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THE FUTURE OF QUALITY MANAGEMENT IS DATA-DRIVEN AND PROACTIVE

THREE INDUSTRY TRENDS THAT WILL HELP QUALITY LEADERS GET DIGITALLY FIT FOR CHANGE

Nearly half (48%) of quality organisations have defined quality processes with limited capability to use their data for proactive quality management[1]. This shows progress from the days of manual and paper-based processes, aided by the rapid adoption of modern quality systems. Yet, more work remains to achieve data-driven, proactive quality nirvana, powered by predictive analytics, artificial intelligence (AI), automation and other advanced capabilities.

Companies looking to take their quality operations to the next level should start by rethinking the role of the manufacturing lab, prioritising validation management and driving quality digital transformation. Here are three ways quality will take a step forward this year and impact the future of quality manufacturing.

THE QUEST TO CONNECT THE MANUFACTURING LAB ECOSYSTEM WILL LEAD TO QUALITY CONTROL MODERNISATION

Driven by the need to improve quality control (QC) lab efficiency, an increasing number of quality leaders are implementing point applications that focus on a specific outcome. Often, each lab uses different tools, even within the same organisation or facility. As a result, today's lab workflows are disconnected and ill-prepared to keep pace with evolving business needs.

To enable an agile digital laboratory, QC leaders will reimagine their approach to quality and implement changes that advance toward a more connected quality ecosystem. This requires thinking beyond a specific tool for a particular problem and considering a holistic approach to modernising QC and how it fits within the context of the organisation's technology modernisation efforts.

A comprehensive solution on a single technology platform can streamline sample management and lab investigation processes and decrease inventory expenses. It can also bring QC and QA processes together, streamlining lab operations for faster batch release.

Quality leaders thinking of embarking on this journey can begin by starting with the problem, building a team of champions across functions and evaluating technologies that enable connectivity across quality.

Start with the problem. QC operations usually include manual processes that depend on paper, spreadsheets and homegrown systems or vendor point solutions. Take a step back and evaluate the complete quality ecosystem. Ask how you can improve multiple business processes by solving one challenge and map out processes end-to-end to determine what activities or systems can be streamlined. Looking at lab issues with a holistic lens can make a significant positive impact on the broader organisation.

Connect people and teams. Establishing a comprehensive platform for quality requires significant time and resource investment. Assemble a team across functions to prioritise capabilities, lead the strategy for change management and keep projects on track. Leverage vendor services and consulting firms for expertise that strengthens the initiative. A committee with internal leaders, quality experts and third-party partners can deliver the right combination of people to drive a successful transformation.

Enable collaboration with technology. Designing a matrix that includes current and future needs and new and existing products, services and support can move the conversation forward. The ultimate goal should be driving more connection and collaboration throughout quality and manufacturing. When deciding on the systems that will support this initiative, consider 24/7 access to data, seamless information sharing and the user experience and interface. Solutions that provide connectivity via open APIs enable easy integration with existing systems, simplifying information sharing across teams.

In a typical scenario, team members use different logins to different systems to upload, download and share files with various departments. Through modernisation efforts, organisations can have a unified document repository, creating a single source of truth and eliminating the pain points associated with various logins and screens.

Connectivity delivers visibility into where data exists and confidence that it is current rather than in a spreadsheet or a binder. Ultimately, quality leaders are empowered to drive change while advancing the entire QC environment.

ENABLING PAPERLESS VALIDATION WILL BE CRITICAL TO MEET THE GROWING NEEDS FOR CGMP COMPLIANCE

The consistent use of paper-based processes to manage validation projects leads to unreliable data and questionable validation. A rise in data integrity violations is leading to change, including new regulatory guidance that promotes compliance with Current Good Manufacturing Practices (CGMP).

In 2022, more companies will establish a path to no guesswork validation by enabling paperless execution of processes. To do so, the industry will need regulatory support and alignment, best practices and guides, and advanced applications.

Regulations emphasise the need to prioritise data integrity throughout the CGMP data lifecycle across the creation, modification, processing, maintenance, archival, retrieval, transmission and disposition of data.[2] The use of digital tools helps to quickly detect unusual results, errors or omissions, especially when compared to legacy processes.

The shift from paper to digital validation management will streamline processes such as organising validation activities, managing a global library of test scripts and digitally executing protocols. Faster and more efficient validation projects can drive stronger data collection practices in both the short and long term. The result is improved audit and inspection readiness, built on a solid data foundation.

The use of industry standards can help organisations prioritise data integrity while driving standardisation. Where using industry standards isn't an option, modern technology solutions can provide embedded best practices that remove friction and prevent quality leaders from rebuilding old processes into a new environment. To start on a path toward validation transformation, here are six best practices:

1. Bring cross-functional stakeholders together into the project early to ensure that needs are met across teams.
2. Create and share the validation vision and process to identify what needs to be done.
3. Consider integrated systems, applications, facilities, utilities and equipment.
4. Before implementing a digital validation solution, create a global governance team to oversee the management of templated validation content.
5. Evaluate technologies such as a flexible, cloud-based solution that meets your organisation's requirements with industry best practices. Explore solutions that enable different experiences, based on user level throughout the validation lifecycle and accommodate onsite and off-site support.
6. Integrate ongoing change management, including training and support. To avoid overwhelming resources, consider a phased approach.

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MORE CDMOs WILL REDUCE VARIABILITY IN THEIR PROCESSES BY USING ADVANCED QUALITY SYSTEMS

After decades of costly regulatory issues and failures that affected the top and bottom line, Contract Development and Manufacturing Organisations (CDMOs) are becoming key partners in speeding time to market. This year, a growing number of CDMOs will establish a foundation for process consistency and compliance using modern quality systems.

This shift has been driven by changing norms around quality manufacturing. Companies usually evaluate new approaches after receiving a recall or warning letter in the past. More companies are taking a proactive approach to leverage 21st-century GMPs, Pharmaceutical Process Analytical Technology, Quality by Design and ICH Q10. The industry is learning from these quality concepts used in other sectors, leveraging process capability, statistical process control, risk assessment and other tools designed to reduce variability.

To support these efforts, regulators emphasise the need to bring quality metrics into day-to-day operations, while pharma companies adopt an organisation-wide quality mindset. This includes reducing variability in their processes and taking a proactive approach to quality as an enabler of operational excellence[3]. As a result, companies are saving millions of dollars per year and using quality as a strategic asset rather than as a cost centre.

The ability to deliver consistent product quality has emerged as an important differentiator. Organisations that leverage data-driven techniques achieve better control over manufacturing processes, whether handled internally or through a CDMO.

According to Melanie Cerullo, senior vice president of quality and regulatory management at Arranta Bio, a CDMO specialising in work with developers of microbiome-focused therapies, cloud-based systems are enabling this positive change. "Paper creates an additional barrier to change," she says, "where the right electronic systems improve efficiency, supporting improved quality and continuous improvements in manufacturing and distribution".

Cloud-based systems improve collaboration because teams don't have to be onsite to see a batch record revision history. They can extract what they need when they need it. For forward-thinking CDMOs and generics manufacturers, the cloud provides a seamless way to aggregate data to gain insights into the root cause of quality issues, such as deviations and Out-Of-Specification (OOS) events.

'The solution is clear: digital technology can help bring together departments, systems, teams and geographies.'

Another key benefit is the improvement of quality metrics and key performance indicators, mainly when used with IoT-enabled devices. "These capabilities, along with assured data integrity, are crucial to reducing quality risks," according to Sérgio Paulo Simões, founder and board member of Bluepharma, a Portugal-based generic pharmaceuticals company.

Below are best practices for CDMO leaders thinking of adopting cloud-based quality applications:

1. Leverage native functionality to speed implementation and stay current with industry best practices.
2. Leverage cloud capabilities to allow external parties to access the application securely, bringing them into your quality processes.
3. Spend the time upfront to understand what the system needs to do on the back end. For example, reports that must run or data that needs to be collected.
4. Take into consideration how the staff will use and access the information to ensure built-in parameters.

Success depends on culture change for any company moving quality data and documentation from an enterprise IT platform to the cloud. CDMOs are helping to lead this effort by digitally transforming their operations to support the industry.

MOVING TOWARD A CONNECTED, DIGITAL, PROACTIVE FUTURE

Let's, as an industry, make it our collective goal to accelerate discovery and outcomes. The solution is clear: digital technology can help bring together departments, systems, teams and geographies. These systems establish a vehicle for standardisation and put quality at the forefront. Solid technology that leverages and encourages the use of industry standards, meets regulatory requirements and brings together teams is the path forward. If done thoughtfully, companies will have the proper foundation for data-driven, proactive quality management to stay a step ahead and speed time to market.

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PROFILES

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