Are These 5 Misconceptions Keeping You From Modernizing QC?

Lab capabilities are advancing fast, but progress could be undermined by legacy QC technology infrastructure.

Biopharma organizations have to balance competing forces as they approach commercialization. From the early stages of drug development, their teams must be ready to scale their activities efficiently without adding cost or slowing time to market. However, scientific advances in new modalities mean products are more complex and costly to manufacture and test. Given the increasing regulatory scrutiny of virtual biotech, even sponsor companies outsourcing these activities must efficiently scale their external partner and quality control (QC) oversight.

To operate effectively, most companies strive to end their teams' reliance on paper-based processes and introduce better data management. Yet addressing specific QC challenges one at a time often leads to a collection of point solutions, each with its own set of problems.

Some systems are difficult to maintain or connect with existing technology; others are not user-friendly. The impact is that QC staff are forced to duplicate their data entry and navigate multiple disjointed systems to execute a single work process. Some might default to paper-based activities to compensate, which undermines operational efficiency and inspection readiness.

Legacy and siloed systems burden QC
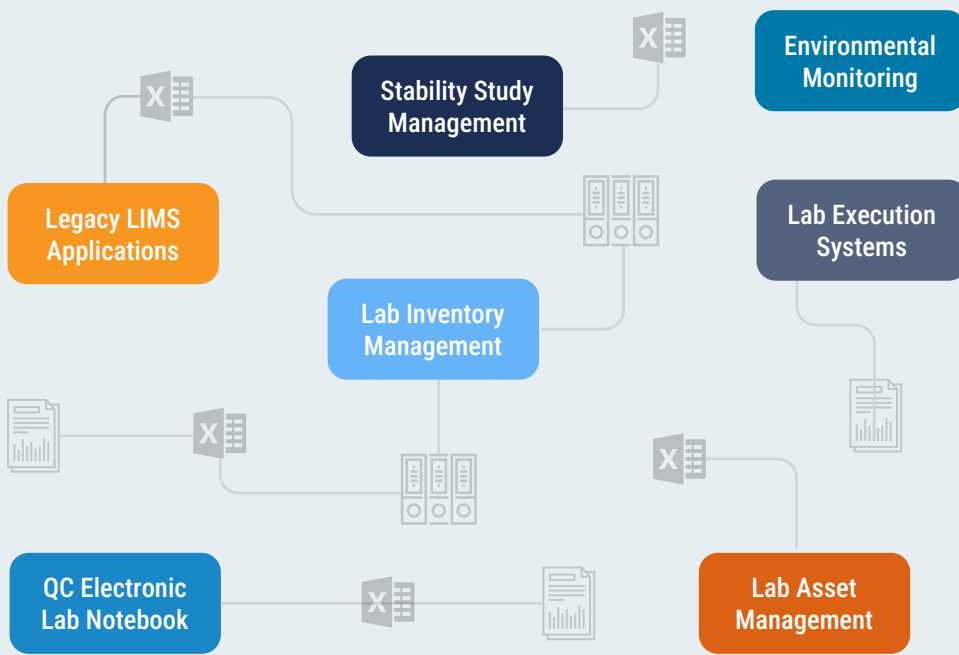
Disconnected
QA and QC systems

High complexity
and technology cost

Inaccurate and
unreliable test execution

Poor lab productivity
and user experience

Removing obstacles on your path to modern QC

Although quality assurance (QA) and QC business processes are connected, the legacy technology underpinning them is not. To manage these tensions, your teams need to be able to collaborate and access data within the same platform. A modern and connected laboratory information management system (LIMS) should increase digital collaboration, reduce the risk of errors, and enable the whole organization to move on from paper-based processes.

In this article, you'll learn about common misconceptions hindering change — and why moving past them early is a competitive advantage when preparing to commercialize. With all quality and manufacturing data available in one place, companies can improve lead times and testing time, as well as enhance inspection and audit readiness.

60-70%
Reduction in lead times when QC labs improve agility and shorten testing time

Source: McKinsey & Co.

Relying on Veeva Vault LIMS to ensure supply at Civica Rx

Agile operations are crucial for Civica Rx, a nonprofit generic drug manufacturer established to ensure U.S. patient access to low-cost drugs and prevent drug shortages. Explaining why Civica embraced Veeva's cloud-based LIMS to modernize its QC operations, Chief Manufacturing and Supply Chain Officer Jay Benson says,

"We guarantee generic drug volumes for our partner hospitals and health systems, so having a cloud LIMS solution is a top priority."

MISCONCEPTION

A QC LIMS only benefits commercial-stage biopharma

REALITY

Return on investment is tangible from an early/clinical stage

Biopharma companies in the early stages of drug development may view implementing a LIMS as a distant priority, but relying on paper-based, manual QC processes presents significant risks. Paper records are error-prone and inefficient, while manual QC processes prevent companies from scaling their operations as they progress through clinical and plan for commercialization.

Implementing a LIMS before commercialization offers tangible benefits. Using a LIMS during the clinical stage streamlines operations for clinical batch release and product stability, making it easier to scale as the number of products, trials, release markets, and manufactured batches increases. As you progress through development, your organization will be able to automate labor-intensive tasks, such as generating reports and assembling regulatory submission content.

Once you've made a regulatory submission, you can expect a regulatory inspection. A LIMS is a core component of the six principal quality systems used to demonstrate Good Manufacturing Practices (GMP) controls. Adopting a solution early helps enforce these controls to improve inspection readiness — and increase confidence in inspection performance.

Implementing a LIMS during the clinical stage allows your organization to streamline key business processes, use automation for better data insights and reporting, and create the foundation for scalability during commercialization.

IMPACT OF LIMS FOR YOUR ORGANIZATION

- Scale easily during clinical stage
- Automate labor-intensive tasks
- Improve inspection readiness and confidence
- Create a foundation for commercialization

MISCONCEPTION		REALITY
✕	**2**	✓
All cloud-based LIMS are equal		**True SaaS LIMS are current and deliver continuous innovation**

It's a legacy perception that all cloud-based LIMS are the same — namely, modern applications accessed through the web, with infrastructure in the cloud. In reality, companies increasingly delineate between cloud-hosted LIMS and software-as-a-service (SaaS) LIMS.[1]

Legacy solutions were commonly built on outdated client/server architecture but are now often vendor-hosted to mimic a cloud solution. As these solutions are implemented with a fixed configuration, they can quickly become stagnant and require periodic large version upgrades. Because they are customer-specific client/server installations, the full burden of IQ/OQ/PQ validation falls on the customer.

A true SaaS LIMS offers significant advantages over legacy solutions. Because they are always current, they deliver continuous value to your organization through regular updates and innovations. They come with industry-standard workflows that can be tailored to your organization's specific needs. As they are already fully IQ/OQ validated, this reduces your validation accountability to a PQ of the configuration changes made to facilitate your specific business process. This ensures your organization benefits from ongoing enhancements (without needing major upgrades) and your system is aligned with the latest QC innovations.

IMPACT OF LIMS FOR YOUR ORGANIZATION

Continuous business value through updates

Industry-standard workflows

Reduced validation accountability

[1] Clarkston Consulting, '2024 Industry Trends: LIMS', 2024

MISCONCEPTION

Replacing paper-based lab execution requires an LES or ELN

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REALITY

Using one system for execution and traditional LIMS capabilities increases analyst productivity

Test method execution is fundamental to laboratory operations, and a key component of the standard QC business process. Traditionally, biopharma companies used standalone solutions, like laboratory execution systems (LES) or electronic laboratory notebooks (ELNs), to manage test execution digitally and replace paper-based methods. However, these systems usually involve additional costs for implementation, configuration, and maintenance, and the data silos they create require complex integrations to resolve.

50-100%
Productivity improvement when well-performing labs go paperless and optimize testing

Source: McKinsey & Co.

Incorporating test execution directly within the LIMS application simplifies the analyst experience, which enhances accuracy and efficiency to improve right first time. It also reduces your QC technology footprint. Modern LIMS platforms unify LIMS, ELNs, and LES,[2] and empower your lab to transition fully from paper by consolidating the entire process into a single application spanning planning, sample and materials management, execution, data review, and reporting.

Using one system for execution and traditional LIMS capabilities would significantly improve lab efficiency and boost user productivity, transforming the way your QC lab operates.

IMPACT OF LIMS FOR YOUR ORGANIZATION

Reduce the QC technology footprint

Simplify analyst experience

Transition fully from paper

[2] Axendia, 'Musings on the Connected Lab', March 2024

MISCONCEPTION

Connecting QA and QC technologies requires costly integrations

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REALITY

Unified QA and QC is readily available off the shelf

QC and QA are highly interconnected within the end-to-end quality business process, but legacy technology failed to mirror these connections. To address this, some companies attempted complex custom technical integrations between LIMS and their quality management systems (DMS, QMS, LMS), but these can be fragile and expensive to maintain. Others used manual paper-based processes, resulting in reduced visibility and efficiency.

Unified industry cloud solutions eliminate the need for expensive custom integrations and paper-based workarounds because they inherently connect the end-to-end business process.

By adopting a LIMS solution natively connected to your core quality business processes, you can leverage controlled content like methods and specifications within your test execution and review. You'll also be able to automate lab investigations and change controls, as well as connect GMP training qualifications to lab activities.

This unified approach facilitates data sharing across applications and improves the likelihood of achieving accurate, right-first-time results. Your organization will be able to ensure that work is assigned and executed fully compliantly without the burden of custom integration.

IMPACT OF LIMS FOR YOUR ORGANIZATION

Eliminate custom integrations and paper-based workarounds

Automate lab investigations and change controls

Ensure work is assigned and completed compliantly

5

LIMS isn't relevant to sponsors without labs that outsource manufacturing and QC

A GMP-compliant, QC-focused LIMS can optimize QC partner oversight

As sponsors increasingly outsource to achieve scale and access specialized expertise, they need robust systems to ensure their external partners adhere to stringent quality standards. Scientific advances have led to increasingly complex pharmaceutical products being developed that rely on extensive supply chains. As a result, some virtual organizations that outsource their manufacturing and QC activities may find it challenging to maintain quality oversight while scaling their businesses.

Navigating this complexity requires a meticulous approach to oversight and coordination, ensuring every stage of production and QC meets the necessary standards for the safe, effective release of pharmaceutical products. Compounding the challenge, managing data across various formats and sources from external partners is labor-intensive and error-prone and can put sponsor organizations at risk of non-compliance.

A LIMS that acts as an extension of a quality management system (QMS) can effectively manage and control external QC data. Having the correct data structure, workflows, and data security could save hundreds of hours typically spent on consolidating, analyzing, and reporting. A LIMS in this environment can assist organizations with partner oversight to improve inspection readiness.

IMPACT OF LIMS FOR YOUR ORGANIZATION

Reduce risk of process and data errors when outsourcing

Oversee compliance of external partners

Single source of data saves hours of manual work

Forge Biologics, a contract development and manufacturing organization (CDMO), used to follow a labor-intensive process for generating certificates of analysis and testing (CoAs and CoTs), which confirm that products meet customer specifications. Analysts and managers had to review hundreds of pages of documentation to verify the results passed acceptance criteria and that testing was performed correctly. Once testing was complete, they had to add data manually to the CoA forms and scan all raw data. After the CoA was populated, a manager would review all associated raw data to ensure that numbers aligned with client specifications and other documents in the QMS.

Since Forge started using Veeva Vault LIMS, the CoA is electronically aligned with specifications so that CoA fields are filled out automatically. This saves 20 to 30 hours of review and data input each time a product is manufactured.

> "[Vault LIMS] is saving our analysts countless hours. It's saving my management team hours and driving a lot of benefits for our clients, who now have more visibility into their data and easier access to results."

Andrew Laughhunn,
Senior Director of QC Analytical Testing, Forge Biologics

Learn more about why Forge chose Vault LIMS.

20-30 hrs

Time saved in review and data input with Vault LIMS each time a product is manufactured

Leaving behind legacy thinking

Your organization may recognize some or all of these misconceptions. When simplification is the guiding principle, new capabilities can be incorporated without large system upgrades.

A holistic approach doesn't require you to do everything at once. Instead, the priority is bringing QA and QC processes together, making it more convenient for end-users to complete their work in a single system and reducing the risk of errors or defaulting to manual processes.

Greater agility will reduce time to market, and be a competitive differentiator as you move to commercialize. This way, your organization can focus on maintaining its culture of quality excellence.

Learn more about Vault LIMS ↗

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