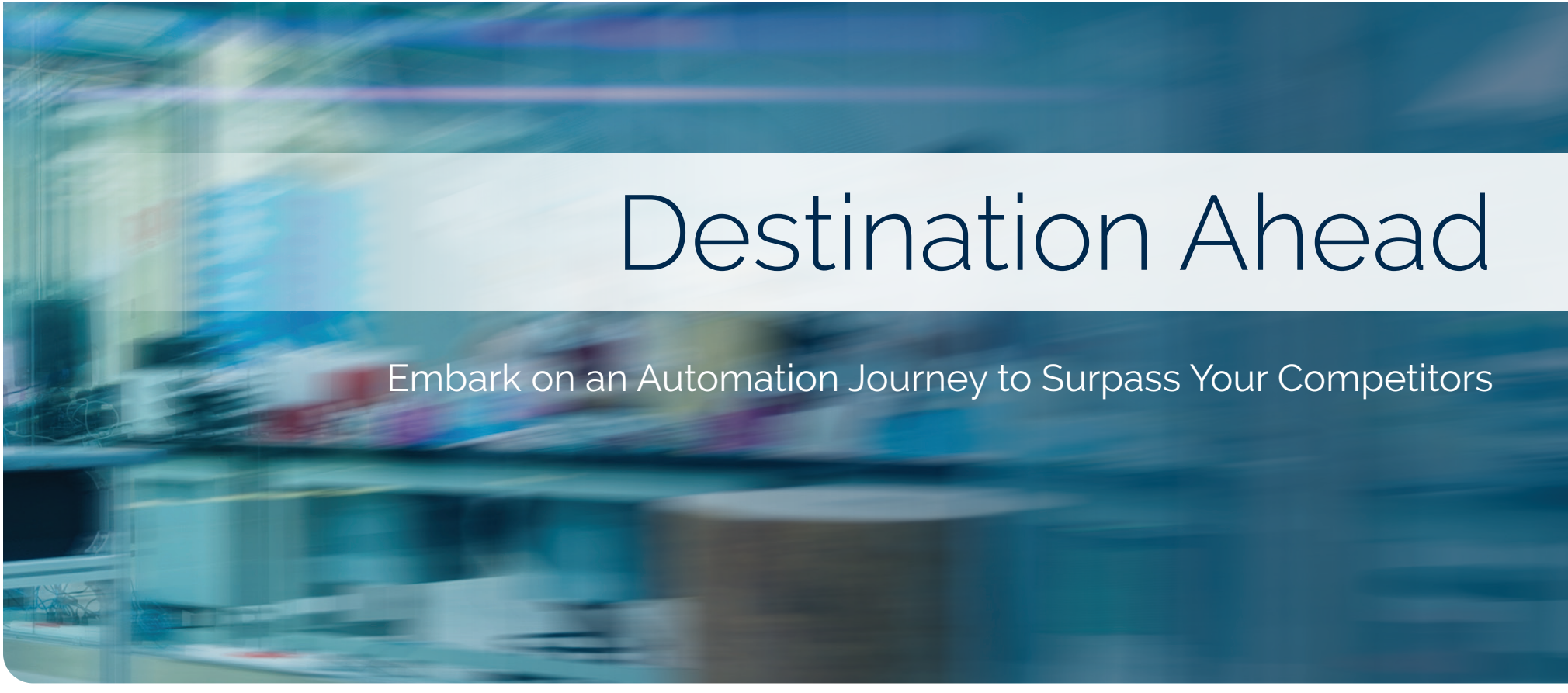
PHASE 7> DEPLOY



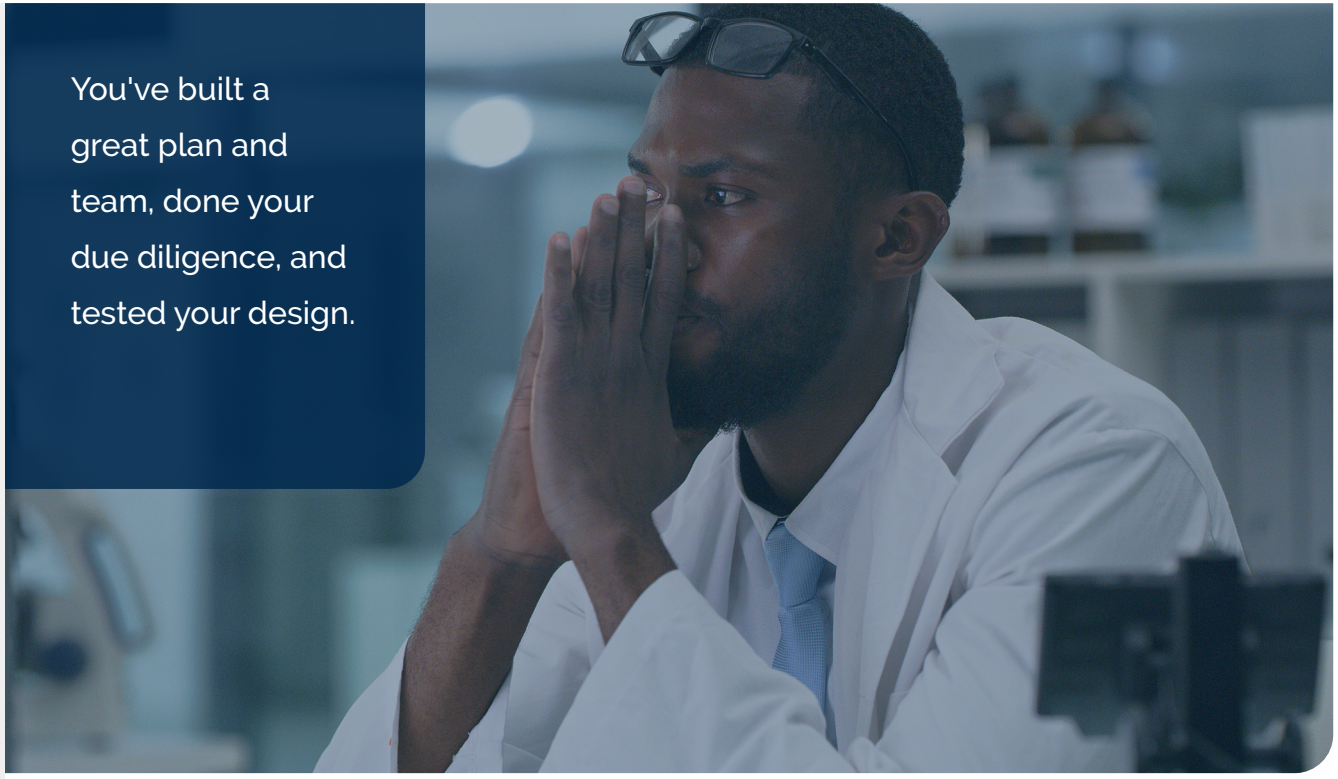
Destination Ahead

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. You built a great plan and team, explored the wide worlds of hardware and software, and applied the team's newly gained knowledge to finalize an ideal system design to suit your organization's needs. The design became reality and was rigorously tested to ensure robust performance before and after it was installed in your facility.



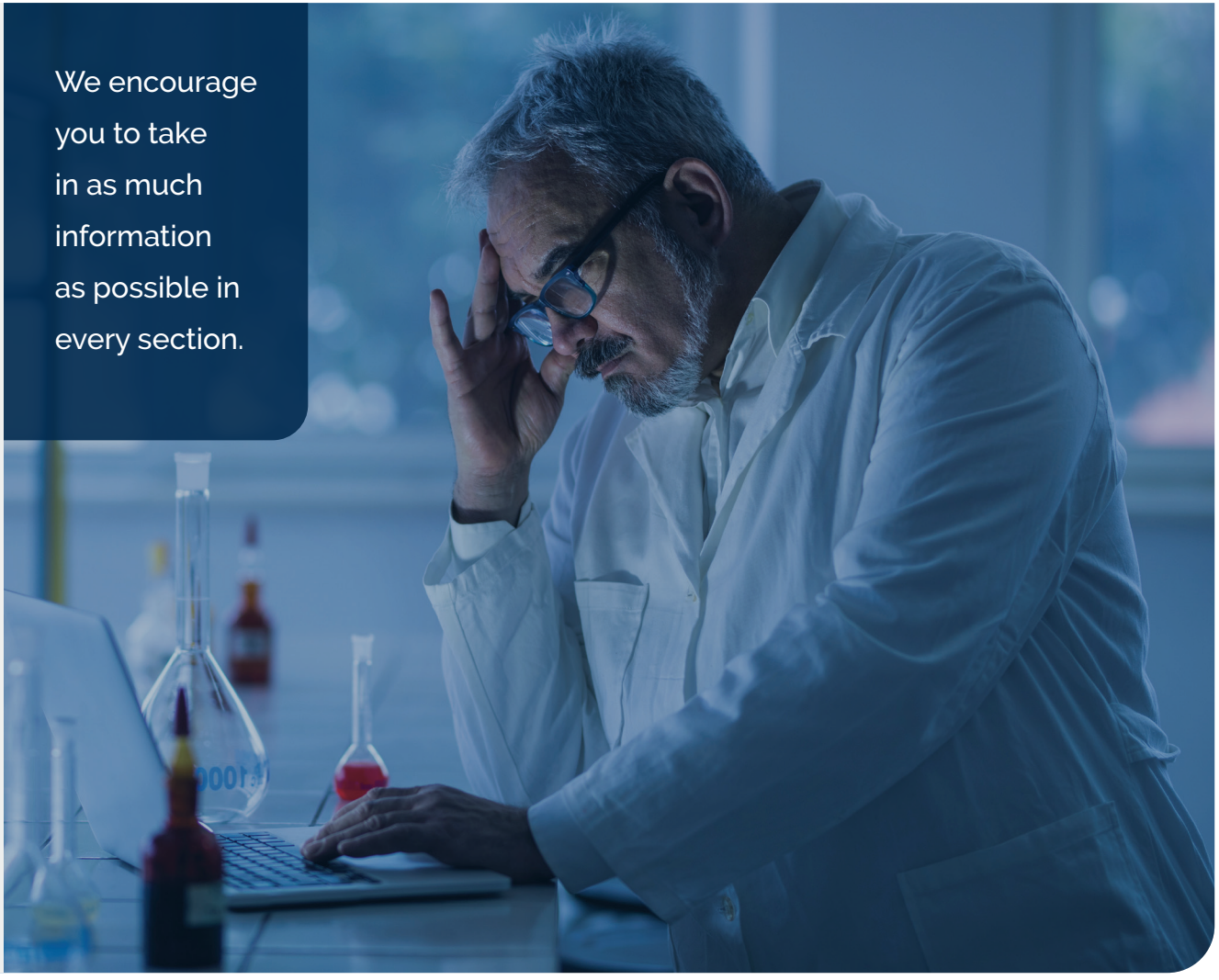
Before launching into exciting production frontiers with the automated system, the last steps in your journey are to ensure user education, fine-tune and validate the process, and maximize the value of data produced by the new system.

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.

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.

YOU ARE HERE

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.


Deploy!

All the prep work is done. Factory acceptance tests (FAT) and any resulting action items are complete. All system components arrived at your site. Vendor teams installed and connected the whole lab workflow system and coordinated with internal teams to ensure a seamless integration into your facility.

The vendor teams also recommissioned the automated system, performed site acceptance tests (SAT), and addressed any root causes and corrective actions to confirm that the overall system, including each component, is performing robustly in your facility.

Read *"Set the Project Build in Motion"* for more information on FAT and SAT.

Vendor(s) have also optimized the whole lab workflow automation system to your expectations as documented in the user requirement specification (URS). The system is now under warranty and service contracts are activated if you elected for them as part of the agreement.

Learn more about URS in our e-book, "Understand Your Situation, Your Goals, and Your Team"

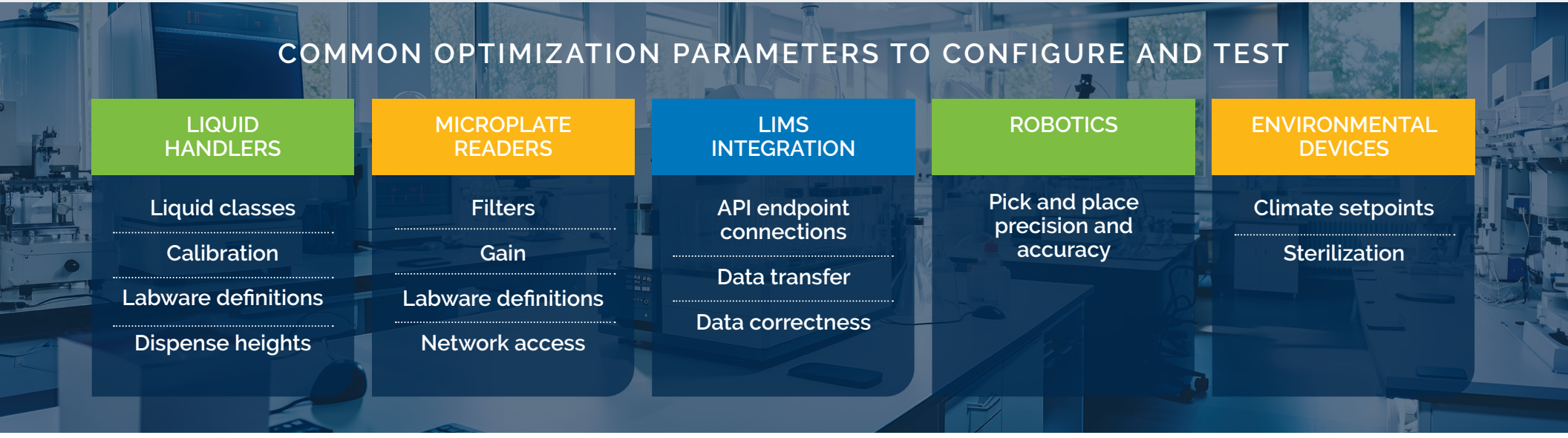
Prior to closing out the project and transferring the title of ownership from the vendor's standpoint, a knowledge transfer is in order.

Training

It's time to familiarize potential users across the facility with the automated system. Dependable vendor experts provide training sessions so that all users can reap maximum utility from the whole lab workflow automation system.

Training sessions can include creating protocols and orders from scratch, operating devices through direct integration, and executing and analyzing the run orders. They can also include teaching robots how to access and move items to specific points in the system, and methods to recover from robotic or device errors. Users can learn where and how to access technical and applications support for the workflow automation system, including all devices and software.

Basic training is suitable for most users, while advanced training provides in-depth knowledge for super users, automation engineers, and internal trainers. These trainings also satisfy documentation necessary for good practice (GxP) and other quality-focused requirements.



COMMON OPTIMIZATION PARAMETERS TO CONFIGURE AND TEST

LIQUID HANDLERS	MICROPLATE READERS	LIMS INTEGRATION	ROBOTICS	ENVIRONMENTAL DEVICES
Liquid classes	Filters	API endpoint connections	Pick and place precision and accuracy	Climate setpoints
Calibration	Gain	Data transfer		Sterilization
Labware definitions	Labware definitions	Data correctness		
Dispense heights	Network access			


Optimization

Again, post-SAT and training activities often mark a major milestone where vendors wind down their project responsibilities and hand the whole lab workflow automation system off to internal teams.

To get this far, you and your team have exerted significant time and effort. However, as much as you may deserve it, this juncture is not quite the right time to hit the ski slopes or relax on a tropical beach. There's still important internal work to do before your project is completed.

Vendor optimization ensures that the system meets your documented performance expectations as outlined in the URS. On the other hand, process optimization fine-tunes the automated system to your nuanced protocol and workflow needs. Process optimization considers sample parameters such as biological and chemical considerations, viscosity, aggregation, solubility, and more.

Here again, top-notch product and service providers can offer expertise, guidance, and helpful tips to help you navigate the optimization process.

Depending on the complexity of your system and applications, optimizing the new automated workflow process can take six months or more.

Validation

As with acceptance and qualification tests, validation can take time. Keep in mind that this time and effort are a small sacrifice compared to the highly valuable reward of a high-performing and long-lasting automated data-producing factory.

As previously stated, validation tests access the end-to-end performance and functionality for scientific protocols and real samples run using the whole lab workflow automation system. Success is based on the quality of scientific data generated.

Get a quick overview on the purpose of qualification and validation tests in our e-book, "Set the Project Build in Motion".

Success is also based on the protocol for automation development (autoDev) quality.

Are you using the original manual protocol on the automated system, or has the protocol been developed and optimized with automation in mind?

Does your protocol allow for streamed or continuous processing?

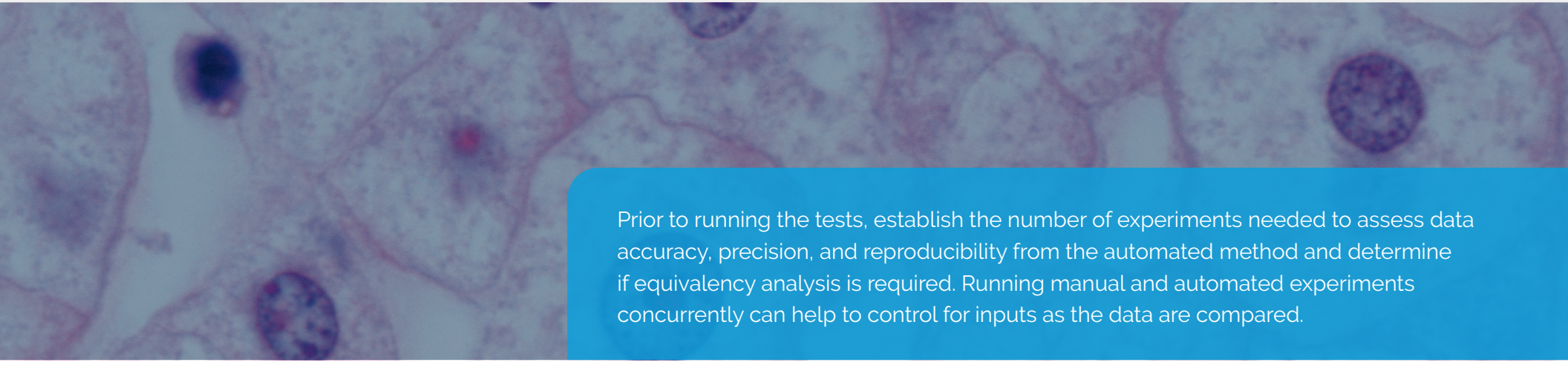
Labs may typically follow either a standard R&D or stringent good practice (GxP) validation path. Both are similar in that they define and document the overall plan and specific validation requirements as well as a risk assessment and metrics including pass/fail criteria.

They both include all the documentation you've compiled so far, including the URS, functional design specification (FDS), qualification plan/tests/results, data integrity and documentation, and any training and communications. Finally, both can either conduct the tests internally or enlist the services of a third party.

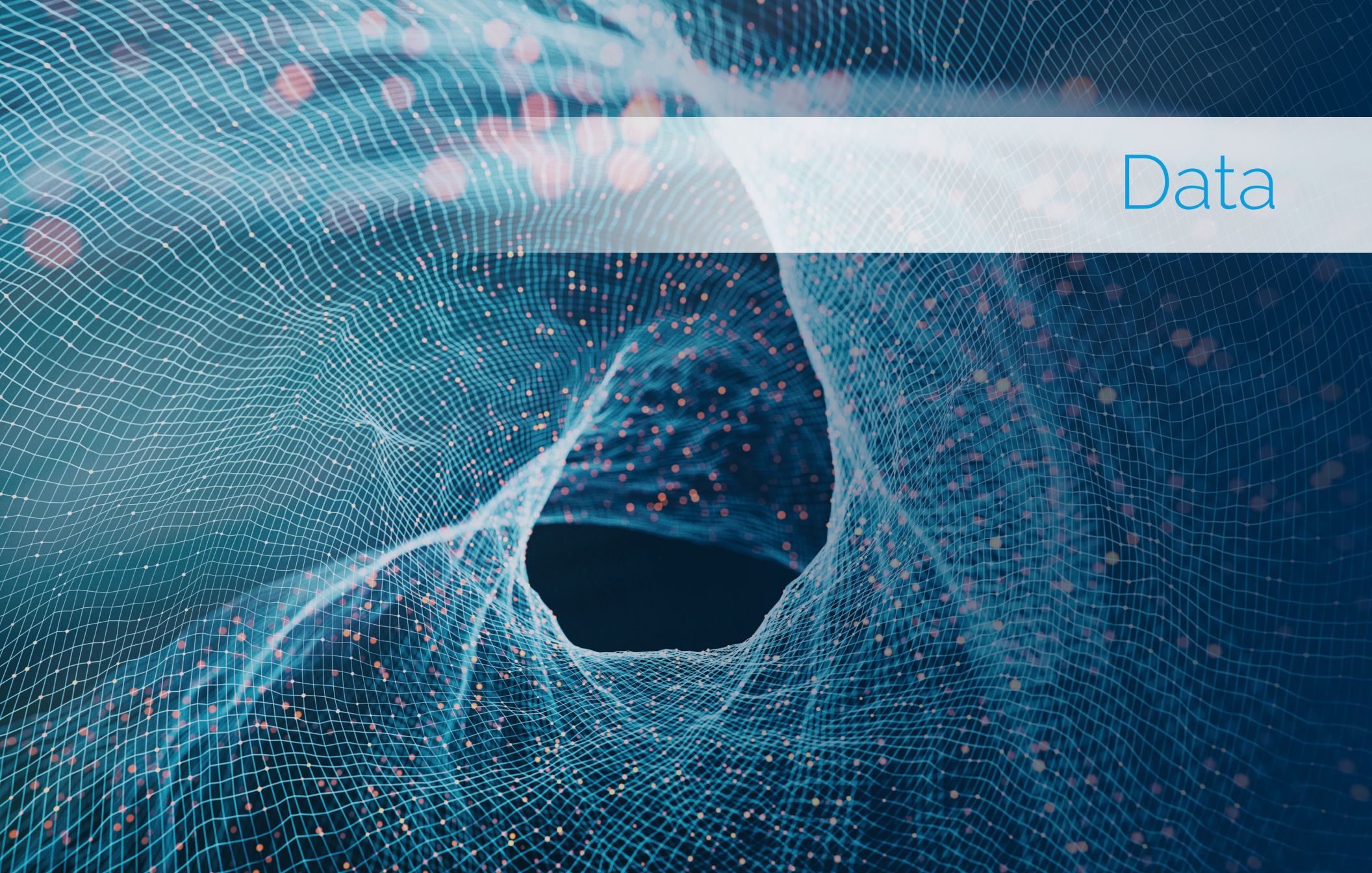
Learn why an FDS is important in our e-book, "Set the Project Build in Motion".

Conversely, while standard R&D validation benchmarks to the internally derived URS and other internal criteria, a GxP validation must meet additional criteria. Depending on the product's intended global target audience, a GxP environment must document compliance to any number of global regulatory body guidelines, including the United States Food and Drug Administration (US FDA), International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), and more.

Additionally, the GxP validation path should include outline documentation control, quality system integration, and change control processes. This stringent validation is subject to continuous monitoring and periodic review.



Prior to running the tests, establish the number of experiments needed to assess data accuracy, precision, and reproducibility from the automated method and determine if equivalency analysis is required. Running manual and automated experiments concurrently can help to control for inputs as the data are compared.

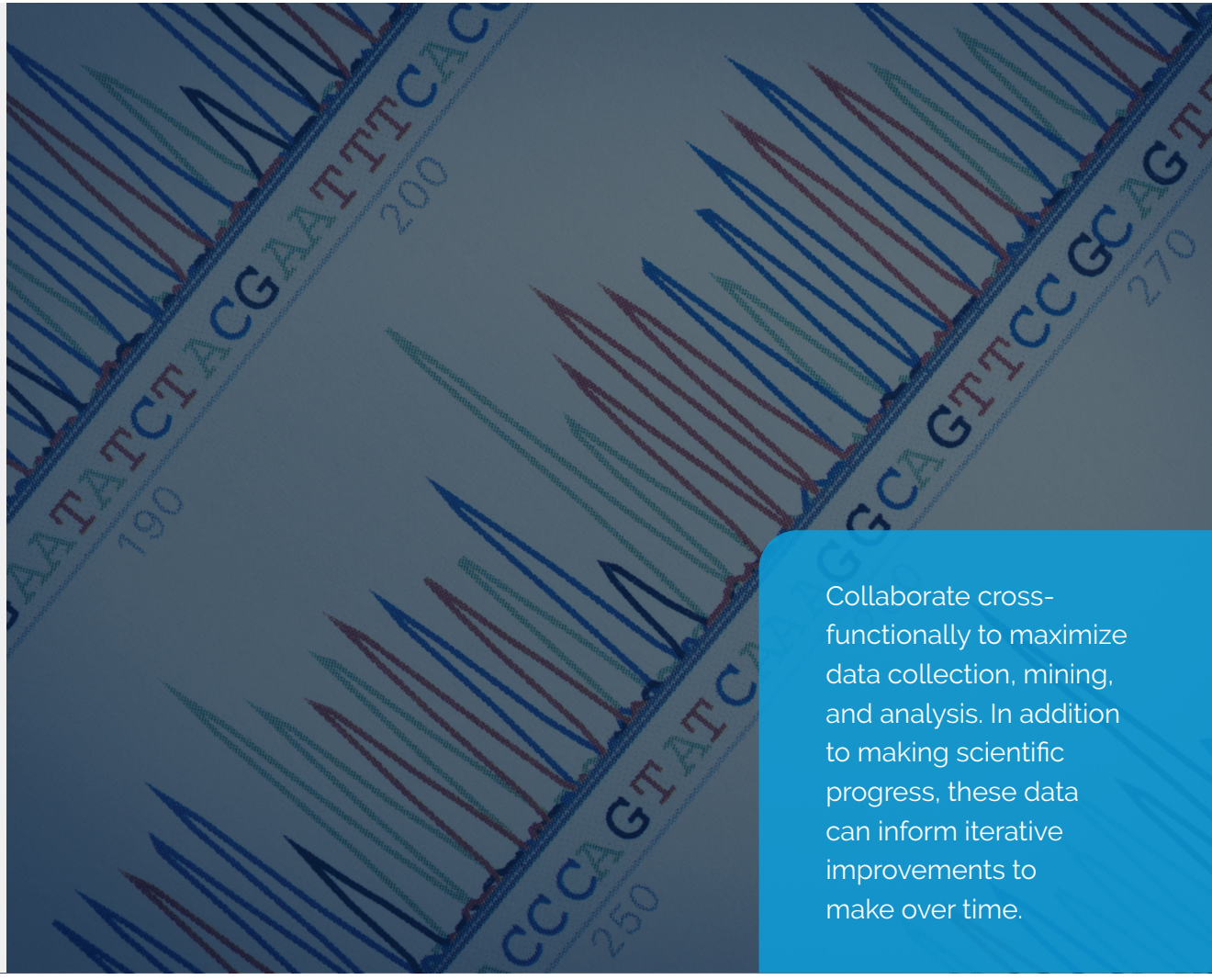

Data

Finally, before signing off on the whole lab workflow automation system project and moving into production, decide how you will best leverage the data generated in your now-expanded data pipeline.

Integrating with an existing data stack or tying it to a laboratory information management system (LIMS) or database integration are great tactics in an overarching data strategy. Note what trends and insights you want to uncover with these data and how they fit into the broader scientific project picture.

Collaborate cross-functionally to maximize data collection, mining, and analysis. In addition to making scientific progress, this data can inform iterative improvements to make over time.

On top of this, much of the data can and should be used to measure progress against your key performance indicators (KPIs) and ultimately calculate your organization's return on the automated project investment.



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.

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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.

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