



Track and Trace Migration Guide

Introduction

Your serialization journey likely started years ago when a range of countries introduced new regulations to govern how prescription drug products move through the global supply chain. At that time, the entire industry was under immense pressure to comply with the new regulations, requiring every manufacturer to move quickly and choose a solution provider that would ensure compliance of their products.

But if you're like many pharmaceutical manufacturers, the track and trace system you implemented to support your "compliance" needs then—may no longer be meeting the full range of "business" needs you have now.

Every day, we hear from manufacturers, distributors and logistics providers who have a track and trace system in place but still face some very significant challenges like:

- EPCIS, serial number and aggregation errors causing shipping delays
- Slow provider response times for critical problems that need immediate resolution
- Prolonged implementation timelines due to the need for fixes that require custom coding
- Failed attempts to solve ongoing problems due to buggy patches and code errors
- Continuous revalidation cycles based on the high volume of recurring issues

And then... there's cost. Increases to annual subscriptions. Unbudgeted IT costs to resolve persistent issues. Additional costs for continuous validation, which wouldn't be necessary if your system was error-free, as promised.



Migration Myth: Implementing Track and Trace Was Hard—Switching Won't Be Easier

Implementing track and trace the first time was complicated. From data exchange and system integration to trade partner connectivity and validation—the entire industry was learning “how” to do it as implementation took place. The investment you made then, while necessary, was significant and labor intensive—and now, it may leave you with the feeling that “we just can’t go through that again despite the ongoing problems we have.”

The good news? While migrating to another track and trace system can be hard—it doesn’t have to be. Whether or not it is will depend on a range of factors, and this guide was created to help. It will walk through some of the most important considerations to make before you decide to transition to a new solution so that you understand how to minimize the disruption you faced the first time around. The guide steps through six “make-or-break” migration considerations, including:

1. Total Cost of Ownership (TCO): How You Can Reduce Cost Over Time
2. More than Just “Basic” Compliance
3. Workflow Fit: Architecture That Works Your Way
4. Serialization Experience: What Your Provider Doesn’t Know Might Cost You
5. The Validation Mystery: Things Are Not Always What They Appear
6. Migration Mayhem: How to Avoid the Chaos (Again)

No company should feel forced to just “live with” the track and trace system they’ve got. The future of traceability for your business demands simplicity, transparency and flexible control—and expecting anything less will be more costly for your brand in the long run.



Make-or-Break Migration Considerations

42% of pharmaceutical manufacturers cite Total Cost of Ownership as the primary reason for switching to a new track and trace provider.

Source: Contract Pharma's Track and Trace Solution Survey, January 2025

1. Total Cost of Ownership (TCO): How You Can Reduce Cost Over Time

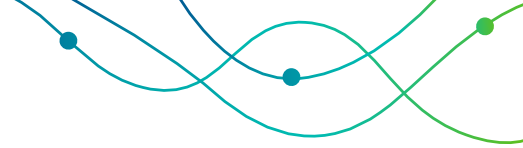
If you've already made an investment in a track and trace system, you're probably aware that your TCO has gone well beyond the initial purchase price or annual subscription fee. Integrating with legacy systems, packaging lines and diverse partner platforms can require significant custom development and ongoing IT support, with costs often exceeding initial estimates, especially if the solution lacks pre-built connectors or a standardized approach to partner integration. In fact, 42% of pharmaceutical manufacturers cite that TCO is the primary reason for switching to a new track and trace provider.

Poor vendor support can also lead to cost increases from procuring help elsewhere, with research showing that 26% of pharmaceutical manufacturers switch vendors due to inadequate service, noting how delays in troubleshooting often result in costly operational disruptions.

Reliable, fast, and proactive vendor support is crucial for minimizing downtime and avoiding hidden costs associated with missed deadlines or regulatory non-compliance. Investigate whether your provider includes as part of its core offering capabilities for exception handling, rework, mobile scanning, proactive error prevention and out-of-the-box regulatory updates. If these aren't included, you're likely to pay for these services if and when you need them later on.

TCO Questions to Ask Track and Trace Providers

- Do you provide upfront scope and transparent pricing?
- What is the cost of validation?
- Does your package include any dedicated service hours?
- Is training and support included in my subscription?
- If we switch, can you absorb any of the cost of our current annual subscription?



Only a system that includes **prebuilt global coverage** can protect you today—and as you expand into new markets tomorrow.

2. More than Just “Basic” Compliance

Every traceability solution provider offers compliance—but the right system for your business must go further. Only a system that includes prebuilt global coverage can protect you today—and as you expand into new markets tomorrow. Choosing a system that just covers the markets you serve today doesn’t future-proof your business and will likely introduce more implementation time and cost later on. That may not seem like something to worry about now but delaying a commercial launch because your track and trace system isn’t ready is unacceptable. Be sure to vet your track and trace provider options by investigating how they stay ahead of evolving regulatory requirements to keep your products compliant without distracting you from your business goals.

Compliance Questions to Ask Track and Trace Providers

- What country-specific regulations does your solution cover?
- How will you support us when we introduce products into new countries?
- How easily can we add a compliance module if we acquire a company that ships to different countries than we do?
- How do you support traceability outside of compliance requirements?
- Do you offer data error prevention to catch EPCIS issues proactively?

Traceability platforms must be able to support your current packaging and distribution workflows—but be flexible enough to adapt quickly when you need to modify them.

3. Workflow Fit: Architecture That Works Your Way

One major industry learning is how some solution providers took the approach of defining a set of very specific business processes and rigid workflows—and mandating that you follow them. At first, this sounded like great advice to follow in order to meet compliance deadlines on time. The reality is that companies don’t work that way. As your business evolves, so do your processes and workflows. Traceability platforms must be able to support your current packaging and distribution workflows—but be flexible enough to adapt quickly when you need to modify them. It’s critical to understand the level of rigidity that a track and trace solution has with respect to adding or updating processes. Some red flags to look for include lists of very specific processes and workflows that you must conform to, or the need for engineers to write custom code whenever the slightest adjustment is needed. Choose a solution with modular components that eliminate custom coding, simplify error resolution and enable rapid onboarding of new trade partners.



Architecture Questions to Ask Track and Trace Providers

- How does your solution support rapid troubleshooting?
- Does your solution require custom coding to accommodate SOP and trading partner changes?
- Does your solution leverage standard connections without the need for custom development?
- Do you offer any modules we can use to address specific challenges alongside our current solution?

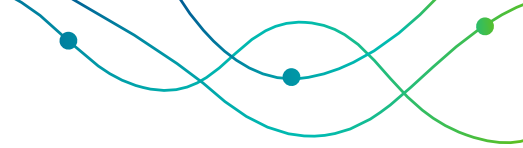
Track and trace providers that **lack deeper serialization and packaging expertise** are unable to address more holistic pharmaceutical challenges where product manufacturing and compliance intersect.

4. Serialization Experience: What Your Provider Doesn't Know Might Cost You

Serialization isn't new—it's been around for decades, as pharmaceutical manufacturers and CMOs have been serializing products far longer than most track and trace providers have been in business. Because many traceability vendors founded their businesses at the same time supply chain regulations were being signed into law, they also narrowed their focus on regulatory challenges and compliance data exchange with trade partners. Both are critically important, but track and trace providers that lack deeper serialization and packaging expertise are unable to address more holistic pharmaceutical challenges where product manufacturing and compliance intersect.

This serialization knowledge gap has led to track and trace solution development that doesn't account for multifaceted SOPs, packaging line integration, aggregation complexities and specific drug manufacturing workflows. On the other hand, track and trace providers that have also been serving the pharmaceutical industry with serialization and packaging solutions for decades bring an unmatched level of manufacturing expertise to their traceability offerings. That intimate understanding is often evident in their track and trace solutions, which are designed to flexibly support hyper-specific pharmaceutical requirements instead of forcing the adoption of unorthodox standards that don't reflect operational reality.

Be sure to investigate the level of serialization and packaging experience of any track and trace provider you may be considering. Failure to do so may conceal change management friction that could have unfortunate consequences for the future of your business.



Serialization Questions to Ask Track and Trace Providers

- Do you have experience deploying aggregation?
- How long have you been supporting global serialization requirements?
- Do you enable supply chain rework through your platform?
- How do you reconcile data issues from the packaging line?
- Does your solution require separate edge system integration?

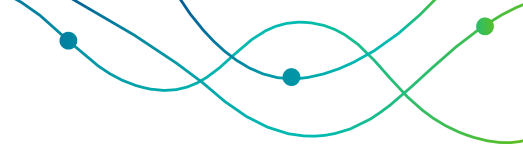
To maximize protection and minimize cost, consider providers that offer **tiered validation packages** and **pricing flexibility** that can be tailored to your specific needs.

5. The Validation Mystery: Things Are Not Always What They Appear

When supply chain regulations were first introduced, track and trace providers recognized that software validation would introduce new challenges, particularly as evolving regulations might require frequent software updates. Without the proper validation, pharmaceutical companies could fall out of compliance and be left to deal with regulatory penalties, product recalls and even loss of market approval for new products.

Validation is a resource-intensive process that requires significant investments in time, staff and documentation. And because regulatory guidelines are often high-level and open to interpretation, it can be challenging to know exactly how much validation is “enough”—and can result in over-validation (wasting resources) or under-validation (risking non-compliance). 42% of pharmaceutical manufacturers express frustration with the extensive validation required for patches and releases. This highlights the need for solutions that minimize disruption and streamline the update process.

Some providers have additional subscription fee-based solutions that promise to automate and simplify the entire validation process for any software updates they make. While that may sound appealing, integrating validation tools into existing infrastructure often reveals compatibility gaps, especially with older serialization hardware or data formats. This introduces the need for custom middleware development, which takes time and adds greater cost to the annual subscription. What’s more, rapid infrastructure updates required to fix other traceability issues can trigger unintended functionality breaks that require time-intensive root-cause analysis and resolution.



To maximize protection and minimize cost, consider providers that offer tiered validation packages and pricing flexibility that can be tailored to your specific needs. Be sure to engage your vendor in careful risk assessment around legacy system integration, testing protocols, pre-connected partner ecosystems.

Validation Questions to Ask Track and Trace Providers

- Do you have a single or tiered validation packages to help us select the option that works best for our business?
- Do you provide test scripts for my specific workflows?
- How often do you release updates that require validation?
- Do you leverage a sunset approach when migrating data and connections?

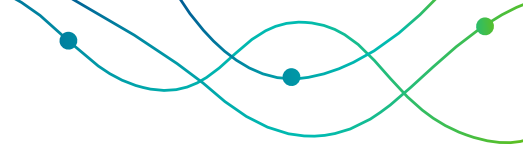
A **modular track and trace solution** may allow you to first deploy certain traceability components alongside your existing system to fix acute problems, such as EPCIS and exception management errors, rework, aggregation and more.

6. Migration Mayhem: How to Avoid the Chaos (Again)

One thing is clear: You don't want to relive the experience you faced implementing track and trace the first time. But the alternative—choosing to stay with your current provider and tolerate existing problems—is not an advisable path forward.

It's a huge decision to move from your current track and trace system to a new one. Even if you're confident that you've found a new provider and solution that is better for your business, the critical nature of migration can't be underestimated, including how you will transition:

- **Business processes** for master data management and serialization
- **Production workflows** for manufacturing and packaging
- **Systems integration** for both your operational infrastructure and the systems at your manufacturing sites, CMOs and trade partners
- **Production data** from your current track and trace system to the new one
- **Validation processes** including documentation, test scripts, user access controls and audit trails.



First and foremost, you need to understand whether your new track and trace provider requires that you replace the entire system at once—or if they offer a modular approach. While most migrations do involve moving entirely from one system to another, a modular track and trace solution may allow you to first deploy certain traceability components alongside your existing system to fix acute problems, such as EPCIS and exception management errors, rework, aggregation and more.

Next, it's important to find out how each track and trace provider approaches the migration process. Many providers will treat it like they do any other track and trace implementation, while others who have experience executing successful transitions offer “migration kits” that include tailored project management, training and service options—and financial assistance associated with absorbing remaining costs associated with current annual subscriptions.

Lastly, be wary of those that won't dedicate “white glove” support throughout the transition, detailed implementation roadmaps tailored to your business, and transparent pricing that guarantees no hidden or additional costs.

Migration Questions to Ask Track and Trace Providers

- Do you approach migration like a new implementation, or do you offer any migration packages that would be tailored to our specific situation and problems?
- Do you offer a dedicated project manager whose only focus is our migration project?
- Do I have to migrate everything at once, or can I start with modules that will work alongside my existing solution?
- If we switch, will you absorb the remaining costs of my current annual subscription?

Turn complexity into connectivity with UniTrace



Achieve global compliance with ease: We've automated compliance and data exchange to handle all major regulatory requirements so you can focus on running your business.



Leverage decades of serialization expertise: UniTrace is the only track and trace solution that is built upon 40 years of experience in packaging optimization by the pioneers of pharma serialization.



Navigate changing requirements instantly: No engineers required to update workflows and lines of code. Our plug-and-play platform modules streamline updates—so you're not stuck with months of implementation.



Broad trade partner connectivity: Interoperate across the entire pharma supply chain ecosystem with seamless trade partner connectivity.



"Exceptional" exception management: Resolve exceptions and errors quickly using our built-in EPCIS data inspector tool, mobile application and integrated scanning—no third-party edge system required.

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+1 800 847 7123 (Global)
+1 609 395 8400 (US)
+49 6252 6736 0 (Europe)

Info@SystechOne.com
SystechOne.com