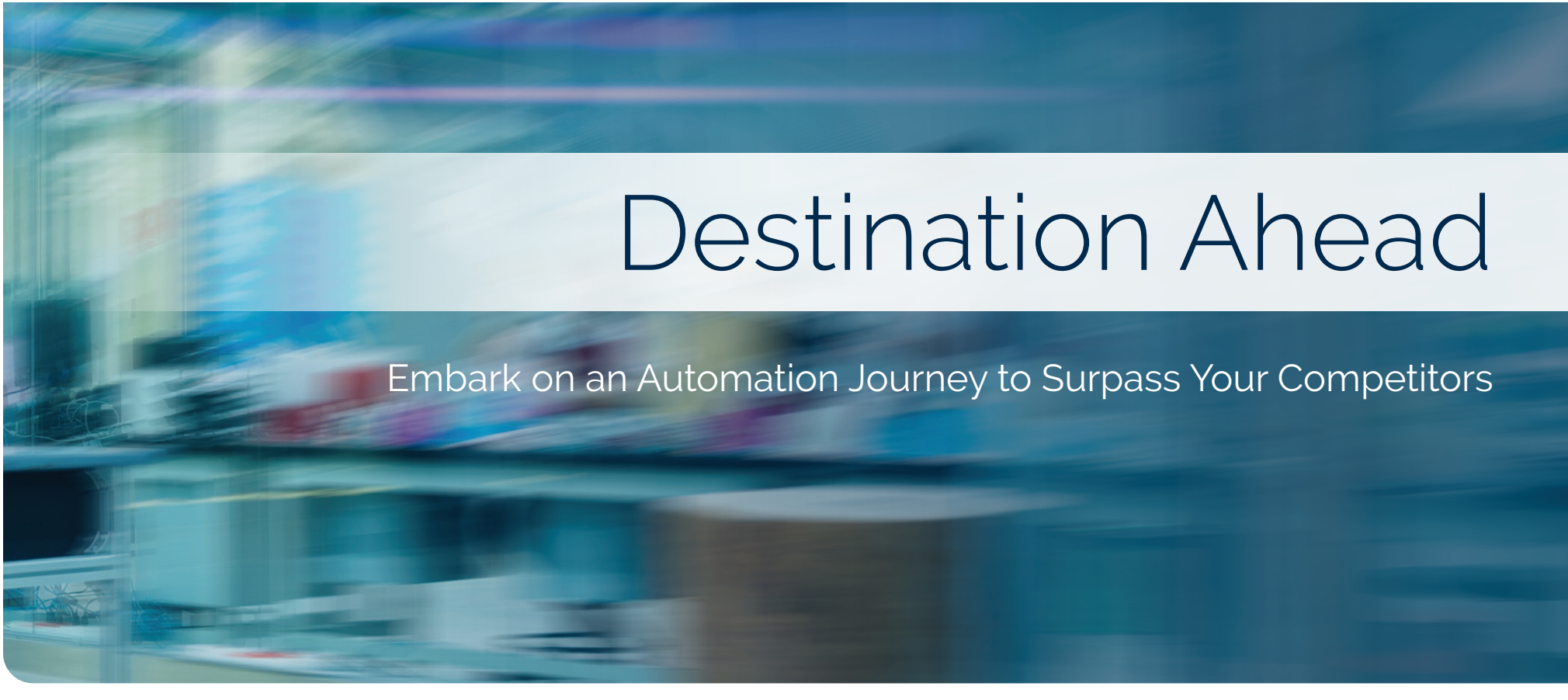


Destination Ahead

Embark on an Automation Journey to Surpass Your Competitors

HighRes® biosolutions

The Need For More

In our previous Destination Ahead e-books, we covered your need to outpace your competition to achieve your vision, and how to start planning for your journey. With the plan and team in place, we explored the wide worlds of hardware and software and used this knowledge to finalize a system design.

With the automated system plan and design in motion, prepare to check, double-check, and even triple-check performance.

So how can you maximize your organization's efforts and surpass those of your competitors?

What To Expect

In this seven-part Destination Ahead e-book series, we'll guide you through major phases that you can expect of your automation journey.

For those well-experienced with automated solutions, you may want to read a few sections to refresh your memory.

On the other hand, for those new to or lightly familiar with automation, and especially whole lab workflow automation, we encourage you to take in as much information as possible in every section.

The **Destination Ahead** e-book series will cover:

PHASE 1

The Beginning & End

Journey from status quo lab workflows to the land of whole lab automation for opportunity and a competitive edge. Whole lab workflow automation experts like HighRes Biosolutions serve as your North Star and personal escort along the way.

PHASE 2

Understand Your Situation, Your Goals, and Your Team

Introspection and a first-class crew make short work of pre-journey planning. Gather and organize your thoughts, and the thoughts of others, as you assemble your goal guideposts.

PHASE 3

Dive Deep into the World of Hardware

Hardware Harbor encompasses a large area. Learn helpful tips to traverse through seemingly endless devices and capabilities. Narrow capabilities and features to those best-suited for your budget as well as your current and future needs.

PHASE 4

Immerse Yourself in the World of Software

The Port of Software is an amazing destination along your journey. Gain an overview of data flow and software types and how to orchestrate all through a single, high-functioning information virtuoso. Then determine which platforms stack up to meet your needs.

PHASE 5

Finalize your Proposed Automated Solution Design

Did you chart the right course, or is a major correction in order? Before committing to a final whole lab workflow automation design, review the project overview and details from multiple perspectives.

YOU ARE HERE

PHASE 6

Set the Project Build in Motion

It's time to navigate from vision into reality. Get your teams and your site ready with close communication, detailed planning, and rigorous testing.

PHASE 7

Deploy!

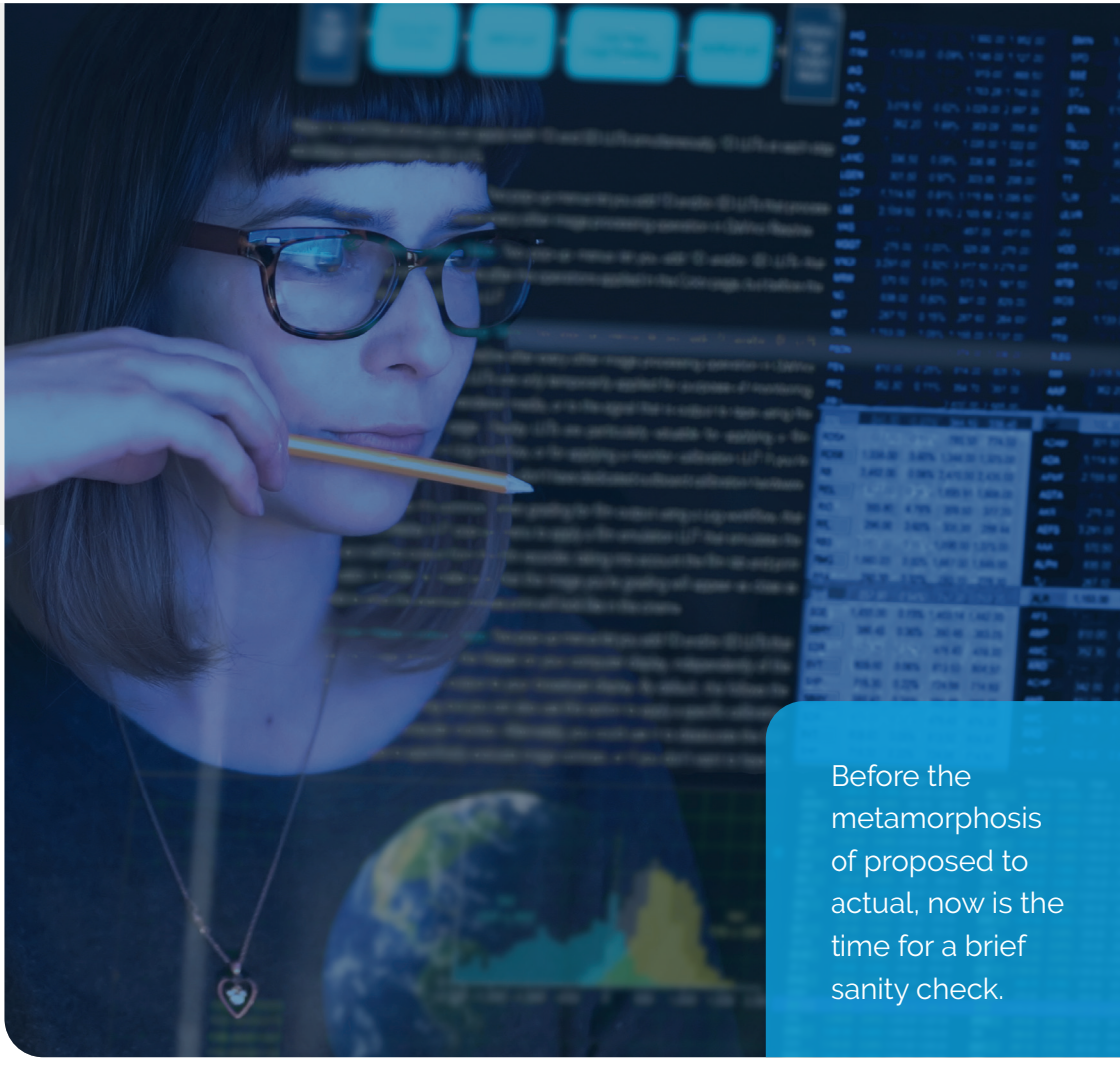
Your automation journey isn't finished once the automated solution is in place. Prepare users and you new whole lab workflow automation system with knowledge transfer and system optimization. Put it to the ultimate battery of tests in your environment and with your samples and a host of quality and regulatory guidelines.


It's really real now

At this point, you are armed with significant knowledge regarding automated devices, software platforms, and helpful support and services through people.

It goes without saying that choosing vendors and issuing purchase orders is not the end of the process, but rather a major milestone to enter the next phase of the automation project journey.

Remember that testing during this phase takes time, but the result is worthwhile. This is an opportunity for the manufacturers and vendors to work out any potential kinks in the automated system using water (sample blanks) or dry runs before consuming expensive reagents and precious samples at your site. The return is a reliable, high-performing, and long-lasting automated data-producing factory.



Before the metamorphosis of proposed to actual, now is the time for a brief sanity check.

Solidify Relationships and Ways of Working

Build steps are a period of frequent and detailed engagement amongst the wider team. As such, it's helpful to develop or reaffirm a clear communication strategy at the onset of the build.

A communication strategy aligns everyone and supports the development of clear messaging to your organization's executive stakeholders. Include detail on meeting frequency, preferred communications, and meeting note formats in the strategy.

There will likely also be **additions to the team** as external vendor specialists like project managers and hardware or software engineers are introduced. Make sure not only that your team understands each new member's role, but also that contact details are available to strengthen communications.

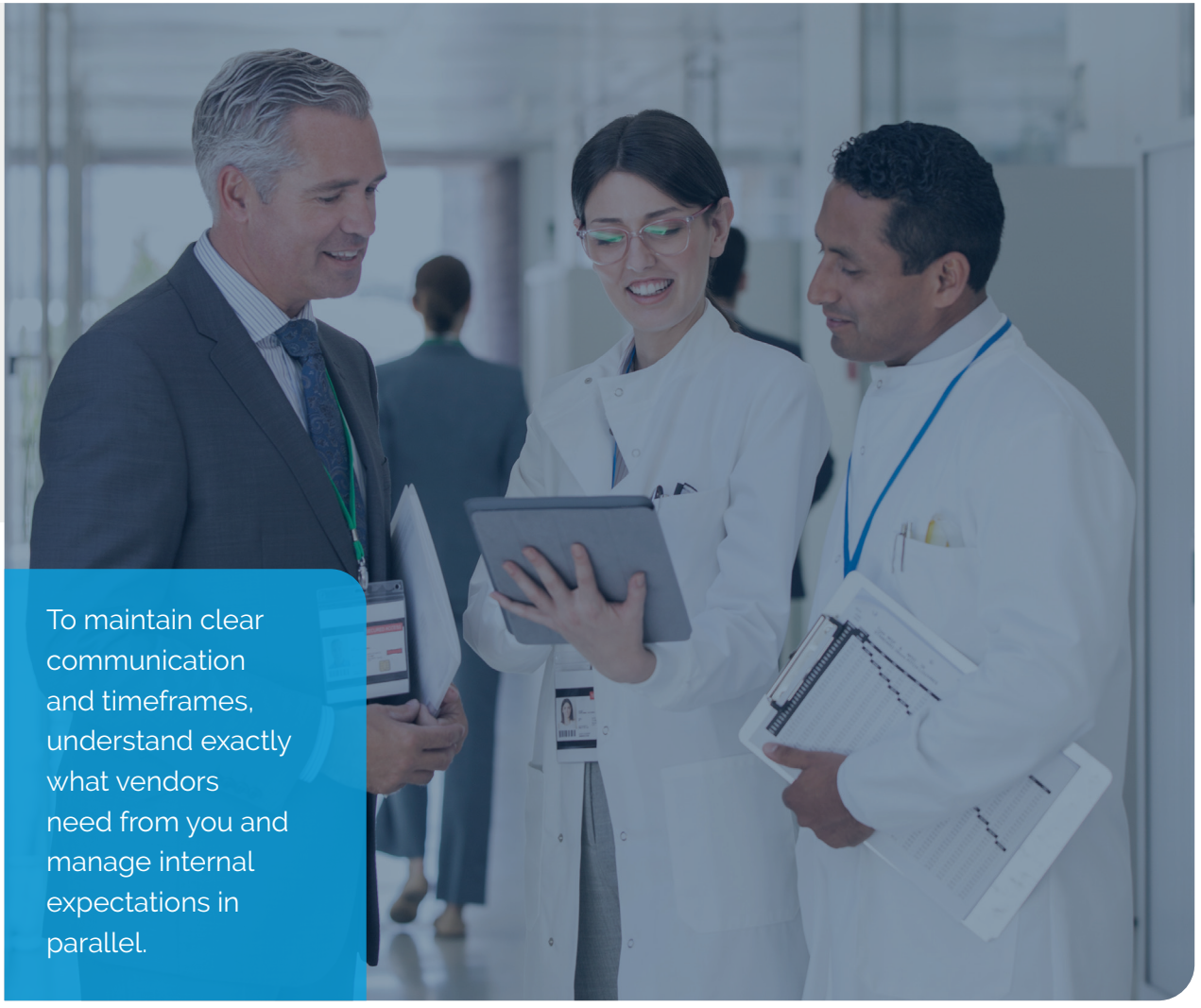
Clarify the project scope and details. Document and align on internal and vendor timelines. Set quantifiable key milestones. Agree on how hardware or software deliverables will be sourced (i.e., internally, vendor, or third-party). List documentation requirements. Agree on an acceptance test plan (described below) to confirm that system requirements are met.

Prepare for the unknown by creating contingency plans in case something is not delivered within the designated timeframe. As we discussed in "*Finalize Your Proposed Automation Solution Design*", your proposed solution may align with your goals and budget, but it's wise to plan for the plan to change.


Assemble your
Single Source of Truth

A functional design specification (FDS) document should be collaboratively created and shared by the internal and external teams. This highly detailed document captures all necessary information about the automated system's hardware and software functionality, build, installation, and testing. In other words, it is your single source of truth for the entire automation project.

Importantly, determine and agree upon the criteria necessary to consider the automated system creation project complete and transfer the title of ownership.

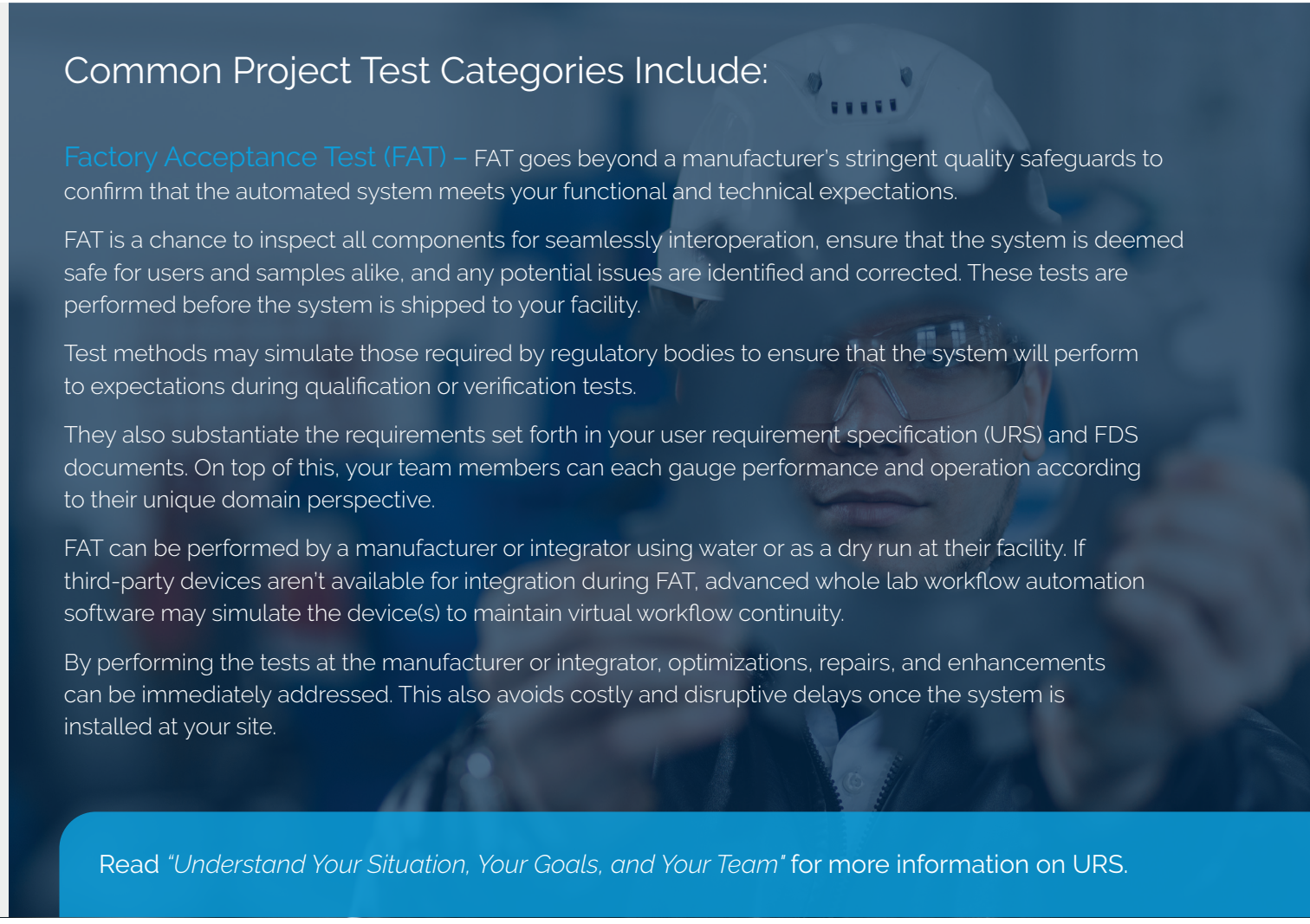


To maintain clear communication and timeframes, understand exactly what vendors need from you and manage internal expectations in parallel.

Develop an Acceptance Test Plan

An acceptance test plan, or ATP, outlines the strategy, approach, and criteria to confirm that the automated system meets your performance requirements before handover. An ATP aligns all team members, vendors, and stakeholders, and can include test categories specific to your needs and applications.

This overarching and highly detailed document includes information such as the purpose, scope, objectives, strategy or approach, team members and stakeholders, system design including software configuration, test methods and deliverables, timeframes, expected results, pass/fail criteria, risks and corrected actions, and approvals.



Common Project Test Categories Include:

Factory Acceptance Test (FAT) – FAT goes beyond a manufacturer's stringent quality safeguards to confirm that the automated system meets your functional and technical expectations.

FAT is a chance to inspect all components for seamlessly interoperation, ensure that the system is deemed safe for users and samples alike, and any potential issues are identified and corrected. These tests are performed before the system is shipped to your facility.

Test methods may simulate those required by regulatory bodies to ensure that the system will perform to expectations during qualification or verification tests.

They also substantiate the requirements set forth in your user requirement specification (URS) and FDS documents. On top of this, your team members can each gauge performance and operation according to their unique domain perspective.

FAT can be performed by a manufacturer or integrator using water or as a dry run at their facility. If third-party devices aren't available for integration during FAT, advanced whole lab workflow automation software may simulate the device(s) to maintain virtual workflow continuity.

By performing the tests at the manufacturer or integrator, optimizations, repairs, and enhancements can be immediately addressed. This also avoids costly and disruptive delays once the system is installed at your site.

Read *"Understand Your Situation, Your Goals, and Your Team"* for more information on URS.

Site Acceptance Test (SAT) – After FAT is approved, the system is shipped to, installed, and commissioned at your intended destination. Now, the system goes through another key milestone known as SAT. This set of tests confirms that nothing was harmed or misplaced during transport. It also ensures that all devices and software are properly installed and connected, and function to technical and performance expectations.

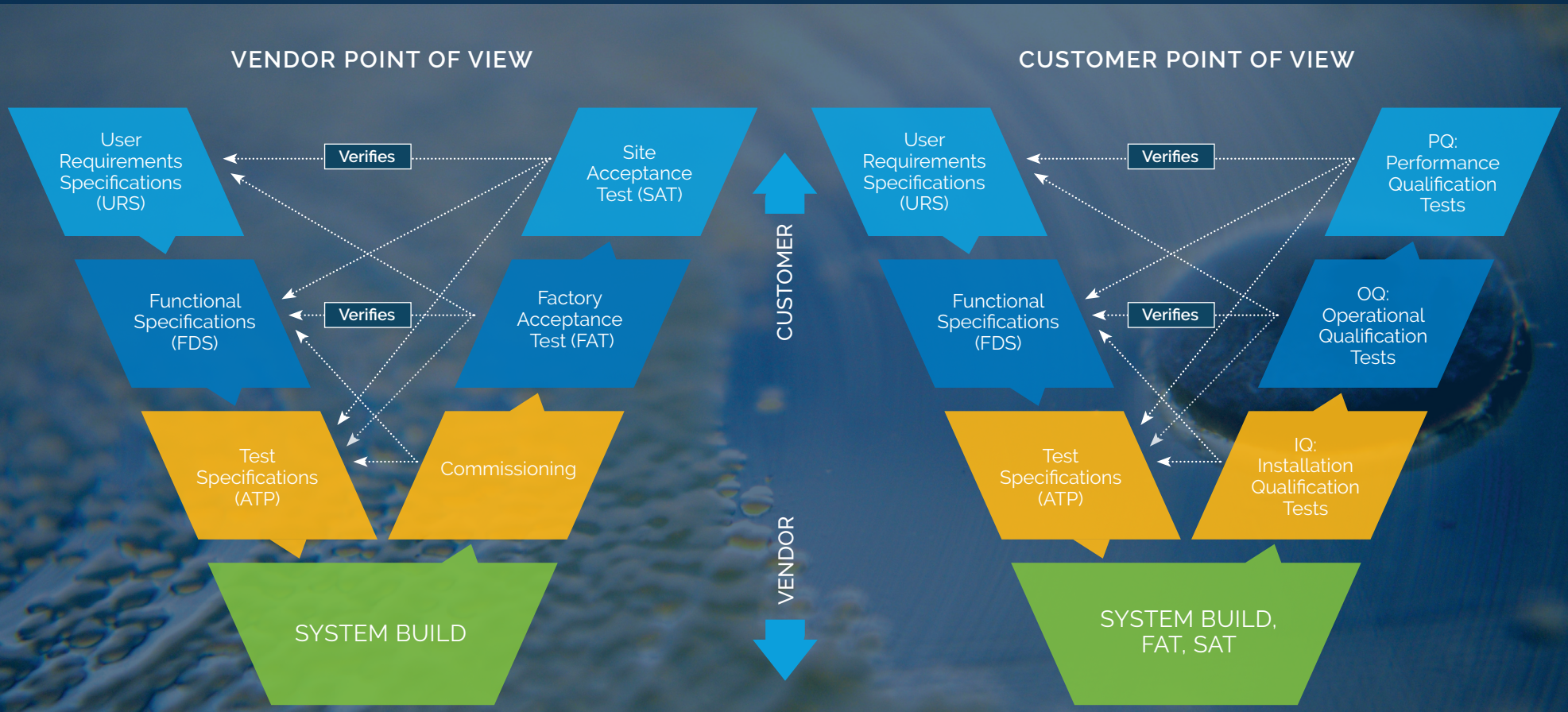
SAT is an opportunity to identify and correct any last-minute challenges before handoff or transfer of ownership to you and your organization.

Like FAT, SAT further establish that the requirements mandated in your URS and FDS are met. SAT is typically performed by engineers without any liquid or using water as the sole liquid. Tests are often identical to those performed during FAT, qualification, and validation.

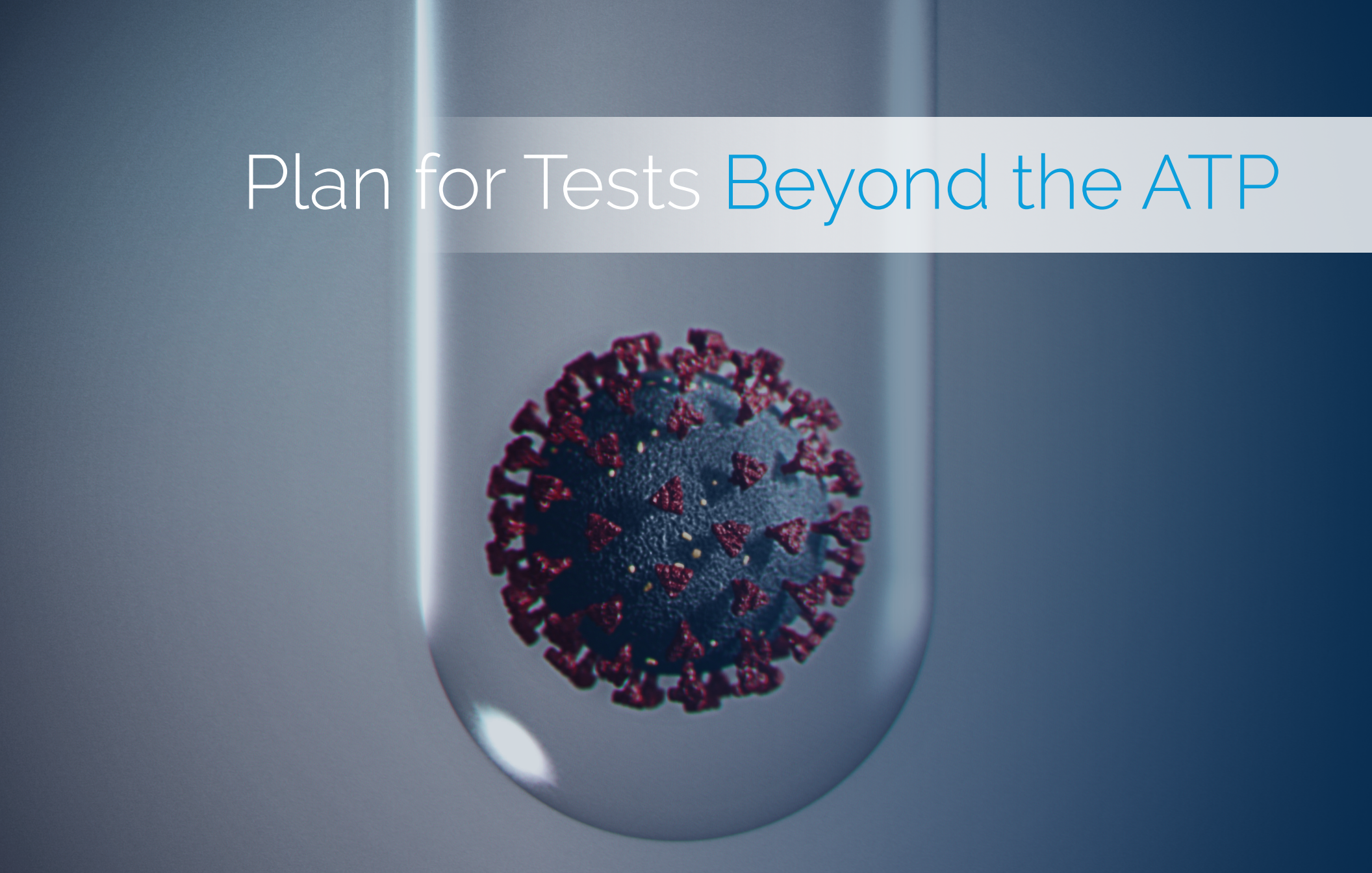
SAT is also an opportunity for your engineers and scientists to become more familiar with the overall system.

Biological or Chemical Acceptance Test – After SAT is approved, the system may be tested with actual biological or chemical samples. Tests may include those conducted during SAT. SAT tests can also include preset verification protocols so that results may be analyzed and compared to previously obtained results.

OVERLAPPING PERSPECTIVES TO ENSURE QUALITY



Plan for Tests Beyond the ATP



Beyond the acceptance plans agreed upon by your team and external vendors, your internal quality testing requirements will most likely include qualification and even validation studies once the system is installed at your facility.

Installation Qualification Test (IQ) – IQ tests confirm that the automated system was properly delivered, installed, networked, and configured per URS, FDS, and other ATP specifications. This includes making sure that all components and accessories were shipped and received, the proper software versions are in place, environmental conditions are satisfied, and more.

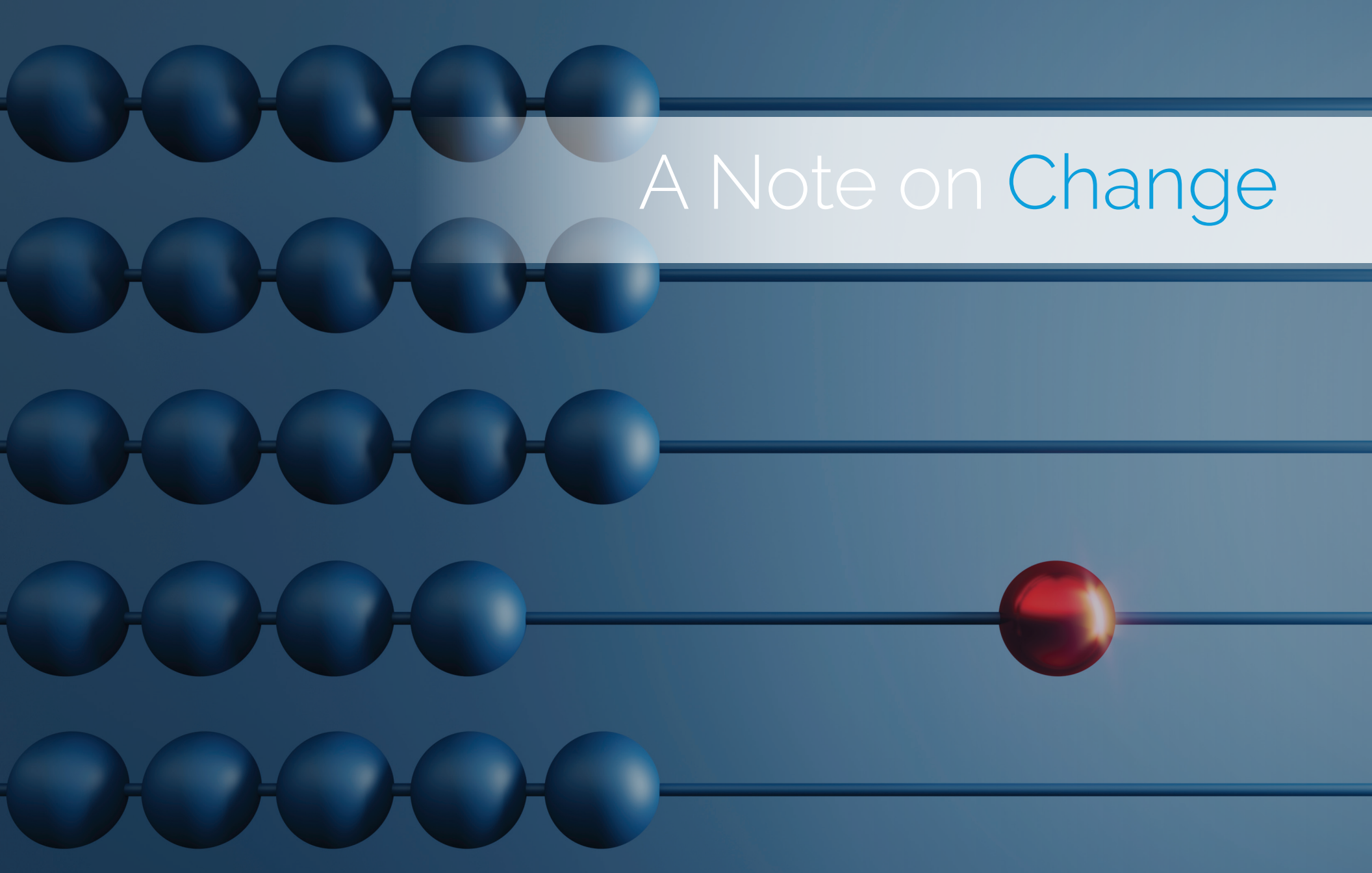
Operational Qualification Test (OQ) – OQ tests verify that the system, including software and devices, functions within operating ranges established by manufacturers and in line with expectations detailed in the URS, FDS, and other ATP specifications.

Performance Qualification Test (PQ) – PQ tests document that the integrated system functions as expected under consistent and safe real-lab conditions. This includes using scientific protocols and generating data that aligns with expectations set in the URS, FDS, and other ATP specifications.

Validation Tests – Whereas qualification tests target functionality and can fall under the context of an overall verification project, specific validation tests focus on the workflow process itself and how it performs in context of the automated system and the scientific data that results. With that said, a well-designed validation path may include performance qualification.

Validation tests are performed under consistent and safe real-lab conditions using established standard operating procedures (SOPs) and validation protocols. Data and outcomes generated from real samples in this manner must be reproducible and accurate within approved limits.

In addition to satisfying quality requirements, all information collected from validation tests may be submitted to external regulatory bodies for review and approval.

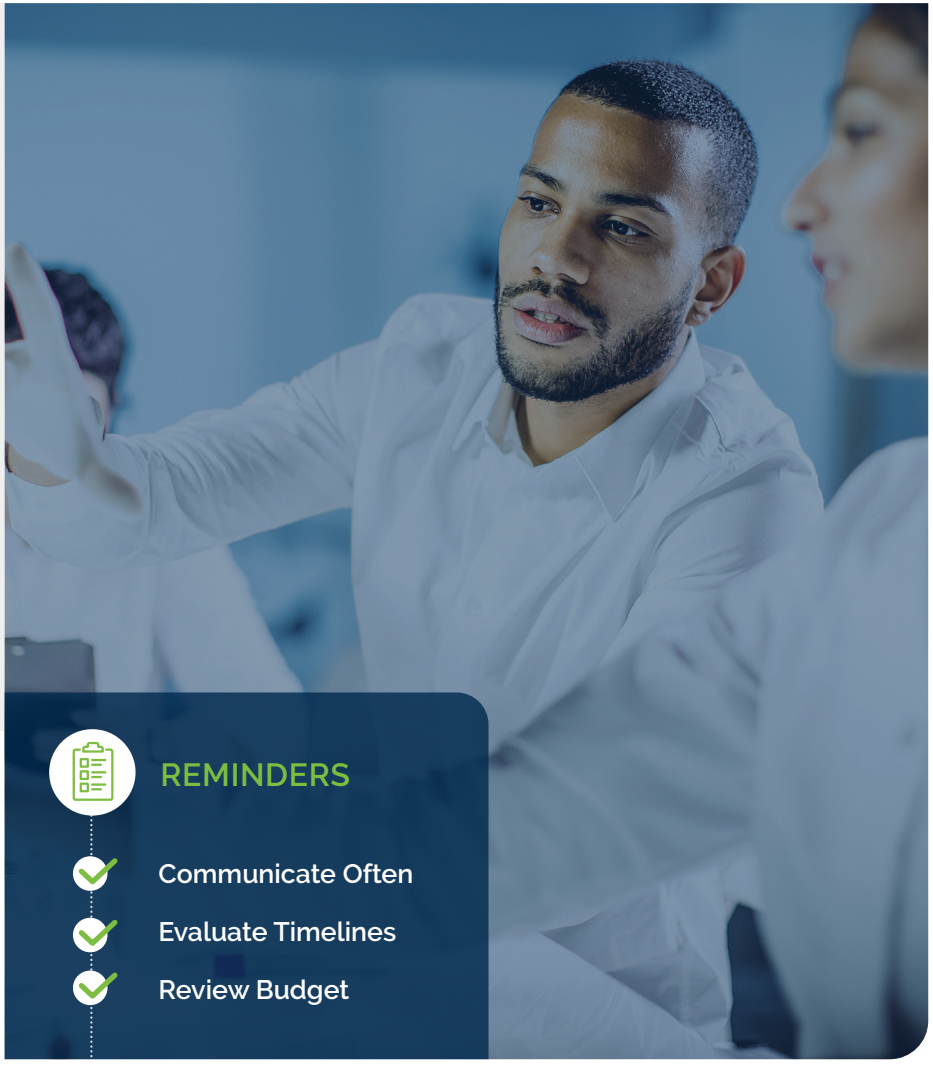

A Note on Change

In context of the overall automation journey, change is inevitable. In a whole lab workflow automation system, changes might manifest as adding, changing, or removing components and services, changing workflow steps, or any number of unforeseen or unavoidable circumstances.

At any time during the project, and especially during acceptance testing when you can tangibly scrutinize the system's layout and performance, you have the opportunity and right to request changes, known as change orders, and variations from the signed contract specifications to satisfy your vision and budget.

On the other hand, changes can add up quickly if you don't have a firm change control process in place. Endless changes and scope creep can slow down or even derail an automation project. The net result can significantly impact fees and timelines.

Before approaching vendors with a change order proposal (COP), make sure that the requests align with the project goals, are decisively justified, and prioritized such that the extra effort, along with time and costs, will bring high impact value to the project.




Finalize Site Preparations

As the system and components go through assembly and FAT at the manufacturer's facility or integrator's site, it's time to make last-minute preparations at your site. If any facility work required construction permits, be sure that final inspections are completed (or scheduled) and the work is approved to safety and local ordinance specifications.

Inspect that electrical, gas, and network connections are appropriately located for convenient hook up to the automated system and that all safety precautions are in place for installation and beyond. If safety training is a requirement, make sure that trainees are identified and have gone through training prior to the system handover.

Review shipping logistics and be sure that any special considerations such as insurance and customs or import laws are addressed in a timely fashion. Verify that your site's shipping and receiving dock has adequate area to receive the many boxes, crates, and pallets containing the automated system components that are part of your new system.

If system components will move from the dock to a staging area, double-check that the pathway is free from obstructions. Same goes for materials moving directly from the dock to the lab, or from the staging area to the lab.

Above all, make sure that your expected dates align with the promised dates from vendors, shipping companies, and other third parties, and communicate these dates to everyone in your facility to align all employees and minimize disruptions.

Additional helpful information in a facility-wide communication includes an overview of the project, timeline, and locations (labs, docks, hallways) to be used or to be avoided during deployment.

In preparation for copious tests, remember to order all assay chemistries and consumables to be used. Qualification and validation tests can take months, so allow for ample supply of these necessary supplies.

Don't forget that consumable types (microplates, lids, other vessels, etc.) will likely change from what was used in the old workflow to what you need today. Rely on vendor experts with deep domain knowledge when identifying the optimal labware relationship for the protocol and system.

Are adequate samples available throughout this testing period?

Once everything is unpacked, you may be left with more materials than you expected.

Will you dispose of, reuse, recycle, or upcycle the packaging materials?

If your organization has disposal guidelines or environmental initiatives in place, you can take the opportunity to serve as a success story by coming up with creative and useful ideas to reuse or repurpose as much packaging material as possible.

SHIPPING MATERIAL REPURPOSING

6 Categories to Spark Your Creativity

ANIMALS – chicken coop, beds/pillows, housing, scratching post

DÉCOR – artwork, flowers, frames, shelves, signs

GARDEN – compost bin, plant stand, raised garden bed

KIDS – artwork/graffiti wall, cardboard string instrument, doll house, theatre prop

STORAGE – bookcase, chest, in-drawer organizer, trunk

WORK AREAS – easel, craft bench, potting bench, utility bench

Connect with Us Before you Take the Next Step

Embarking on an automation journey? Depend on HighRes Biosolutions to be a friendly and experienced team member! Our multi-faceted experts are on hand to provide personalized guidance, helpful insights, and actionable tips through each phase of your unique journey.

Before you take that next step into automation, including whole lab workflow automation, reach out to us at sales@highresbio.com.

North American Headquarters

102 Cherry Hill Drive
Beverly, MA 01915 USA
Tele: 781-932-1912

European Headquarters

Unit D2, Broadoak Business Park
Ashburton Road West
Trafford Park, Manchester
M17 1RW UK

EB-DIG-240203-07_RevA

Learn More

We invite you to read the seventh and last e-book in this Destination Ahead series, *"Deploy!"* The system is released to your organization and the journey is almost complete.

HighRes® biosolutions