



Advancing Toward Proactive Quality Management

More organisations have adopted modern quality systems to move beyond manual and paper-based processes. However, a recent survey found that nearly half of companies that were modernising their quality management practices still had limited ability to use data for proactive quality management.¹ More foundational work will be needed if the industry is to harness the power of automation, predictive analytics, and artificial intelligence (AI) for trending and improved decision-making.

The first step in this work is to assemble cross-functional teams to analyse processes from different user perspectives and standardise them. This article will focus on two critical areas that are receiving more attention: improving quality control laboratories, processes, and systems and establishing paperless validation management.

Improving QC Laboratory Efficiency

As part of incremental efforts to improve QC lab efficiency over the years, quality leaders at many companies installed different point applications to optimise specific outcomes. Over time, this resulted in a situation where each lab, even those within the same organisation or facility, was using different tools with different logins, making it difficult to find, share, and report on data with colleagues in other divisions. Disconnected workflows left companies ill-prepared to keep pace with evolving business needs. Given the importance of QC to business goals, focusing foundational work in this area alone can significantly impact business results.

To develop more agile digital laboratories, QC leaders whose systems have become disconnected will need to reimagine an approach that advances a connected quality ecosystem. This requires thinking beyond specific tools and problems to consider a holistic approach to modernising QC and how it will fit within the organisation's overall technology modernisation efforts.

Before considering potential technology solutions, quality leaders need to evaluate the problem carefully and from different points of view. Accomplishing this goal will require a cross-functional team whose daily work processes depend on quality data to develop the best approaches for resolving it. The team will eliminate bias by considering processes within a broader cross-functional context. Together, members can consider such questions as whether standards might be used to organise work processes or whether procedures might be combined or improved.

For this challenge, a comprehensive solution based on a single technology platform could streamline sample management and lab investigation processes and decrease inventory expenses.

It could also bring QC and QA processes closer together, streamlining lab operations for faster batch release.

However, selecting technology should formally start only after the team has analysed the problem in depth from different perspectives. In this case, the need for connectivity should drive analysis and consideration of potential solutions.

QC operations usually include manual processes that depend on paper, spreadsheets, homegrown systems or vendor point solutions. First, the cross-functional team needs to take a step back and evaluate the complete quality ecosystem. The team should ask how multiple business processes could be improved and then map out processes end-to-end to determine what activities or systems can be streamlined. Looking at lab issues holistically is key to more effective overall results.

It's never too early to think about change management because technology users do not accept will never result in change. Assemble another team across functions to lead the strategy for change management, prioritise efforts, 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.

Itemise Current and Future Needs

To move the conversation forward toward technology selection, design a matrix that includes current and future needs, as well as new and existing products, services, and support. 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 must use different logins to different systems to upload, download, and share files with various departments. Through modernisation efforts, users will gain a unified document repository, creating a single source of truth and eliminating the pain points associated with multiple logins and screens.

Ultimately, taking this approach, and focusing on one problem, empowers quality leaders to drive change while up-leveling the entire QC environment.

Moving to Paperless Validation to Eliminate Data-Integrity Issues

Managing validation projects is an area in need of innovation and advances efforts to enable proactive quality management.



Historically, using paper-based processes for validation management has led to unreliable data and questionable results. A rise in regulatory citations for data integrity violations is driving change in the industry, including regulatory guidance that re-emphasises the need for compliance with current good manufacturing practices (cGMPs).

More companies are establishing a path to streamlined validation by enabling paperless process execution. 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 Digital tools make detecting unusual results, errors, or omissions easier and faster, especially compared to older IT systems.

Moving 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 will lead to robust data-collection practices in the short and long term. Built on a solid foundation of quality data, the result is improved audit and inspection readiness.

Industry standards can also help prioritise data integrity efforts while driving standardisation. In cases where using specific industry standards isn't possible, some modern cloud technology solutions offer embedded best practices so that quality leaders don't recreate old processes in a new environment.

The following best practices can help your organisation advance validation transformation:

1. Bring cross-functional stakeholders 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. Consider integrated systems, applications, facilities, utilities, and equipment.
3. Create a global governance team to oversee the management of templated validation content before implementing a digital validation solution.
4. Evaluate technologies such as flexible, cloud-based solutions that meet your organisation's requirements against industry best practices. Explore solutions that enable different experiences based on user level throughout the validation lifecycle and accommodate both on- and off-site support.
5. Integrate ongoing change management, including training and support. Consider a phased approach to avoid overwhelming teams adjusting to new processes.

Align with Contract Partners

As outsourcing continues transforming pharma manufacturing, more large pharma companies have included their contract

partners in quality modernisation efforts. One company, which counts on contract partners for about 70% of its output, used cloud-based quality applications to onboard all manufacturing partners and collaboratively author product specs, quality agreements, and other critical documents. It also implemented a compliant digital archive of validation records. Contract development and manufacturing organisations (CDMOs) are also establishing their own foundation for process consistency and compliance using modern quality systems. 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, some companies benefit from process improvements and use quality as a strategic asset rather than a cost center.

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

A More Connected, Digital, Proactive Future

The industry's goal is to accelerate discovery and access to new therapies and improve patient outcomes. Digital cloud technology can help make this happen by bringing together departments, systems, teams, and geographies. Robust technology that leverages and encourages industry standards, automates processes, and meets regulatory requirements, offers a path from reactive to proactive quality management.

However, the proper foundation must first be established, with a cross-functional view and seamless, standardised processes. How you get to that foundation via localised projects or a 'big bang' effort is up to you, but once you do, powerful tools are there to automate processes and bring more insights from quality data to improve business results.

REFERENCES

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