Veeva

WHITE PAPER

Learn, Confirm, Then Scale

A leader's guide to transforming quality control

Legacy lab applications not only stifle quality control (QC) transformation but also hinder large biopharma organizations from advancing toward the "lab of the future".

It's a familiar scenario when pursuing digital transformation in the QC lab: no shortage of options yet a lack of choice. There are dozens of lab software and instrument vendors, as well as on-premises point solutions. Yet the industry still has to navigate a tangled web of infrastructure, layers of customized software, and complex integrations.

Once implemented, organizations contend with a higher-than-expected total cost of ownership rather than an immediate and tangible return on investment (ROI). This is due to unexpected infrastructure and validation costs, and the large IT footprint required to maintain custom integrations, configuration, and master data. Because traditional on-premises software quickly becomes stagnant, IT and quality leaders have to make incremental, costly, and disruptive 'major-version upgrades' every few years. These do not solve the underlying problem of stagnant technology and consume budgets that could otherwise be used for innovation.

Legacy lab technology will not support the industry to make the most of exciting opportunities on the horizon: from new drug modalities and scientific discovery, to investing in advanced manufacturing sites. To achieve its potential, the lab of the future has to be something different: a natively-connected digital environment, built on simplified and standardized cloud technology, that is easier to deploy, own, and maintain. Critically, it must be "always current" and adhere to the latest regulatory requirements so it can benefit from innovations and updates (such as agentic AI) without disruptive major-version upgrades.

When fear means missing out

Biopharma organizations often assume that implementing new technology means starting from scratch, which risks replicating past IT failures. These expensive and never-ending IT projects were characterized by extensive customization and a burdensome validation process to satisfy regulatory requirements.

No quality organization wants the business disruption and resource capacity issues that come with those types of IT projects. And since legacy systems are still functional, it would be difficult to make the financial case for a new deployment. The assumption is there will be significant sunk costs (e.g., detailed customization, ongoing master data investments), as well as a large internal IT footprint for maintenance afterward. Change fatigue could also negatively affect user adoption.

The industry is missing out on a modern way of working in QC because it is reluctant to abandon the status quo of legacy laboratory information management systems (LIMS). Organizations shouldn't worry: cloud-based LIMS solutions directly address their concerns **[Figure 1]**.

Modern SaaS solutions like Veeva LIMS collapse the fragmented landscape of LIMS and laboratory execution systems (LES). By seamlessly connecting to adjacent quality assurance (QA) workflows and data, Veeva LIMS reduces the need for complex architectures and custom integrations. It delivers continuously for the business through industry-standard digital workflows, GMP-compliant data management and reporting, and standard connectivity without complex custom code.

For biopharma organizations that want to innovate in QC but are fearful of replicating past IT failures, a different path can derisk their transformation.

FIGURE 1:

Cloud-based SaaS LIMS offers a modern way of working

MODERN LIMS PRODUCT

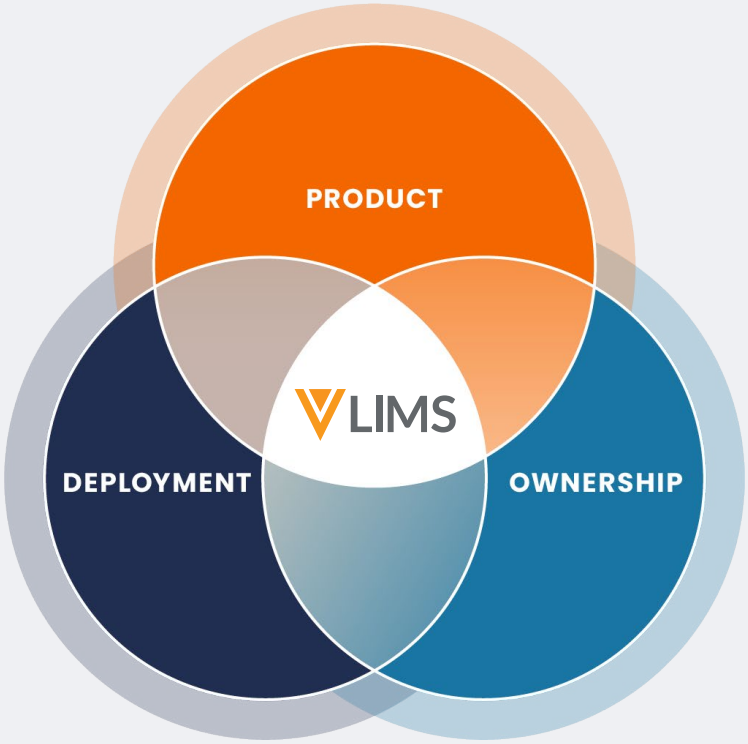
- Unified QA & QC
- Simplified
- Standardized

MODERN CLOUD DEPLOYMENT

- Rapid cloud implementation
- Configuration without custom code
- Vendor IOQ validated

MODERN SAAS OWNERSHIP

- Always current
- Continuous innovation 3x/year
- Appreciating asset



Source: Veeva Systems

Lab innovation on hold

Quality leaders know what an optimized digital lab should look like. Until recently, however, the QC lab was primarily served by antiquated on-premises solutions with layers of appended technology, hindering modernization **[Figure 2]**.

Legacy on-premises solutions require time-consuming and resource-intensive installation, customization, and validation. Integrating systems and instruments is challenging and uses custom code. Sites are also usually compelled to rely on custom code and so implement different processes and data structures, complicating the application of AI.

True cloud SaaS solutions reduce technology debt. As they don't use custom code and are reliably configured to your organization, the validation burden is lower. Integration capabilities are robust and configurable: some can even natively connect with other systems, processes, and data on a platform of applications. Both IT and the lab benefit from a consolidated, simplified, and standardized experience. Being always current means AI capabilities are easier to leverage.

FIGURE 2:

What's the difference between legacy and cloud SaaS LIMS?

	Legacy on-premises solutions	Cloud SaaS solutions
Installation	On-premises installation	Multitenant cloud
Lab user experience	Inefficient, complex, multiple applications	Paperless, simplified lab experience
GMP-compliant	Further customization needed for GMP compliance	Already aligned with industry standards and regulations
Validation accountability	Mostly with the customer	Mostly with the vendor
Customization	High customization to meet business processes, regulatory requirements	No custom code; point-and-click configuration
Integrations	More integrations required	Native connectivity with other (quality) applications
AI capabilities	Difficult to leverage	Ready to leverage over time

Source: Veeva Systems

The path to QC lab transformation

For years, organizations have been compelled to invest in implementing, deploying, and upgrading LIMS solutions despite feeling they were ill-suited to future needs.

Abandoning this approach can be daunting, but the industry is now at an inflection point. If they embark on another cycle of major-version system upgrades, organizations could miss out on the potential of AI, promising new therapies and modalities, and the opportunities derived from advanced manufacturing and QC sites.

To derisk this transformation, organizations must move quickly to confirm their business and technology strategy. And while the full application of AI in the QC lab is still a few years away, decisions taken today will determine how effectively teams leverage these capabilities in the future.

Persevering with systems that cannot scale with your organization will constrain lab capacity and put business goals at risk. Many large biopharmas would prefer to investigate other technologies over yet another upgrade to their legacy environment. However, they are wary of breaking with the status quo because of their prior painful experiences.

OPPORTUNITIES ON THE HORIZON

Expand into new markets and TAs

Add manufacturing sites

Expand supply chains

Leverage AI capabilities over time

Better strategy to deploy a modern LIMS

Learn, confirm, then scale

For global biopharmas, a rapid and small-scale 'learn and confirm' program is an effective alternative to a wholesale 'rip and replace'. Organizations that successfully piloted a modern LIMS solution (with a cloud SaaS deployment and ownership model) experience benefits at a fraction of the cost of introducing new technology following the usual (slow) 'big bang' approach.

BENEFITS INCLUDE

✓ Reduced long-term operational risk

✓ Improved stakeholder trust and buy-in

✓ Greater conviction in the wider deployment strategy

Successful programs achieve production use in an environment with wide business applicability, adding measurable business value. Because a cloud-based LIMS will start generating data almost as soon as it comes online, you'll be able to track real-world key performance indicators (KPIs) and organizational benefits, strengthening the business case and supporting expansion across the global footprint **[Figure 3]**.

There are several ways to initiate a learn and confirm program capable of meeting business goals and objectives without disrupting existing priorities. The four common phases are:

01. Define your strategy

02. Identify target pilot location(s)

03. Move with speed

04. Scale

FIGURE 3:

A redefined 'learn and confirm' approach

Source: Veeva Systems

01 Defining your strategy

First, set your strategy for the learn and confirm program with clear, ambitious objectives for transformation. Once defined, this will be your blueprint for proving the value of new technology and building the business case for global replacement of legacy solutions.

Moving at the "speed of cloud" will result in a quicker time to value, so commit to rapid and agile execution as you get started. Instead of following traditional software implementation methodologies, opt for a proven cloud vendor implementation approach. This prioritizes quick, iterative delivery with an effective feedback loop.

To streamline implementation and maximize returns, aim to leverage simplified, industry-standard processes available within the SaaS application. While tempting, avoid replicating custom legacy workflows or other requirements that deviate from industry standards. Remember, the goals are to modernize, support global alignment, and simplify and reduce the costs of long-term ownership.

Project objectives should align with long-term business strategy, so that effort is directed toward the organization's future state vision. The primary output of the pilot is real-world data for a global replacement business case, including metrics on process optimization, implementation speed, adoption, and reduced total cost of ownership (TCO).

Finally, assess the partnership and influence on your vendor's product roadmap and evolution. If your organization is considered a key partner, the vendor is more likely to prioritize product development that addresses your transformation needs.

Two principles should guide your strategy:

01. **Compartmentalize the pain of legacy technology.** Ensure the pilot is a contained effort that minimizes disruption from old ways of working.
02. **Keep an open mind.** Be flexible and accept change in order to simplify and optimize.

02 Identifying target pilot location(s)

Successful programs hinge on choosing the right pilot locations. The selection process should commence immediately after executive engagement and strategic alignment.

When identifying potential locations for your pilot, consider site leadership, culture, the state of operations, as well as the desire for change and innovation. Sites that fulfil specific criteria usually lead successful pilots.

- ☑ Smaller and less complex
- ☑ Greenfield
- ☑ Underserved by existing technology stacks
- ☑ Acquired and other inorganic scenarios
- ☑ Smaller-scale clinical or manufacturing operations

Choosing your pilot site

What types of sites deliver a strong proof of concept? The correct answer will vary by organization but there are common indicators **[Figure 4]**.

01. **Look for a compelling event**
Approached opportunistically, a business event could be a catalyst for doing something differently: for example, an acquisition, a greenfield site, a paper-based site, or aging systems that would entail yet another upgrade.

02. **Identify your change champions**
People and culture are an underestimated component of a successful pilot. Those open to (and excited about) change may even raise their hands to lead the pilot.

03. **Choose a representative site**
Before scaling globally, it's worth focusing on sites that accurately reflect your primary line of business and global processes. If company revenues are mostly in pharma, pick a finished product testing facility (rather than, say, a consumables testing site).

04. **Feed the business case**
A pilot site must be capable of generating relevant proof points for quality manufacturing QC. This way, insights will be understood and accepted, adding value to the business case.

05. **Excess capacity is a plus**
Avoid sites with high volumes of work in favor of those with room for improvement on audit readiness and other areas. A site that previously received a regulatory warning letter could be a promising candidate.

06. **Get the location right**
Consider the geographic location of the site relative to where IT and business leadership are situated. Being in the same timezone will facilitate collaboration.

FIGURE 4:

Key questions when choosing a pilot site

Is there a compelling event?

Who would champion this program?

Which sites represent our primary use cases?

What KPIs and proof points do we need to generate?

What's the right size and scale for our ideal site?

Which geographic locations do we need to focus on?

03 Moving with speed

Executing with speed is critical to your learn and confirm program remaining focused and cost effective. Cloud SaaS LIMS enables rapid execution because it has:

- A validated software environment available from Day 1
- Point-and-click configuration activities
- Industry-standard workflows.

Before getting started, you'll need to agree high-level requirements and objectives for your organization, e.g., major workflows to be delivered. Overanalyzing is a common pitfall at this stage. It's more important to be agile than to have a perfect set of requirements, explore every technical option, or conduct exhaustive comparisons. Staying focused will contain the cost of your pilot program to a nominal total investment. In any case, there will be opportunities to refine product capabilities during the program.

Once you've defined your objectives and accepted standard functionality within the technology, you'll be able to make rapid decisions. Lean resourcing will support faster execution further down the line. By prioritizing speed over exhaustive detail, your team will preserve its capacity to learn, confirm, then scale.

04 Scaling across global QC

There is no set timescale for a pilot, but usually there is a stabilization period before roll-out to additional sites.

Analysis from this time will inform how you choose to scale. Perhaps you'll discover wider benefits to your organization from rapid connectivity. Having seen the early impact of SaaS cloud in the lab, you may decide to connect your LIMS solution to other quality applications after deployment (such as content management, learning management, QMS, batch release, and lab equipment); or even to other functions, such as clinical, commercial, and medical.

A cloud-based LIMS will start generating data immediately after your site goes live **[Figure 5]**. As you prepare to communicate your findings, include important KPIs for the post-implementation period and in the short term (e.g., six to 12 months).

FIGURE 5:

Collecting data that counts for your business case

	KPIs	BENEFITS TO THE ORGANIZATION
POST-IMPLEMENTATION	• No. of people maintaining / building master data • Resources spent on planning and executing upgrades • Implementation and deployment timeline and costs • Site adoption rate	• Faster data connectivity and accessibility • Immediate execution
SHORT TERM (6–12 MONTHS)	• Reduction in paper	• Shorter batch cycle time • Faster decision-making • Improved right first time (RFT) • Reduced TCO

Guiding your organization through change

After testing and proving a radical alternative to replacing lab technology, it's time to assess whether your business is ready to operate differently **[Figure 6]**.

01. Prepare the lab for transformation

Lab professionals operate within a demanding environment and must consistently deliver with speed and accuracy. They will require support to manage even temporary disruptions while new technology is being introduced.

Early transparent communication of the vision and case for change creates space for lab users to contribute to the design process. Remember, your champions for the program are likely to be in these teams. You'll also need to assess the readiness of affected groups for change and start mapping impacted processes.

02. Enable your end-users

Because technology adoption is the goal, your lab end-users are the focus of the execution phase. Design and deliver training that sets up new ways of working. Ideally, your curriculum should account for different learning styles (e.g., virtual classrooms, self-guided vs. instructor-led) to maintain high engagement.

Your change champions are critical when cascading communication. Once training is complete, be sure to define, set up, and measure the evolution in end-user adoption.

03. Achieve superior lab outcomes

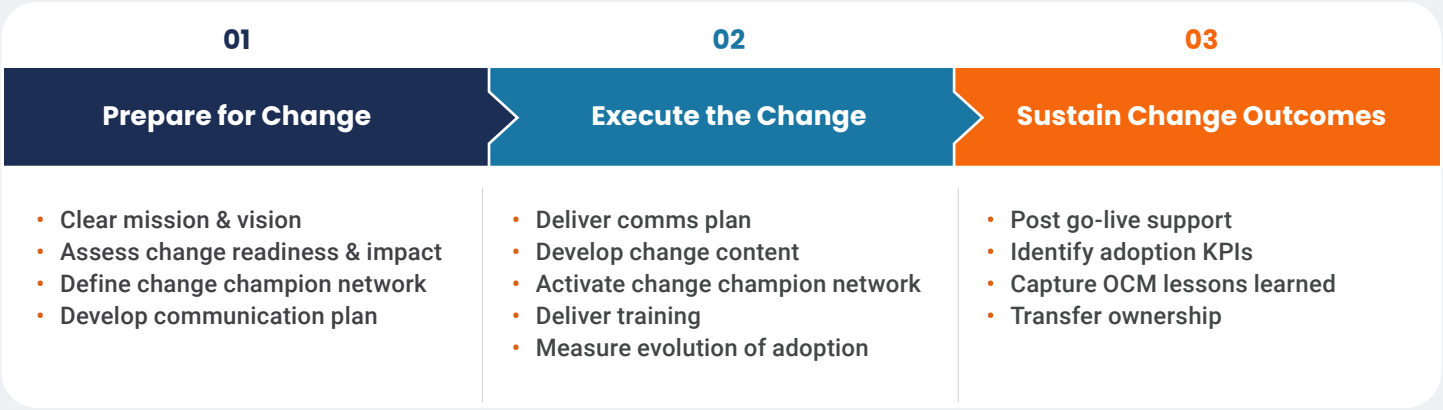
Change management doesn't stop once your LIMS solution has been implemented. To improve user adoption and confidence, your lab users will need opportunities to share feedback, best practices, and outcomes.

Make sure to identify KPIs to measure adoption. Also consider tracking KPIs such as instrument utilization rates, downtime, staff productivity, rejection rates, QC pass rates, and others to demonstrate value realization. Taken together, these should contribute to your organization's understanding of overall ROI, including time to value realization, user satisfaction, and year-over-year savings.

Speak to Veeva Business Consulting about organizational change management during your learn and confirm strategy.

FIGURE 6:

Successful change management is an ongoing process



Source: Veeva Business Consulting

Start small, think big

QC transformation doesn't have to be overwhelming or risky. Organizations following the learn and confirm approach often find breaking with the status quo less daunting than investing in legacy solutions they've outgrown.

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. A comprehensive solution unifies test method execution and traditional lab capabilities, and benefits from rapid connectivity (e.g., to lab equipment, other quality applications), so you'll see impact straight out of the gate.

As a strategy, 'learn, confirm, then scale' turns the page on high-risk global deployment. Starting with just one site helps prove speed of execution and carefully manages the pace of change, setting your organization on the path to a modern LIMS.

Learn how to modernize QC with Veeva LIMS.