Building the Business Case for LIMS

Scientific advances in biologics and new modalities have produced therapies that are more complex and costly to manufacture and release.

For life sciences companies racing to market with limited resources, the opportunity costs of relying on manual, paper-based quality control (QC) processes encompass operational inefficiency, scalability challenges, and compliance risks.

A modern QC laboratory information management system (LIMS) can help you avoid opportunity costs, whether you perform manufacturing and QC testing in-house or manage a complex ecosystem of external manufacturing and QC partners. It also directly contributes to your business goal of speeding time to market.

Implementing a cloud-based solution provides industry-standard digital workflows, GMP-compliant data management, automated reporting, and connectivity with other critical quality systems. This means your organization can increase efficiency without adding headcount, as well as improve right first time (RFT) and inspection readiness.

The competitive advantages of adopting a solution early include frictionless scalability, improved compliance, and lower total cost of quality — all of which mean your organization can focus on bringing treatments to patients faster.

As you develop the business case for a QC LIMS, your team must decide between legacy on-premises solutions (typically built on client/server architecture and now sometimes vendor-hosted) or true Software-as-a-Service (SaaS).

Given that each solution is associated with different costs, budget expectations, timings, and resource requirements for managing implementation and ongoing ownership, a strong business case should explore these differences and be specific about the rationale and expected return on investment (ROI).

The results of these comparisons may surprise you. For instance, SaaS solutions are provided on a subscription basis and eliminate the burden of hardware procurement and maintenance, heavy validation, and continuous upgrade cycles. One global biotech found when it calculated ROI for the 12 months ahead, the added capacity to its business exceeded the estimate for its on-premises system. The company's director of Veeva platform explains: "We saw a higher projected ROI with Veeva LIMS than for the legacy system."

50–100%

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

Source: McKinsey & Co.

1. Make do or modernize

The opportunity costs of manual QC

Many organizations rely on a paper-based, manual QC process despite its negative impact on lab output and quality. Paper record management is error-prone and resource-inefficient, while manual QC processes create bottlenecks that are difficult to identify and resolve. Disconnected workflows and data impact right first time (RFT), resulting in longer batch cycle times.

The opportunity costs of disconnected processes go beyond the internal QC lab. Sponsors that outsource manufacturing and QC activities to external partners manage large volumes of data across various formats and sources. Yet they remain responsible for ensuring that every stage of production and QC meets the required standards for the safe, effective release of pharmaceutical products. Unless your company has clear data and status visibility across its partner relationships, it may be at risk of non-compliance.

If you're developing products within the late clinical stage, manual processes introduce risk at a pivotal time as you prepare your submission under regulatory scrutiny. A LIMS helps to derisk, as it serves as a core component of the principal quality systems used to demonstrate Good Manufacturing Practices (GMP) controls. Adopting a solution early enforces these controls for improved inspection readiness.

OPPORTUNITY COSTS OF MANUAL QC

Lab output goals at risk

Decreased audit and inspection readiness

Longer cycle times

2. Choose once, choose right

Your business case should evaluate LIMS solutions on their system architecture and domain focus.

System architecture:

Legacy LIMS applications are implemented with on-premises hardware that consumes significant procurement and maintenance attention. Further, they require expensive and disruptive periodic version upgrades. Due to their customer-specific implementations, they are often highly customized one-off solutions, so the customer bears the full burden of the installation, operational, and performance qualification (IQ/OQ/PQ).

The total cost of ownership is often higher than anticipated due to infrastructure and validation costs, as well as a large IT footprint for integrations and ongoing maintenance. This approach is not always viable for organizations with lean IT teams.

Some legacy applications have shifted to a hybrid solution, which means they have the same architecture as on-premises solutions but are vendor-hosted in a private cloud. Private cloud solutions shift the responsibility for security, access, and (in some cases) general maintenance from the customer to the vendor. However, they do not fully address the challenges with on-premises software, such as scalability, maintenance costs, customer-specific customization, and perpetual version upgrades.

A true SaaS solution is built with its 100% vendor-managed infrastructure in the cloud, so it is always current and delivers continuous value to your organization through regular updates and innovations. Industry cloud solutions provide industry-standard workflows and best practices that can be tailored to your organization's needs, resulting in rapid implementation and streamlined maintenance. Already fully IQ/OQ validated by the vendor, these solutions reduce your validation accountability to performance qualification (PQ) of the configuration changes specific to your business process, reducing ongoing maintenance costs and the need for a large IT footprint.

Domain focus:

Many LIMS solutions were designed to serve several lab-centric industries and scientific domains instead of being tailored to the needs of a particular industry. You should assess whether their current and future capabilities are optimized for your QC lab and C-level objectives within quality manufacturing.

Instead of prioritizing innovation that aligns with your needs, a vendor with a general lab focus will work to provide general laboratory features and may have commitments to other industries.

3. Focus on your competitive advantages

A strong business case for a modern QC LIMS will highlight expected outcomes directly tied to C-level objectives. As modalities and product complexity increase, being able to shorten cycle times helps you to stay competitive and improve patient care. So, make sure to explain how your recommended solution reduces time to market through accelerated batch release.

You could emphasize how a SaaS QC LIMS supports your company's commitment to high product quality while reducing the total cost of ownership; or why a GMP QC-focused solution simplifies compliance and readiness for new regulations.

If you're in the clinical stage, implementing a SaaS QC LIMS will make it easier to scale as the number of products, trials, release markets, and manufactured batches increases. Using automation and controlled data to assemble submission content, your company will move faster than competitors that assemble data and content manually due to their reliance on paper-based QC management.

4. Identify the right value metrics

A modern QC LIMS application that supports a bigger footprint of QC business capabilities can generate a quick return on investment.

For example, test method execution is traditionally completed in paper notebooks or standalone applications, such as laboratory execution systems (LES) or highly customized electronic laboratory notebooks (ELNs). If you are currently using an LES or ELN, a modern solution that incorporates more digital capabilities (such as embedded test execution) immediately reduces paper execution sources, your existing QC technology footprint, and ongoing maintenance costs.

Your business case should specify metrics and timescales for generating value in the short term (e.g., lower costs, rapid implementation, greater data accessibility for external stakeholders) as well as longer-term advantages, such as greater accuracy (from replacing paper and simplifying applications for analyst interaction) and quicker batch release.

COMPETITIVE ADVANTAGES OF TRUE SaaS:

	Lower TCO
	Scalability from clinical stage
	Faster batch release

Verve: Digital-first quality in the QC lab

Leveraging Veeva LIMS, gene editing pioneer Verve Therapeutics moves with speed, from receiving samples of externally manufactured product material into the lab to testing and approving QC results and generating an automated certificate of analysis (CoA). Once QC activities are complete, the Verve QA team is notified to review the data, driving an efficient batch release.

Verve uses a unified platform for quality process and document management, GxP training, and quality control testing. This ensures its QC teams always work from the right version of the test method procedure and that analysts are appropriately trained on a method before execution. "Having LIMS connected to QMS and training ensures only people who are appropriately trained can run the assay," notes Por Bjerke, senior manager of quality control internal operations.

Being on the same platform with partners and suppliers means external teams have access to the current version of a CoA for a drug substance, mitigating shipping delays. "Instead of emails back and forth, or popping by someone's desk and they are not there, people can really work from anywhere. They get the notifications right away, so there is no time lost," explains Bjerke.

Verve anticipates a significant improvement in RFT by reducing the impact of human error. Built-in process and data verification checks, and audit trails, within Veeva LIMS flag possible numerical typos, missing information, and calculation mistakes, reducing the back-and-forth within teams to confirm data integrity and correctness.

Value metrics:

- Out-of-the-box (rather than custom) configuration
- Improvement in initial approval compared to paper

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> **We are designing the system with the end game in mind, so it is out of the box rather than custom configured. We're able to grow with the system and while we grow, we can incorporate the other modules that Veeva has."**
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> **Por Bjerke,**
> Senior Manager, Quality Control Internal Operations, Verve Therapeutics

Learn how Verve Therapeutics puts digital-first quality at the heart of its QC lab.

Global biotech: Scaling ahead of commercialization

A key differentiator for Veeva LIMS is that it can be incorporated into existing workflows without business disruption. After receiving its Health Authority (HA) approvals, one biotech realized its legacy system couldn't adequately support rapid product expansion or global launches, so it chose to modernize its workflows and data control with Veeva LIMS.

The biotech maintained operational continuity while driving greater efficiency as it moved to Veeva LIMS. Certificates of analysis could be generated directly within the Veeva LIMS application and made immediately available for quality and regulatory professionals to access in the same way as before, from within Veeva QualityDocs. "Jaws were literally dropping as we saw how smooth the transition would be for something like CoA," explains the company's director of Veeva platform.

A familiar interface has improved user adoption, which had stalled at five percent for its legacy system. The biotech was confident that Veeva LIMS would be a better fit because its workforce knew the Veeva ecosystem in quality (QualityDocs, Training, and QMS), clinical (Veeva eTMF), and regulatory (Veeva RIM), making navigation easier in Veeva LIMS **[Figure 1]**.

Value metrics:

- Increased capacity for product launches
- Higher user adoption
- Business continuity during LIMS transition

Read why one global biotech broke with the status quo to redefine LIMS.

Figure 1: Making the case for Veeva LIMS

No formal RFP created
Veeva product was a natural fit

Current Veeva Platform
Quality (QualityDocs, Training, QMS), Regulatory (RIM), and Clinical (eTMF)

Considerations on adopting a new LIMS

- ✓ **Shorter implementation time:** Potential to implement new capabilities more quickly
- ✓ **Integration:** Evaluated how easily new LIMS solutions could integrate with existing processes and systems
- ✓ **Future capabilities:** Considered the scalability and flexibility of new solutions to meet future business needs
- ✓ **Resource reallocation:** Need to use people strategically for higher value tasks

Source: Global biotech

5. Optimize resourcing to deliver value quickly

Executive sponsor:

Every business case needs an executive sponsor. Their role is to secure board-level buy-in for your solution by conveying the rationale and benefits, addressing any concerns, and helping leadership move to a decision. As advocates for QC modernization in the wider organization, they ensure the initiative is viewed as a business transformation rather than an IT project.

Implementation resources:

A SaaS QC LIMS implementation typically requires fewer IT and QA validation resources than a traditional legacy LIMS implementation, as there is no on-premises installation, heavy customization, or IQ/OQ validation to perform.

Additionally, choosing Veeva LIMS avoids custom technical configurations as it is inherently connected with other quality systems (e.g., DMS, QMS, LMS).

A project manager will spend a fraction of their week on the project **[Figure 2]**, and you'll only need a few business process owners during configuration to make decisions for key functional areas (supported internally by a couple of business SMEs).

Figure 2: A guide to getting resourcing right

Role	Dedication
Executive Sponsor	**5% dedication per week for the project duration**
Project Manager	**25% dedication per week for the project duration**
Business Process Owner One key decision-maker per functional area	**50% dedication per week during the configuration phase**
LIMS Users / SMEs One or two influencers per functional area	**10-25% dedication per week during the configuration phase**
Training & OCM Leads	**20% dedication per week during training & deployment phases**
QA Validation Lead	**50% dedication per week during the validation phase**
IT Integrations Lead Technical resource coordination, integrations, systems access	**25% dedication per week for the project duration**

Source: Veeva Systems

6. Embed new ways of working

As your SaaS solution is deployed, your organization may grapple with how best to manage change consistently during and after the roll-out.

Change management for SaaS solutions is designed not to be onerous and to minimize business disruption. A good place to start is identifying the standard operating procedures (SOPs) that may need to be revised in your content management solution. Next, leverage your digital training solution to customize and distribute training materials to end-users (who are already accustomed to the training interface) to support adoption. Vendors can help with other post-implementation enablement (such as assisting with new features) but should be transparent about the additional costs of a managed service.

Evolving ways of working may also require changes to your operating model, support securing buy-in to new processes, or expertise in quantifying and tracking the value realized by the organization.

Speak to Veeva Business Consulting about organizational change management during a Veeva LIMS implementation.

CASE STUDY

How to make a head-and-heart decision

Disrupting the status quo can trigger emotional resistance. One global biotech director describes the reaction to switching to a modern LIMS at an IT workshop: "We were reviewing tactical and strategic ideas for next year, and I put up a sticky note saying 'Veeva LIMS' on the board under 'strategic'. I will never forget the look I got across the room. We got a lot of 'nos' right there."

Instead of seeking harmony, she advises understanding team emotions and objections. End-users will have valid concerns that the business case should address. Inviting them to join demos puts the onus on your technology partner to prove their worth, as skeptics ask the toughest questions and will be among the most difficult to impress.

After the second demo of Veeva LIMS, the director recalls receiving a message from a key stakeholder saying, "This looks annoyingly good", reinforcing confidence in the decision to switch.

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Our decision to move to Veeva LIMS was driven by practical and emotional factors. We've now made a choice that we think will position us for future success."

Director,
Veeva Platform, Global biotech

Letting go of legacy thinking

A modern and connected QC LIMS increases digital collaboration, reduces the risk of errors, and enables your organization to move on from paper-based processes.

By choosing a SaaS QC LIMS with a GMP QC focus, your quality function can prioritize its core activities rather than building and maintaining technology systems. Greater agility will reduce time to market and be a competitive differentiator as you commercialize.

Learn how to modernize
QC with Veeva LIMS.