactive decisions and quality best practices throughout your product's life cycle.

“ More data is captured than ever before, advanced analytical tools such as machine learning and AI could strengthen FDA's predictive capabilities, thereby enhancing our ability to detect potential safety issues with food products and more effectively prioritize inspections and work based on modern risk prioritization techniques.”

–Stephen Hahn<sup>9</sup>



# Conclusion

Today more than ever life sciences companies need to evolve if they wish to stay competitive. Digital technology is transforming the way all organizations operate, and the adoption of robust digital tools has become essential for survival in the market. The implementation of practices that improve efficiency, speed and adaptability gives enterprises an edge while elevating the entire industry. This modern approach requires proven, scalable solutions.

MasterControl works closely with companies to accelerate digital transformation. Our cloud-based platform delivers applications that help organizations connect enterprise quality, manufacturing and external stakeholders. MasterControl's proven solutions increase visibility, improve decision-making and enable the operational agility companies need to master change in a rapidly evolving industry.



Quality

## MasterControl Quality Excellence™:

Smart, dynamic enterprise, plant and supplier quality management that enables you to manage product quality, compliance and risk using an intelligent, digital solution.



Manufacturing

## MasterControl Manufacturing Excellence™:

Fast, flexible production management and execution for process and discrete manufacturing that connects your shop floor workers and delivers right-first-time results without the cost and complexity of a traditional MES.



Insights

## MasterControl Insights™:

Modern data architecture and advanced analytics allow you to turn product quality and operational data into a competitive advantage

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