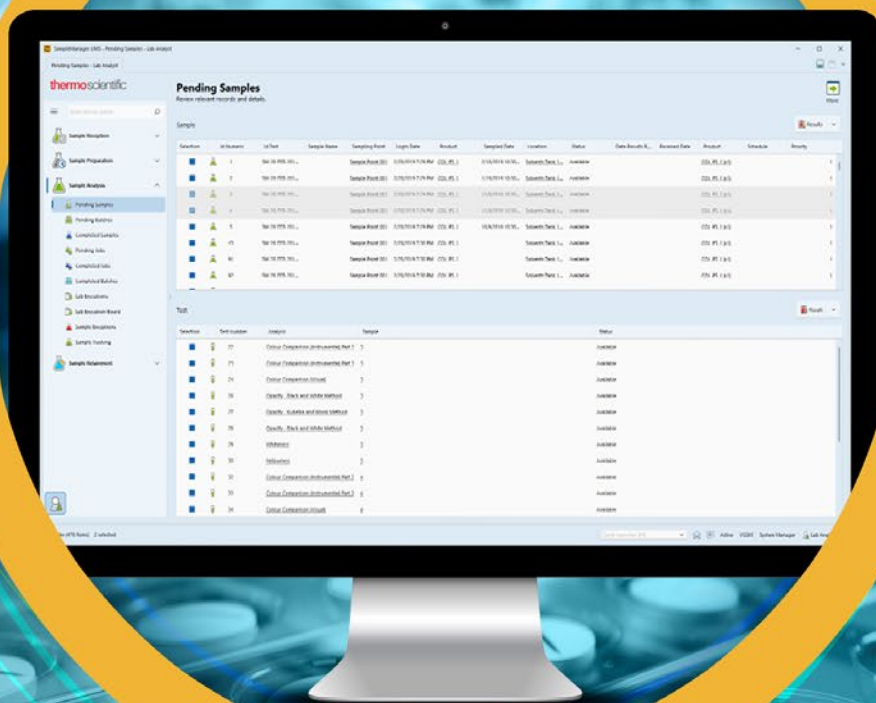




Modernizing pharmaceutical QA/QC laboratories

A practical guide to reducing complexity, increasing confidence, and building a future-ready laboratory

Executive summary

Modernization is an opportunity to strengthen the laboratory, not simply replace a system.

Many pharmaceutical organizations are reassessing whether their existing laboratory informatics environment is equipped to support the next stage of the business. For some, the catalyst is ageing technology. For others, it is the growing effort required to maintain, adapt and extend an environment that has evolved over many years.

This guide explores the practical considerations that support successful laboratory modernization. Rather than focusing solely on implementation activities, it examines the broader decisions that influence long-term outcomes, from defining business objectives and preparing the organization for change to sustaining value after go-live.

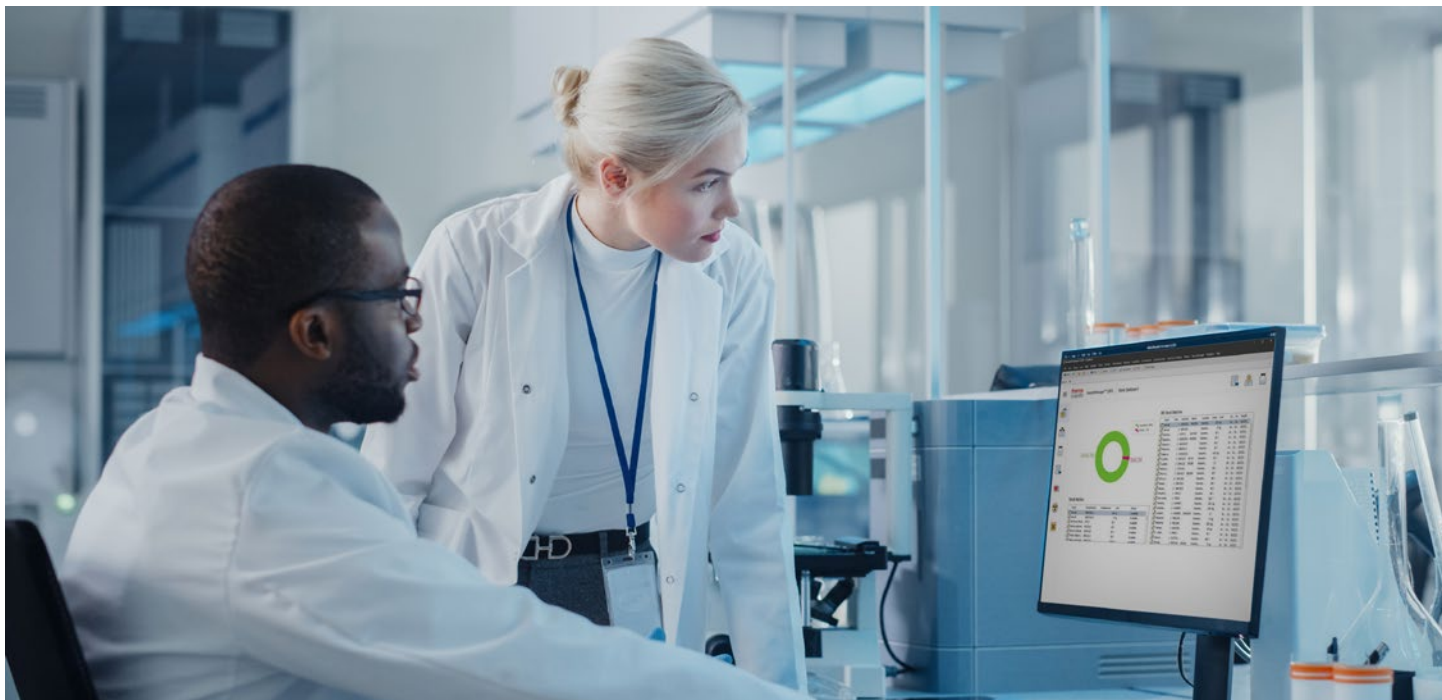
The guide is organized into five parts:

Part I Why modernization matters Page 3 - 6	Part II Planning for success Page 7 - 14	Part III Executing with confidence Page 15 - 19	Part IV Maximizing long-term value Page 20 - 24	Part V Putting modernization into practice Page 25 - 30
Examines why pharmaceutical organizations are modernizing laboratory operations and why modernization is fundamentally different from system replacement.	Explores the planning, governance and organizational decisions that establish the foundation for successful modernization.	Provides practical implementation guidance covering project delivery, data migration, validation and implementation lessons.	Explores how organizations can sustain, expand and continue realizing value long after implementation is complete.	Brings a practical framework to align stakeholders, identify strengths and gaps, and build a shared modernization strategy before implementation begins.

Modernization is not defined by the successful deployment of technology alone. Its lasting value is determined by how effectively the laboratory is prepared to adapt, improve and support the needs of the business in the years ahead.

Part I

Why modernization matters



The pharmaceutical QA/QC laboratory has changed

Laboratories are no longer expected to simply generate accurate analytical results. They are expected to deliver trusted information that supports quality, compliance and operational decision-making across the manufacturing enterprise.

Pharmaceutical QA/QC laboratories have always played a critical role in ensuring product quality. What has changed is the environment in which they now operate.

Today's laboratories support increasingly complex manufacturing operations, generate larger volumes of analytical data and interact with a broader ecosystem of digital systems than ever before. This places greater importance on laboratory informatics environments that support connected workflows, data integrity and operational visibility.

Emerging technologies are adding another dimension to that conversation. As pharmaceutical organizations explore artificial intelligence (AI) and advanced analytics, the quality, accessibility and context of their data become increasingly important.

Preparing for these capabilities starts with establishing a digital foundation that can make trusted laboratory data available for new ways of working as they develop.

As laboratory responsibilities continue to expand, many organizations are rethinking the role of laboratory informatics. Increasingly, the question is no longer how to support today's laboratory, but how to prepare for tomorrow's.

Modernization begins by asking:

What capabilities will the laboratory need to support the business not only today, but in the years ahead?

When legacy environments become business constraints

Most laboratories don't decide to modernize because something suddenly stops working. The need for modernization usually develops gradually, as years of incremental decisions reshape the informatics environment supporting laboratory operations.

Organizations rarely decide to modernize because of a single event. More often, the need develops through a series of well-intentioned decisions. As laboratories evolve, new workflows are introduced, integrations are added and local requirements are accommodated to support changing business needs.

Individually, these decisions often make perfect sense. Collectively, however, they can create an informatics environment that becomes increasingly difficult to maintain, validate and adapt. As complexity grows, introducing change often requires significantly more effort than it once did. Laboratory teams may find themselves managing workarounds, coordinating changes across interconnected systems or investing increasing amounts of time maintaining existing processes rather than improving them.

Modernization therefore should not be viewed simply as a response to ageing technology. It is an opportunity to simplify complexity, improve consistency and create an operating environment that better supports the laboratory's long-term direction.

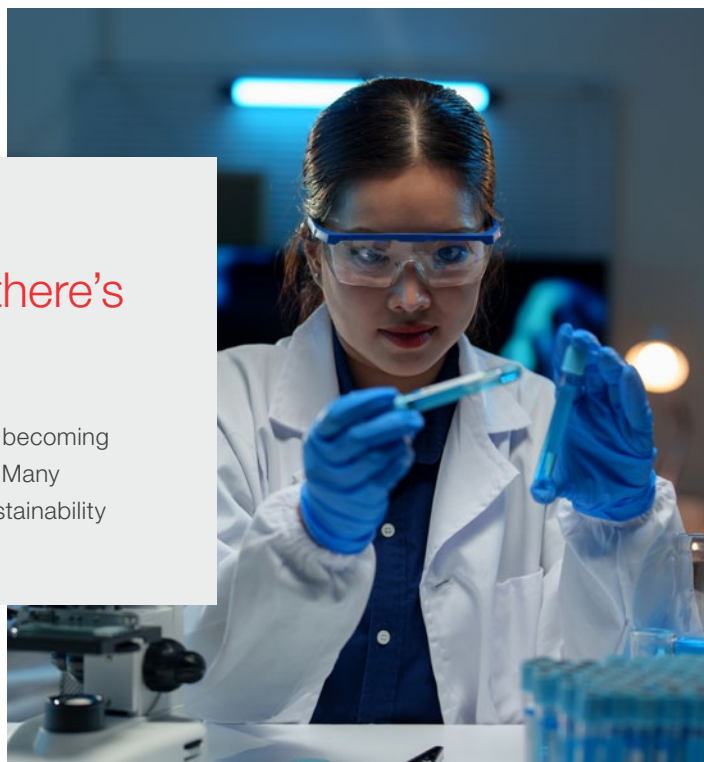
These challenges rarely indicate that an existing system has failed. More often, they suggest that the laboratory has outgrown the operating model on which the current environment was originally built.



Common misconception:

“If the system still works, there’s no reason to modernize.”

Operational systems can continue to function while becoming increasingly difficult to maintain, validate or extend. Many modernization initiatives are driven by long-term sustainability rather than immediate technical limitations.



Modernization is not migration

Replacing a system is a technical exercise. Modernizing laboratory operations is a strategic opportunity to improve how the laboratory works today while preparing for the demands of tomorrow.

For many organizations, the decision to replace an existing Laboratory Information Management System (LIMS) begins with a practical objective: move data, preserve business continuity and implement a new system. While these are important considerations, viewing the initiative solely as a migration can limit the long-term value of the investment.

A **migration** focuses on transferring an existing environment from one LIMS to another. In many cases, it seeks to recreate existing processes, workflows and configurations with minimal disruption. This approach may appear to reduce short-term risk, but it can also carry forward years of accumulated complexity, inconsistent processes and configurations that no longer reflect how the laboratory wants to operate.

Modernization takes a broader perspective. It should evaluate more than whether a new LIMS can reproduce existing requirements.

The goal is not to build a better version of yesterday's laboratory.

It is to create the foundation for tomorrow's.

Instead of asking:

“How do we rebuild what we have today?”

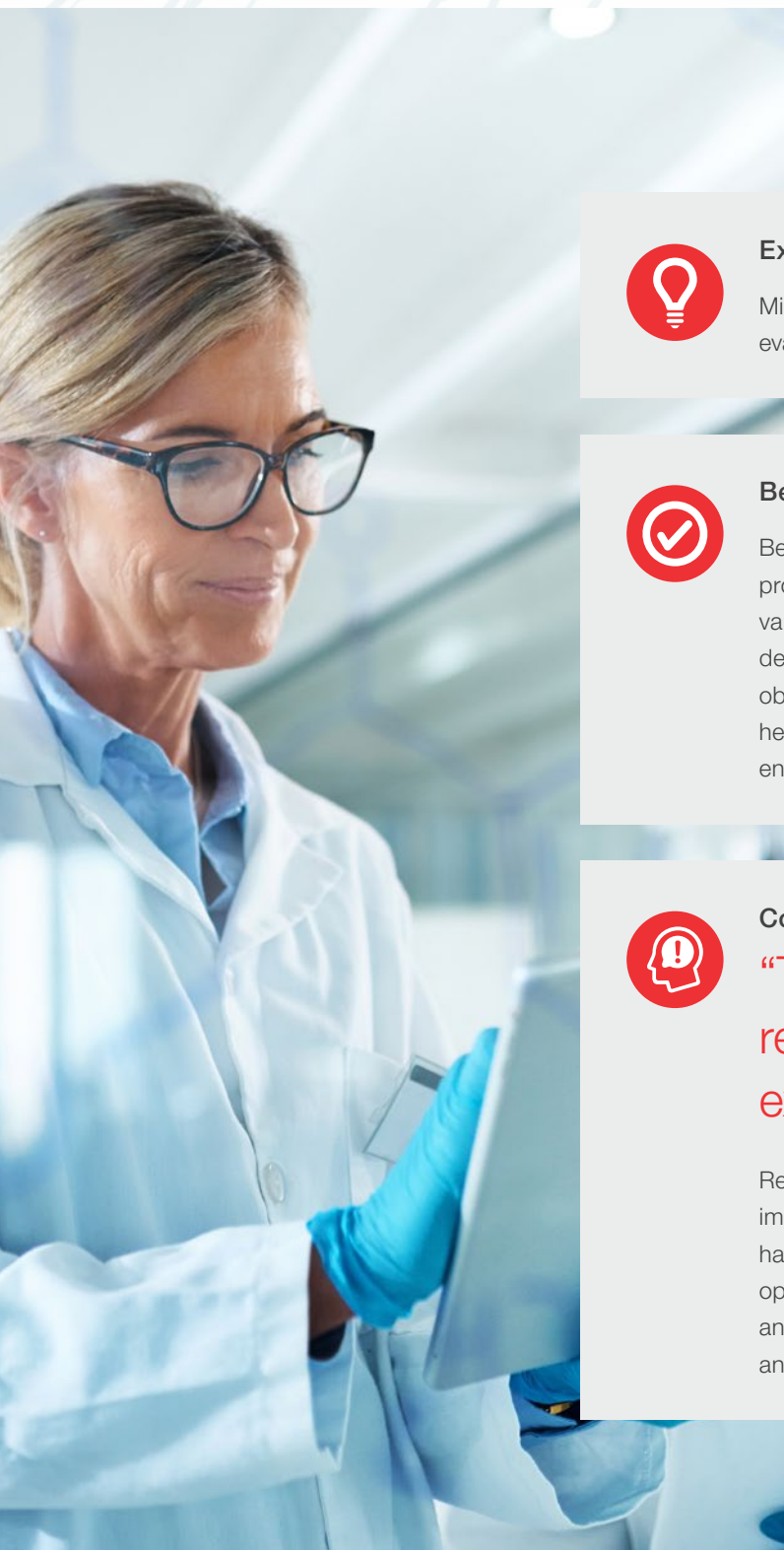
Ask:

“How should the laboratory operate in the future?”

Migration vs. modernization

Migration	Modernization
Recreates the current environment	Designs the future operating environment
Focuses on technology replacement	Focuses on business improvement
Preserves existing processes	Evaluates and optimizes processes
Carries forward existing complexity	Reduces unnecessary complexity
Measures project completion	Measures long-term business value

Note: This is a conceptual comparison intended to illustrate different implementation approaches rather than prescribe a single methodology.



Executive insight:

Migration transfers an existing environment. Modernization evaluates whether that environment is still the right one for the future.



Best practice:

Before defining system requirements, review existing laboratory processes with cross-functional stakeholders. Identify where variations exist, understand why they were introduced and determine whether they continue to support current business objectives. Process harmonization before implementation can help establish a more consistent and sustainable operating environment.



Common misconception:

“The safest approach is to reproduce the current system exactly as it exists today.”

Recreating every existing process and configuration may reduce immediate change, but it can also preserve complexity that has accumulated over many years. Modernization provides an opportunity to evaluate which practices continue to deliver value and where greater standardization can simplify future maintenance and ongoing evolution.

Part II

Planning for success

Assessing modernization readiness

Successful modernization begins long before implementation. It starts with understanding whether the organization is prepared for change.

Technology selection is only one part of that preparation. Before implementation begins, project teams need a clear view of what modernization is expected to achieve and whether the organization is ready to deliver those outcomes.

Business objectives provide the starting point. Connecting modernization priorities to measurable operational or business outcomes helps establish why the program matters, guides investment decisions and provides a basis for measuring success.

With that direction established, readiness can be considered across three interconnected dimensions: **people, processes and technology**. 'People' considers sponsorship, subject matter expertise, governance and the resources required to support the program. 'Processes' examines opportunities to harmonize, standardize and define the future operating model. 'Technology' considers the current environment, integrations and data landscape that will shape implementation.

Looking at these dimensions together helps expose gaps before they become implementation issues. It also gives stakeholders a common view of priorities, dependencies and areas requiring further planning.

Readiness discussion guide

Use these questions to facilitate discussion across quality, laboratory operations, IT and project leadership before implementation begins.



What business or operational outcomes are expected to justify the modernization program?



Where could laboratory processes be simplified, harmonized or standardized?



How will we measure whether those outcomes have been achieved?



Have the current technology, integration and data environments been assessed?



Are executive sponsors and project stakeholders aligned on those objectives?



Are the people and resources required for implementation available?



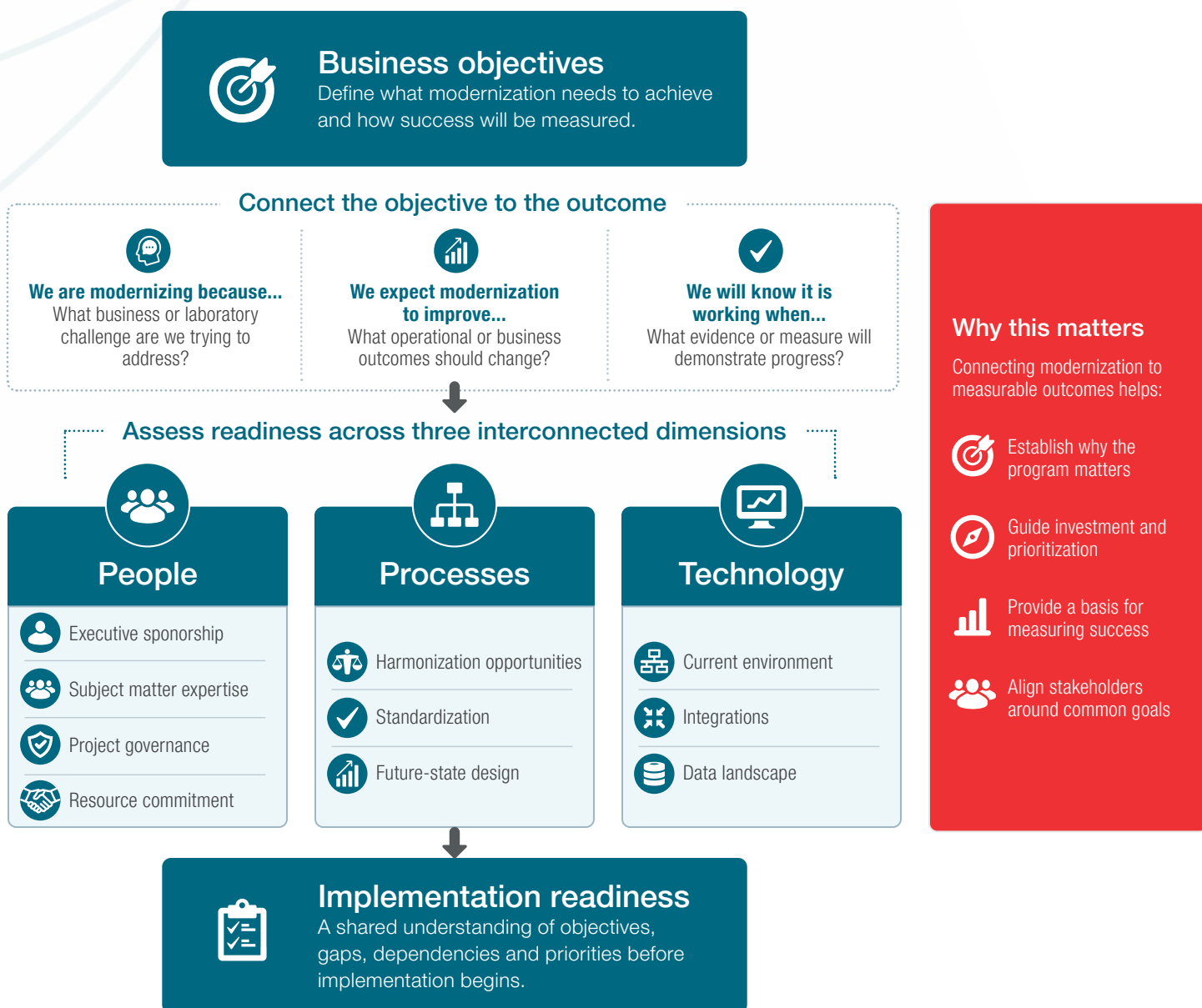
Have the right subject matter experts and decision-makers been identified?

Should existing processes simply be recreated, or is this the opportunity to establish a more standardized way of working?

Modernization readiness framework

Modernization readiness framework

A clear view of objectives and preparedness across people, processes and technology creates the foundation for successful implementation.



Standardize before you configure

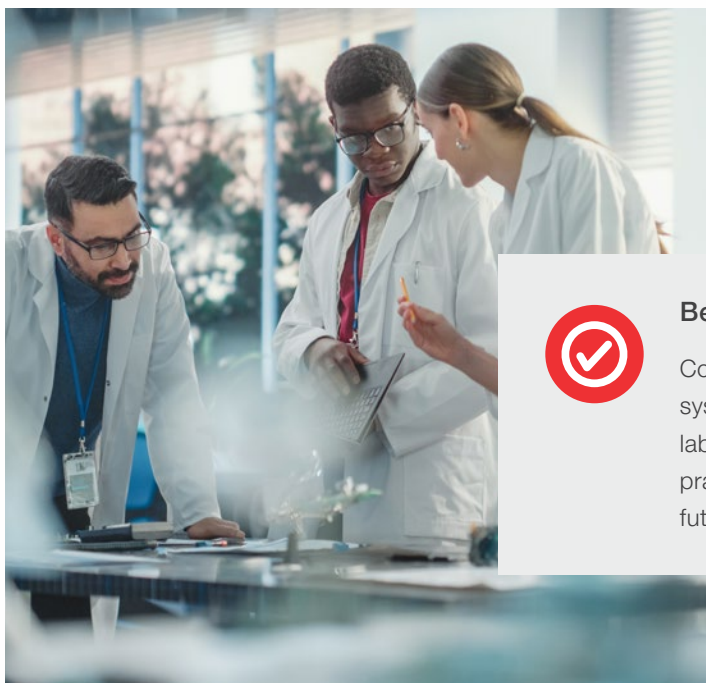
One of the greatest opportunities in a modernization program is not implementing new technology, it is simplifying the way the laboratory operates before the new environment is designed.

As laboratories evolve, their processes naturally adapt to changing business needs. New products are introduced, regulatory requirements develop and local teams establish working practices that reflect their operational priorities. Over time, these changes can result in multiple ways of performing similar activities across the organization.

These variations are rarely introduced without good reason. Some continue to support legitimate scientific, regulatory or operational requirements. Others may exist primarily because they evolved over time or were introduced to accommodate historical system limitations. Distinguishing between the two helps organizations standardize where it creates value while preserving necessary flexibility.

Once future-state processes have been agreed, system configuration becomes significantly more purposeful. Rather than configuring technology around multiple local variations, organizations can implement a more consistent operating model that is easier to support, validate and enhance as business requirements evolve.

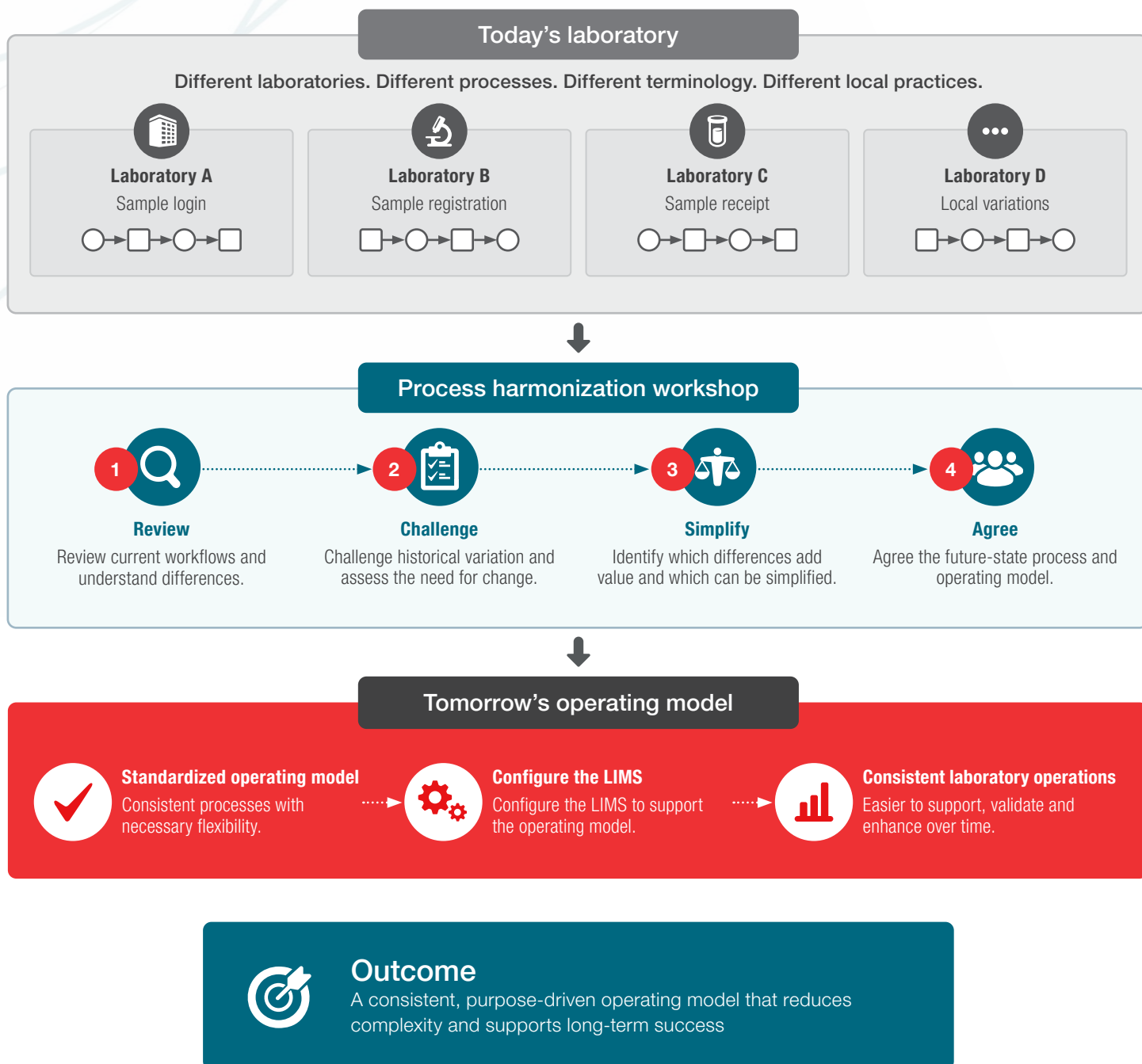
Importantly, standardization should not be viewed as limiting flexibility. Instead, it establishes a common operational foundation from which laboratories can continue to grow, introduce new capabilities and respond to changing business needs without continually increasing complexity.



Best practice:

Conduct process harmonization workshops before detailed system design begins. Bring together representatives from quality, laboratory operations and other key stakeholders to review current practices, understand why differences exist and define the future-state operating model collaboratively.

Process harmonization workshop



Workshop discussion



Why do our laboratories perform this activity differently?



Which variations exist because of historical practice?



Which variations support genuine business or regulatory requirements?



If we were designing this process today, would we do it the same way?

Designing the future-state laboratory

Modernization provides an opportunity to design an informatics environment that supports where the laboratory is going, not simply where it is today.

Every laboratory reflects years of adaptation to changing business needs, regulatory expectations and scientific advances. As organizations evolve, so too does the operating environment that supports them.

Today's question:

“How do we replicate our current environment?”

Better question:

“What capabilities will our laboratory need to support the business in the years ahead?”

This perspective shifts planning away from individual system requirements and toward broader operational objectives. Project teams can focus on how laboratory processes, information flows and digital capabilities should evolve to support the organization's long-term direction.

Developing a future-state vision requires input from quality, laboratory operations, information technology and business stakeholders. Bringing these perspectives together helps ensure implementation decisions reflect long-term operational priorities.

Not every business requirement needs to be addressed during the initial modernization program. Establishing a flexible, scalable foundation allows new capabilities to be introduced over time without continually redesigning the operating environment.

This becomes especially important as laboratories explore emerging capabilities such as AI and greater automation where access to trusted well-managed data can influence what becomes possible.

By defining the future operating model before detailed solution design begins, organizations can make implementation decisions that support long-term business objectives rather than short-term technical requirements. This creates a stronger foundation for ongoing improvement while helping avoid decisions that may unnecessarily limit future flexibility.

Ultimately, the objective is not to predict every future requirement. It is to establish an informatics environment that can evolve alongside the laboratory as scientific, operational and business priorities continue to change.

Questions to ask



If we were designing our laboratory today, what would we do differently?



What capabilities might become important over the coming years?



Which future business priorities should influence today's implementation decisions?



Which decisions made during implementation could limit future flexibility?

A well-defined future-state vision provides direction, but achieving that vision depends on more than technology. Lasting success requires effective governance, engaged stakeholders and organizational commitment from the earliest stages of the program



Best practice:

Develop a future-state vision that extends beyond the immediate implementation. Consider how the laboratory may evolve over the next five to ten years, including potential business growth, new manufacturing sites, additional analytical capabilities, evolving regulatory expectations and broader digital transformation initiatives.

Leadership drives successful modernization

Modernization is a cross-functional initiative. Quality, laboratory operations, information technology, validation, manufacturing and business leadership all influence implementation in different ways. Bringing these groups together around shared objectives, clear governance and consistent decision-making creates the foundation for successful delivery.

Leadership establishes direction.

Successful modernization begins with clear sponsorship and shared objectives. Leaders help establish priorities, maintain organizational alignment and reinforce the reasons for change throughout the program.

Governance creates consistency.

Clearly defined decision-making responsibilities help project teams evaluate priorities, manage scope and make implementation decisions that remain aligned with business objectives.

Stakeholder engagement builds ownership.

Subject matter experts and laboratory personnel contribute operational knowledge that strengthens solution design while helping prepare the organization for new ways of working.

Communication maintains momentum.

Regular communication keeps stakeholders informed, reinforces project objectives and provides opportunities to address questions before they become barriers to adoption.

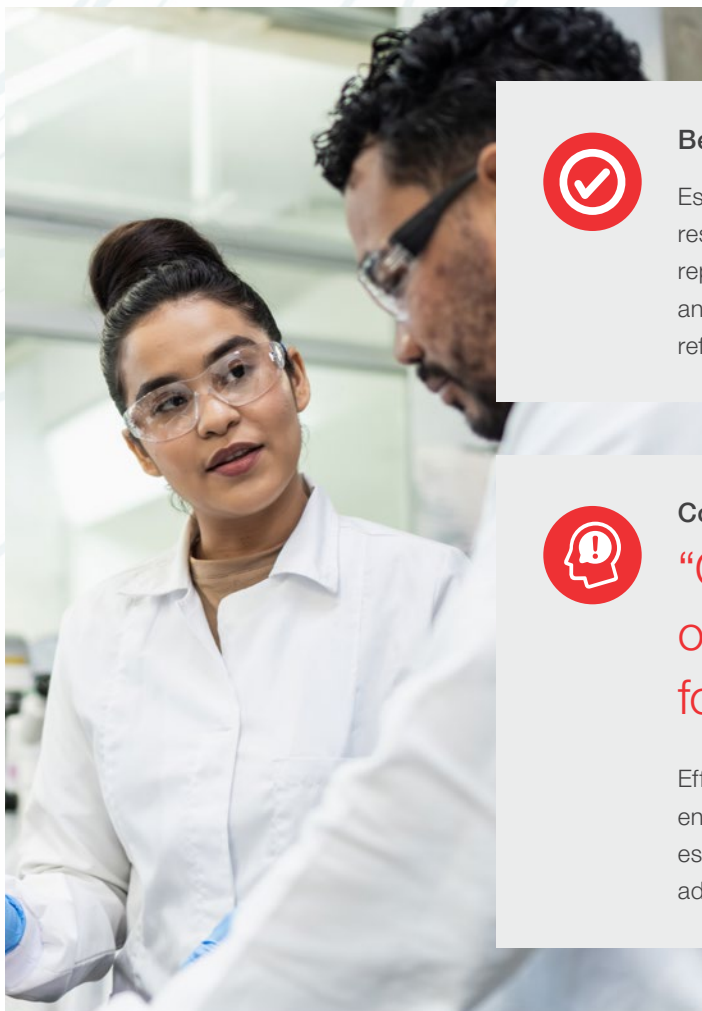
Training supports long-term adoption.

Training, knowledge transfer and ongoing support help laboratory teams build confidence in the new environment and establish the foundation for continued improvement after implementation.

Technology enables modernization.

People enable success.





Best practice:

Establish a cross-functional project team with clearly defined responsibilities and decision-making authority. Include representatives from quality, laboratory operations, IT, validation and executive leadership to ensure implementation decisions reflect both business priorities and operational realities.



Common misconception:

“Change management begins once the new system is ready for users.”

Effective change management begins much earlier. Stakeholder engagement, governance, communication and shared ownership established during planning often have a greater influence on adoption than training delivered immediately before go-live.

By the time implementation begins, many of the most important decisions have already been made. Clear objectives, standardized processes, effective governance and organizational alignment create the conditions for successful delivery. The next phase of the journey focuses on putting those plans into action while managing complexity, reducing risk and maintaining momentum from project initiation through go-live.

Part III

Executing with confidence

Four principles for successful implementation

Every modernization program introduces uncertainty. New technology, revised business processes, evolving requirements and cross-functional dependencies all create decisions that must be managed carefully throughout implementation. While uncertainty cannot be eliminated, thoughtful planning helps project teams respond effectively as challenges emerge.

Principle 1:

Establish realistic expectations

Modernization is a business transformation program rather than a software deployment. Requirements evolve, project teams learn more about future-state processes and priorities may change as implementation progresses. Recognizing this early helps teams respond constructively rather than viewing every change as a setback.

Principle 2:

Governance supports better decisions

Clear governance helps project teams evaluate new requests, manage scope and maintain alignment with agreed business objectives. It provides a consistent approach for balancing changing requirements while maintaining project momentum.

Principle 3:

Identify dependencies early

Infrastructure readiness, data preparation, validation activities and resource availability all influence implementation. Understanding these dependencies early helps teams anticipate challenges rather than reacting to them later.

Principle 4:

Communicate continuously

Regular communication helps maintain alignment, reinforces project priorities and provides opportunities to address issues before they affect project delivery.

Successful implementation is not about avoiding change. It is about creating the structure needed to respond to change with confidence.



Lessons from experience:

Projects rarely remain unchanged from initiation to go-live. The organizations that navigate implementation most successfully are those that establish governance early, communicate openly and treat change as a normal part of the modernization journey.

Managing implementation successfully depends on more than governance alone. Data migration presents another important opportunity, not simply to move information, but to decide what should move into the future environment.

Data migration with purpose

A successful data migration is not measured by how much information is transferred. It is measured by how effectively the information supports the future laboratory environment.

Data migration is often one of the most closely scrutinized activities within a modernization program. Laboratory data represents years of scientific work, quality records and operational knowledge, making it understandable that organizations want to preserve this information as they transition to a new environment.

However, modernization presents an opportunity to do more than simply transfer data from one system to another.

As laboratory systems evolve, so does the data they contain.

Four questions to ask before migrating data



What information supports future laboratory operations?

Determine which information will be required within the future operating environment.



What information should remain accessible?

Some historical information may need to remain available without necessarily forming part of the operational environment.



What information requires preparation?

Data quality, ownership, mapping and standardization should all be considered before migration begins.



Who should be involved?

Data migration is not solely an IT activity. Quality, laboratory personnel and subject matter experts all contribute to ensuring that migration decisions support operational requirements.

Ultimately, the objective is not simply to preserve historical information. It is to ensure that trusted, relevant and well-managed data continues to support laboratory operations long after implementation is complete.



Best practice:

Develop a data strategy before migration planning begins. Define data ownership, determine which information supports future operations, establish data quality expectations and agree how historical information will be retained where appropriate.



Common misconception:

“Every record from the existing system should be migrated into the new environment.”

Not all historical information necessarily needs to reside within the new operational system. Organizations should evaluate business, operational and regulatory requirements to determine which data should be migrated, which should remain accessible through archival approaches and whether any information would benefit from cleansing or standardization before migration.



Planning consideration

Data migration decisions are most effective when business and technical stakeholders work together. Understanding how information is created, used and maintained across laboratory operations helps ensure that migration supports the future operating model rather than simply preserving historical structures.

Once data has been prepared for the future environment, attention turns to another critical element of implementation: validation. For many pharmaceutical organizations, validation represents one of the most significant project activities. While it supports regulatory expectations, its purpose extends beyond compliance by providing confidence that the system performs as intended and supports its intended use.

Validation starts with planning

Validation provides documented confidence that a laboratory informatics environment performs as intended and supports organizational quality and regulatory requirements. Because validation is closely integrated with solution design, configuration, testing and implementation, it should be considered from the earliest stages of a modernization program rather than treated as an activity that begins once system development is complete.

Planning ahead allows project teams to define validation responsibilities, identify required documentation and align validation activities with the overall implementation schedule. This integrated approach helps reduce unnecessary rework and provides greater visibility into the activities that will be required throughout the project.

The decisions made during solution design can also influence the effort required during validation. Organizations that adopt standardized processes and configurable capabilities often establish a more consistent foundation for documentation, testing and ongoing system management. Conversely, introducing unnecessary complexity into the solution may increase the activities required to validate and maintain the environment over time.

Validation should also be viewed as a collaborative responsibility. Quality, laboratory personnel, validation specialists, IT and implementation teams each contribute different expertise throughout planning, testing and system acceptance. Early engagement between these groups helps ensure that validation activities remain aligned with both business objectives and regulatory expectations.

Validation should not be viewed solely as a regulatory obligation. It establishes confidence that the modernized laboratory environment is ready to support routine operations and future business needs.

Putting these principles into practice

Thermo Fisher Scientific supports validation activities through standardized implementation documentation, including Installation Qualification (IQ), Operational Qualification (OQ), traceability documentation and pre-executed OQ scripts for supported capabilities. These resources are intended to help organizations plan and execute validation activities more efficiently.

Validation planning checklist

Before implementation begins use this validation planning checklist to ensure you're set up for success:

- ☐ Validation responsibilities defined
- ☐ Documentation requirements understood
- ☐ Review and approval process agreed
- ☐ Validation milestones aligned with implementation
- ☐ Cross-functional responsibilities confirmed

The modernization compass

Four principles for guiding the modernization journey

While every modernization program follows a different path, several principles can help organizations navigate the decisions that shape long-term outcomes. Together, they provide a practical framework for planning, implementation and the years that follow.

The modernization compass



These principles are not sequential steps. They should guide decision-making throughout the entire modernization journey.

Part IV

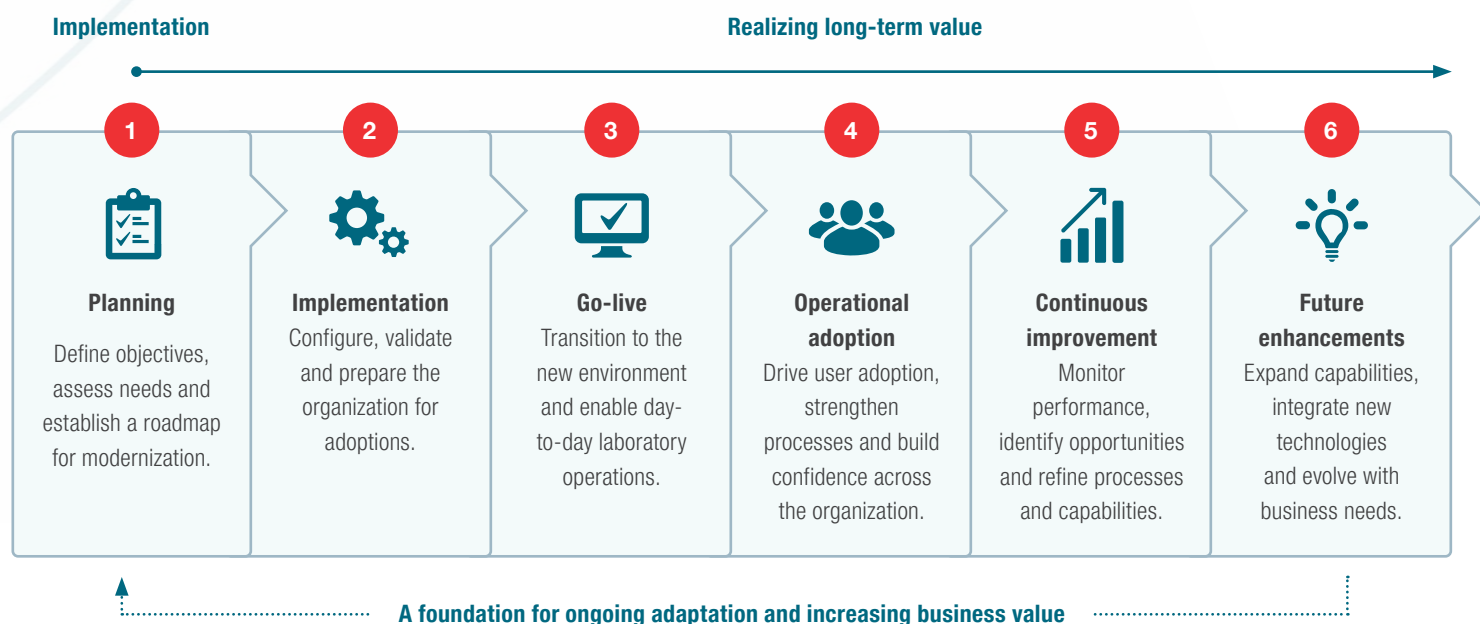
Maximizing long-term value

Go-live is the beginning, not the destination

Go-live is an important milestone, but it is not the end of the modernization journey. It marks the point at which the laboratory begins realizing the value of the planning, design and implementation activities that came before it.

Long-term value is created through continued adoption, thoughtful governance and a willingness to refine the operating model as business priorities evolve.

The modernization journey



Managing change without reintroducing complexity

The decisions made during implementation influence how easily the laboratory can respond to future business needs. Designing for change from the outset helps create a more sustainable informatics environment.

Every laboratory environment continues to evolve after implementation. The challenge is not deciding whether change will occur, but how it should be managed.

Not every improvement request strengthens the operating model. Effective governance helps distinguish between changes that create long-term value and those that gradually reintroduce unnecessary complexity.

Organizations frequently identify new ideas once users begin working within a modernized environment. Some improvements may represent valuable opportunities to enhance laboratory operations. Others may reflect local preferences or historical ways of working that could gradually reintroduce the complexity the modernization program sought to reduce.

Establishing governance for future changes helps organizations evaluate these requests consistently. By considering business value, operational impact and alignment with the future-state operating model, project teams can make informed decisions that support continuous improvement while maintaining a sustainable environment.

Designing for change is therefore less about anticipating every future requirement and more about creating an operating environment that can continue evolving without unnecessary complexity.



**Best practice:**

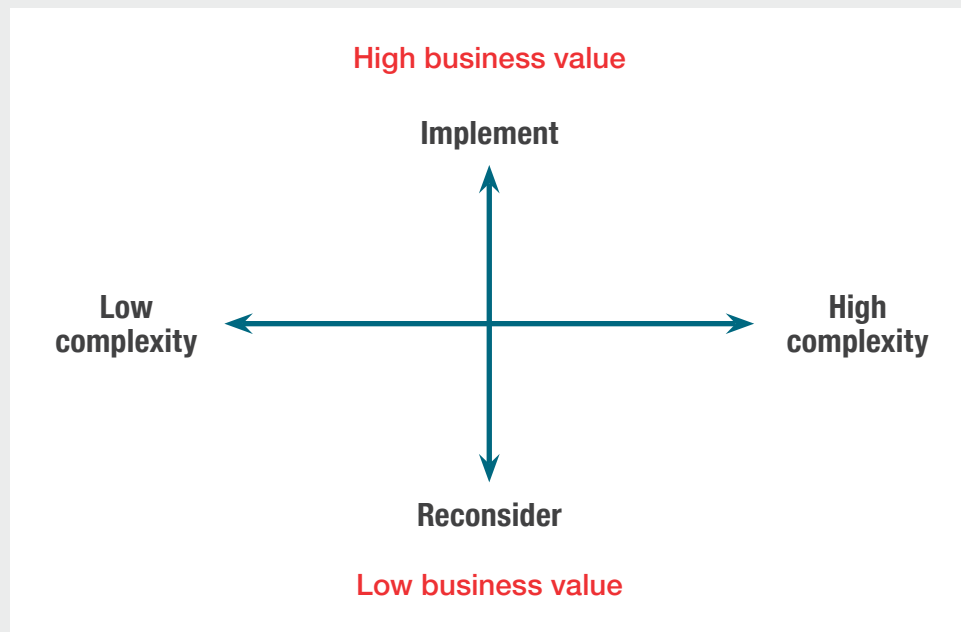
After implementation, establish a structured process for evaluating enhancement requests. Consider how each proposed change supports business objectives, aligns with standardized processes and affects the long-term maintainability of the informatics environment before it is introduced.

Decision filter

Before approving an enhancement, ask:

- ✓ Does it solve a genuine business problem?
- ✓ Does it align with the future operating model?
- ✓ Can it be achieved using standard capabilities?
- ✓ Will it simplify or increase long-term support?

Another helpful tool is the **enhancement decision matrix**:

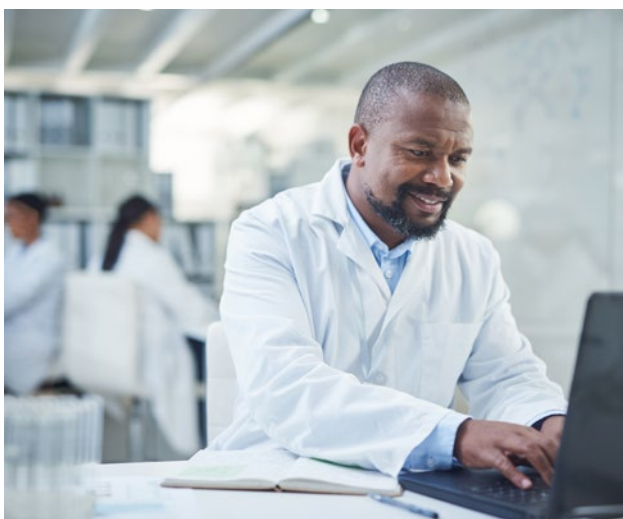


Building on the foundation

Modernization establishes more than a new system. It creates a foundation that supports continued growth as laboratory and business requirements evolve.

Not every capability needs to be implemented during the initial modernization project. A well-planned informatics environment allows new capabilities to be introduced over time as priorities change, building on the existing foundation rather than continually replacing or redesigning it.

As new requirements emerge, additions should strengthen the operating model established during modernization. New capabilities can complement standardized laboratory processes, improve access to information and support broader business objectives without reintroducing unnecessary complexity.



Putting modernization into practice

One advantage of establishing a standardized informatics foundation is the ability to expand capabilities over time rather than replacing existing systems as new requirements emerge.

Depending on business priorities, organizations may choose to extend their laboratory informatics environment with capabilities such as:

- Scientific Data Management Systems (SDMS)
- Electronic Laboratory Notebooks (ELN)
- Additional instrument integrations
- Enterprise connectivity
- Reporting and analytics

This staged approach is reflected in Thermo Fisher's laboratory informatics portfolio, allowing organizations to expand their environment as business needs evolve while continuing to build on a common foundation.



Best practice:

Alongside the implementation roadmap, consider developing a long-term informatics roadmap. Consider which capabilities may become important over the coming years and ensure that implementation decisions support future expansion without adding unnecessary complexity.

Measuring success beyond go-live

The true measure of modernization is not whether implementation was completed successfully. It is whether the laboratory is better equipped to support the business in the years that follow.

Successful modernization should be evaluated against the objectives established before implementation began. While project milestones help measure implementation progress, long-term success is determined by how effectively the laboratory supports the business after go-live.

The most valuable measures of success are those that reflect operational outcomes rather than project completion.

Executive modernization framework

Question	What success looks like
Are laboratory processes more consistent?	Standardized ways of working across the organization
Can the laboratory respond more easily to changing business requirements?	New capabilities introduced without unnecessary complexity
Are governance processes supporting better decisions?	Structured evaluation of future changes
Are users confident using the environment?	High adoption and effective day-to-day use
Is the environment prepared for future growth?	New capabilities can be introduced without redesigning the foundation

Reviewing these questions regularly helps ensure the laboratory informatics environment continues to support changing business priorities while delivering long-term operational value.



Best practice:

Schedule periodic business reviews after implementation to evaluate whether the modernization program continues to support organizational objectives. Include representatives from across the organization to discuss operational performance, future priorities and opportunities for continuous improvement.



Leadership reflection:

The success of modernization is not measured by the day a system goes live. It is measured by the organization’s ability to continue adapting, improving and creating value long after implementation is complete.

Part V

Putting modernization into practice

Laboratory modernization planning checklist

A practical discussion tool for assessing organizational readiness before implementation begins.

How to use this checklist

Every laboratory's modernization journey is different, but the planning considerations are remarkably consistent.

Use this checklist to facilitate discussion across quality, laboratory operations, information technology and project

leadership before implementation begins. Rather than serving as a formal assessment, it is intended to help identify strengths, highlight areas requiring additional planning and support alignment around a shared modernization strategy.

For each statement, consider whether your organization is:

Ready



In progress



Needs attention



Business objectives

Assessment	Planning question
☐ ☐ ☐	Have we clearly defined why we are modernizing?
☐ ☐ ☐	Are executive sponsors aligned on the desired business outcomes?
☐ ☐ ☐	Have we established how success will be measured?

Organizational readiness

Assessment	Planning question
☐ ☐ ☐	Have we identified the stakeholders who should participate throughout the program?
☐ ☐ ☐	Are governance roles and decision-making responsibilities clearly defined?
☐ ☐ ☐	Have we committed the people and resources required throughout implementation?

Putting modernization into practice

Laboratory operations

Assessment	Planning question
☐ ☐ ☐	Have current laboratory workflows been reviewed?
☐ ☐ ☐	Have opportunities for harmonization and standardization been identified?
☐ ☐ ☐	Have historical process variations been challenged to determine whether they continue to provide business value?

Technology & data

Assessment	Planning question
☐ ☐ ☐	Have current laboratory data and integration requirements been assessed?
☐ ☐ ☐	Have future business and informatics requirements been considered?
☐ ☐ ☐	Does the proposed operating model support future growth without introducing unnecessary complexity?

Validation

Assessment	Planning question
☐ ☐ ☐	Has validation planning begun alongside implementation planning?
☐ ☐ ☐	Are validation roles, responsibilities and documentation requirements understood?
☐ ☐ ☐	Are validation activities aligned with the overall implementation plan?

Long-term sustainability

Assessment	Planning question
☐ ☐ ☐	Has a post-go-live governance approach been established?
☐ ☐ ☐	Is there a roadmap for introducing future capabilities over time?
☐ ☐ ☐	Have we established how the environment will be reviewed and continuously improved after implementation?

Discussion notes

Key strengths	
Areas requiring additional planning	
Priority actions before implementation	

This checklist is not intended to produce a perfect score. Its purpose is to encourage discussion, build stakeholder alignment and identify opportunities to strengthen planning before implementation begins.

Organizations that can confidently address these questions are often better positioned to begin modernization with clear objectives, realistic expectations and a stronger foundation for long-term success.



Putting modernization into practice

Every modernization program begins from a different starting point. Turning modernization plans into a sustainable laboratory environment means navigating decisions around processes, technology, validation, people and long-term support without introducing unnecessary complexity along the way.

Thermo Fisher combines pharmaceutical QA/QC informatics, implementation expertise and ongoing support around three principles that help organizations put modernization into practice.

Three reasons to believe

Start from a more established foundation

Standardized and preconfigured pharmaceutical capabilities provide a more established starting point for implementation. Rather than recreating every requirement through bespoke configuration, project teams can focus effort on the processes and requirements that genuinely differentiate their operating environment.

Follow a structured implementation journey

Defined implementation stages provide a clear path from project initiation through go-live. Project management, technical, consulting and training expertise contribute throughout the program, while workshops bring subject matter experts and end users together to connect current laboratory processes and future requirements with solution design.

Continue beyond go-live

Training, knowledge transfer and technical support extend beyond implementation, helping laboratory teams transition into routine operation and continue realizing value from the environment. As requirements change, the informatics foundation can also develop to support new laboratory and business priorities.

Putting modernization into practice

From project kick-off to ongoing support

Thermo Fisher's implementation journey provides a structured path from project initiation through go-live and into ongoing support.

Initiate ○

Project kick-off

Establish a common starting point

Review the agreed scope, bring project teams together, define roles and responsibilities, identify risks and establish expectations for governance, communication, deliverables and timelines.

Deliver ○

Product training

Build foundational knowledge

Introduce project teams to the LIMS and its core functionality, helping participants develop the product knowledge needed to contribute effectively as implementation progresses.

Workshops

Connect current operations with the future environment

Bring subject matter experts and end users together to review current laboratory processes, explore the desired future state and translate operational requirements into the proposed solution design.

Complete ○

Build

Turn requirements into a working environment

Configure and test the solution using an approach appropriate to the project, while addressing dependencies such as data migration, infrastructure readiness, resources, user training and acceptance testing.

Validate

Establish readiness for use

Complete the qualification, testing and documentation activities required to demonstrate that the environment is ready to move into routine operation, including IQ, OQ and user acceptance testing as applicable.

Go live

Move into routine operation

Prepare the system, data and users for transition, complete final readiness activities and provide dedicated support as the laboratory begins operating in the new environment.

Support

Continue the journey

Transition from implementation support into ongoing technical support according to the organization's solution and support arrangements.



Built for pharmaceutical QA/QC

Putting modernization principles into practice requires more than selecting new technology. It requires an informatics foundation, implementation approach and long-term support model that reinforce the future operating environment the organization is trying to create.

Thermo Scientific™ SampleManager™ LIMS for pharmaceutical QA/QC provides standardized and preconfigured workflows that support laboratory activities including sample management, testing, review and approval, and environmental monitoring, with integration options for chromatography data systems and enterprise applications.

Validation resources for supported pharmaceutical capabilities include OQ test scripts, pre-executed OQ scripts and traceability documentation to support a risk-based validation approach. Combined with standardized workflows and reusable functionality, these resources give project teams an established starting point for validation and can help reduce the effort required to demonstrate that the system performs as intended.



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modernization program?

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