# Data you can defend: the role of IT in GxP compliance

## Build connected systems that enforce data integrity automatically, reducing manual touchpoints and audit risks.

Nobody wants another compliance headache. But if you want to modernize your IT infrastructure without regulatory nightmares keeping you awake at night, you can sometimes feel like you're caught between two worlds.

Your business demands cloud agility, real-time analytics, and seamless integration. Meanwhile, FDA inspectors expect bulletproof data integrity, complete traceability, and systems that meet ALCOA+ standards without compromise.

Here's what some IT leaders get wrong: they think modernization and compliance are opposing forces. You don't have to choose between innovation and regulatory adherence.

After all, the FDA isn't asking you to stay in the Stone Age. They're asking for data you can defend—data that's attributable, traceable, and audit-ready. Here's how you architect your systems to deliver that defensibility.

## Compliance doesn't have to be an obstacle

If any of the following are part of your current processes, your current approach to GxP compliance is probably costing you more than you realize:

- Manual data reconciliation.
- Week-long preparation for regulatory inspections.
- Systems that can't talk to each other and force your teams into endless spreadsheet exercises.

However, that doesn't mean you're stuck. The FDA's Computer Software Assurance guidance now emphasizes risk-based validation approaches. This means you can focus your compliance efforts on high-impact areas while streamlining everything else. Cloud-first strategies aren't just possible; they're becoming the standard for organizations that understand how to validate and control modern infrastructure properly.

## Embed compliance into a connected ecosystem

In a fragmented environment, your data lives across manufacturing systems, quality management platforms, and supply chain applications. Every compliance task becomes a manual integration nightmare because your infrastructure fights against itself.

The solution isn't more systems. It's a unified system.

Start with data integrity by design. Build governance frameworks that enforce ALCOA+ principles automatically. When your manufacturing execution system talks directly to your ERP, and both maintain synchronized audit trails, you eliminate the manual touchpoints that create vulnerabilities.

Cloud connectivity, when properly validated, actually strengthens your compliance posture. Modern platforms like SAP Cloud ERP Private provide built-in GxP capabilities: electronic signatures, role-based access controls, and comprehensive audit logging. The FDA's focus on Computer Software Assurance means you can leverage vendor-provided validation evidence rather than starting from scratch.

Integration challenges become manageable when you establish clear data flow documentation and end-to-end testing protocols. Your APIs and middleware need qualification just like any other system component, but the payoff is enormous: consistent data across all platforms with no manual reconciliation gaps.

# The ERP-centric approach to GxP excellence

An ERP-centric approach changes how you think about compliance. This isn't just about operational efficiency; it's about creating a single source of truth that regulators can trust.

Your ERP becomes your compliance command center. Every batch record, quality check, and distribution transaction flows through one validated system with complete traceability. Instead of chasing records across ten different databases during inspections, you pull comprehensive reports in minutes.

Electronic Batch Records replace paper-based processes, eliminating transcription errors and providing real-time visibility into production status. Quality Management integration ensures that procurement, manufacturing, and distribution data all connect seamlessly. When a deviation occurs, your system automatically triggers the appropriate workflows and captures every response.

The audit trail capabilities in modern ERP systems directly address FDA 21 CFR Part 11 requirements. Every transaction gets timestamped, attributed to specific users, and locked against tampering.

## Validation in a connected infrastructure

System validation in a connected ecosystem requires a different approach than traditional point solutions. You're not just validating individual applications—you're qualifying entire data flows and integration points.

The integrated nature of an ERP makes ongoing compliance easier in many ways. Changes are centralized, so you don't have to chase modifications across 10 different databases. A robust change management process tied to your ERP means any update to the system (like a configuration change or a patch) can be evaluated for compliance impact in one place. Plus, SAP solutions offer pre-configured "best practice" processes for life sciences that are FDA-compliance ready. Thus, by planning for validation from the outset and using these tools, you can avoid costly retrofitting and ensure compliance is "built in" during implementation.

Here is the general framework:

**Platform integration:** Consolidate GxP-critical systems onto a unified platform that maintains comprehensive audit trails and enables real-time traceability. Eliminate manual data transfers that create compliance gaps.

**Process automation:** Build regulatory checkpoints directly into operational workflows. Make compliance monitoring continuous rather than periodic, with real-time alerts for deviations that require investigation.

**Change control:** Implement rigorous change management that assesses every system modification for GxP impact. Maintain test environments that mirror production for safe validation of updates before deployment.

**Continuous Monitoring:** Deploy tools that automatically audit system activities and quality parameters. Track compliance metrics to identify strengthening opportunities before they become regulatory findings.

## Build continuous traceability and electronic records

True end-to-end traceability is where connected systems shine. Every ingredient lot number connects to production batches, which link to quality test results, which tie to distribution records and customer shipments.

Product recall scenarios become your litmus test. Can you identify every affected lot and its destination within hours? Your integrated platform should generate complete traceability reports automatically, showing the complete chain of custody from raw materials to patients.

Data lineage documentation ensures that every calculated value or averaged result can be traced back to its source measurements. When regulators ask how you derived a stability conclusion, your system shows the individual data points, statistical methods, and approval workflows that led to that decision.

Real-time monitoring capabilities, enabled by IoT integration and advanced analytics, provide the necessary visibility into your processes. Equipment data synchronizes with operator entries and quality checks, creating a complete timeline of every production event.

# Lead through digital modernization

When you build validation into your modernization strategy from day one, regulatory requirements become design constraints that actually improve your systems. Audit trails don't slow down operations—they provide operational efficiency. Data integrity controls don't limit functionality—they ensure reliable decision-making.

Your investment in a system that is compliant-by-design pays dividends beyond regulatory adherence. Teams spend their time analyzing data instead of gathering it. Inspections become routine demonstrations of system capabilities rather than stressful document hunts. Quality issues get detected and resolved faster because your integrated systems flag anomalies in real-time.

The competitive advantage becomes clear when you consider the broader implications. While your competitors struggle with fragmented compliance approaches, you're leveraging unified data for predictive analytics, automated reporting, and strategic insights that drive business growth.

Data you can defend empowers your organization to innovate at scale while maintaining absolute trust with regulators, partners, and patients. This is how you win—not by choosing between modernization and compliance, but by making them inseparable.

**About NTT DATA Business Solutions**

We Transform. SAP® Solutions into Value

We understand the business of our clients and know what it takes to transform it into the future. At NTT DATA Business Solutions, we drive innovation - from advisory and implementation, to managed services and beyond, we continuously improve SAP solutions and technology to make them work for companies – and for their people.

**Learn more about NTT DATA Business Solutions**

nttdata-solutions.com

Through strategic consulting and advanced technology, we enable experiences that transform organizations. Discover why we are your perfect partner in the age of digitalization.

NTT DATA