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A guide for today's biopharmaceutical labs

Integrity and compliance for data in flight

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Keeping data clean, reliable, and compliant

Novel therapeutics and vaccines are the new norms for the biopharmaceutical industry—and a critical part of precision medicine and the prevention of disease.

To ensure safety, efficacy, and quality, the industry has developed a well-defined regulatory framework for ensuring data integrity over the entire product development lifecycle—including times when data needs to be transformed in flight.

Unfortunately, legacy informatics often lack the underlying architecture to efficiently track the results of that transformation, putting data integrity at risk.

But all isn't lost. And this guide can help you find your way to clean, compliant data.

Chapter 1:

Getting the guidelines

The FDA defines data integrity as the *completeness, consistency, and accuracy of data*.

To make things easy for us, they created an acronym that clearly outlines the data integrity guidelines used by regulated industries since the 1990s: **ALCOA**.

Integration, aggregation, and automation in the lab shine an even brighter light on the importance of data integrity. And keeping an eye on the acronym can help analytical labs safely and smoothly complete their digital transformations.

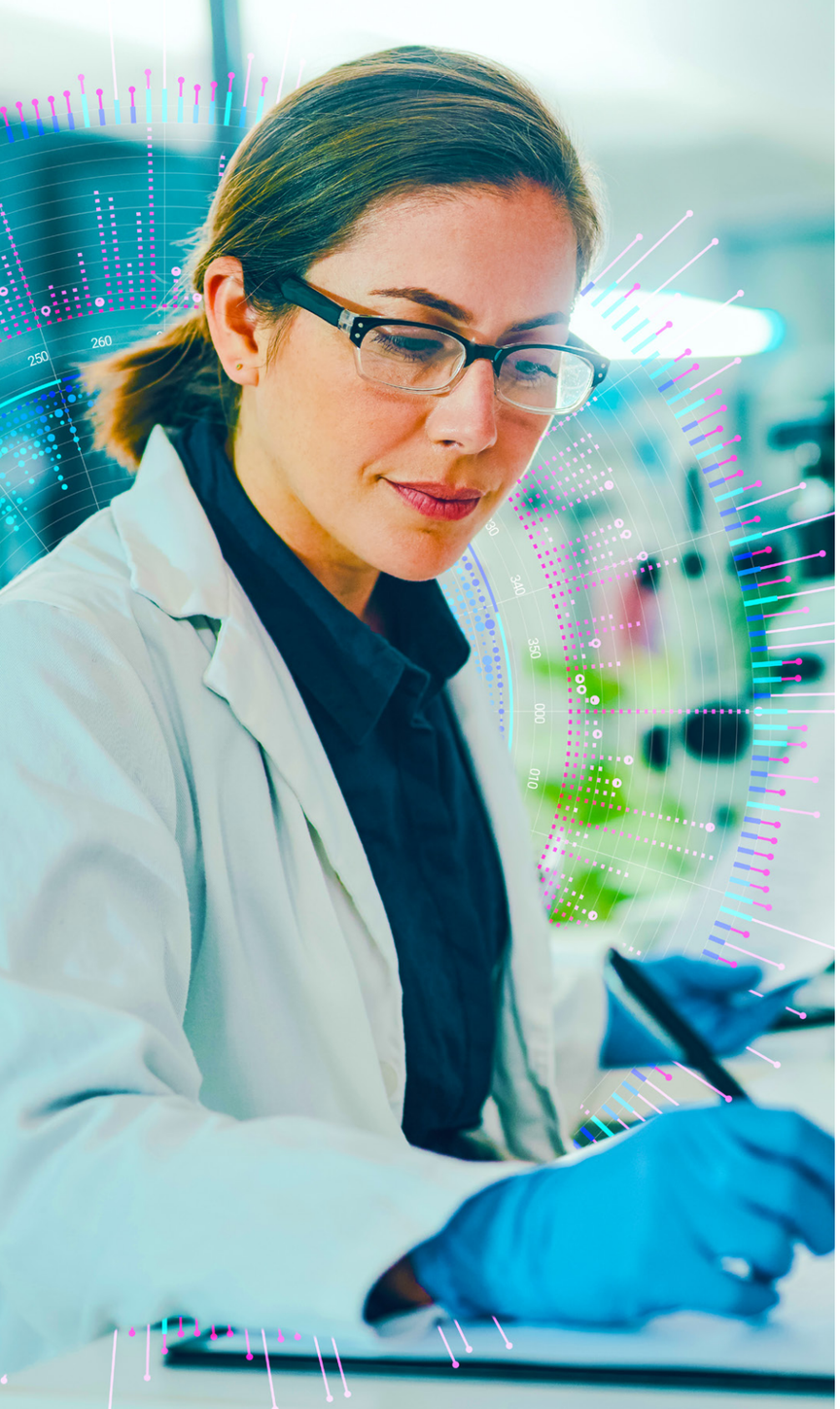
Attributable: Data must be accountable to the person generating it—and include documentation of every attributable action

Legible: Data must be comprehensible and permanent—as must any meta-data that supports an electronic record

Contemporaneous: Data must be time-stamped at the time it's generated—and cannot be back-dated.

Original: Data must be collected in a durable format that preserves the original data records

Accurate: Data must be complete, truthful, error-free, and reflective of any relevant observations



Chapter 2:

Defending the data

Whenever data in flight is replicated or transferred, there's a chance its integrity could be compromised. And in our increasingly digitized labs, error-checking protocols and validation procedures have become essential to any system that stores, processes, or retrieves data.

To maintain data integrity is to ensure that it's recorded as intended—and preserved over time. This ensures that information stored in a database will remain complete, accurate, and reliable no matter how long it's stored or how often it's accessed.

With an optimal platform in place, your lab will be poised to maintain data integrity and ensure compliance.

So, it's vital to implement the right digital platform, which will enable you to:

- Construct event-driven lab workflows and multi-destination data flows
- Configure an event-driven data exchange between instruments and applications
- Set up event notifications that flag required reviews of lab actions
- Connect to and interact with streaming data systems and non-PC-based instruments
- Add notes, pictures, or videos throughout any given workflow
- Apply business logic and processing for data in flight
- Capture and reconstruct complete records of every digital transaction

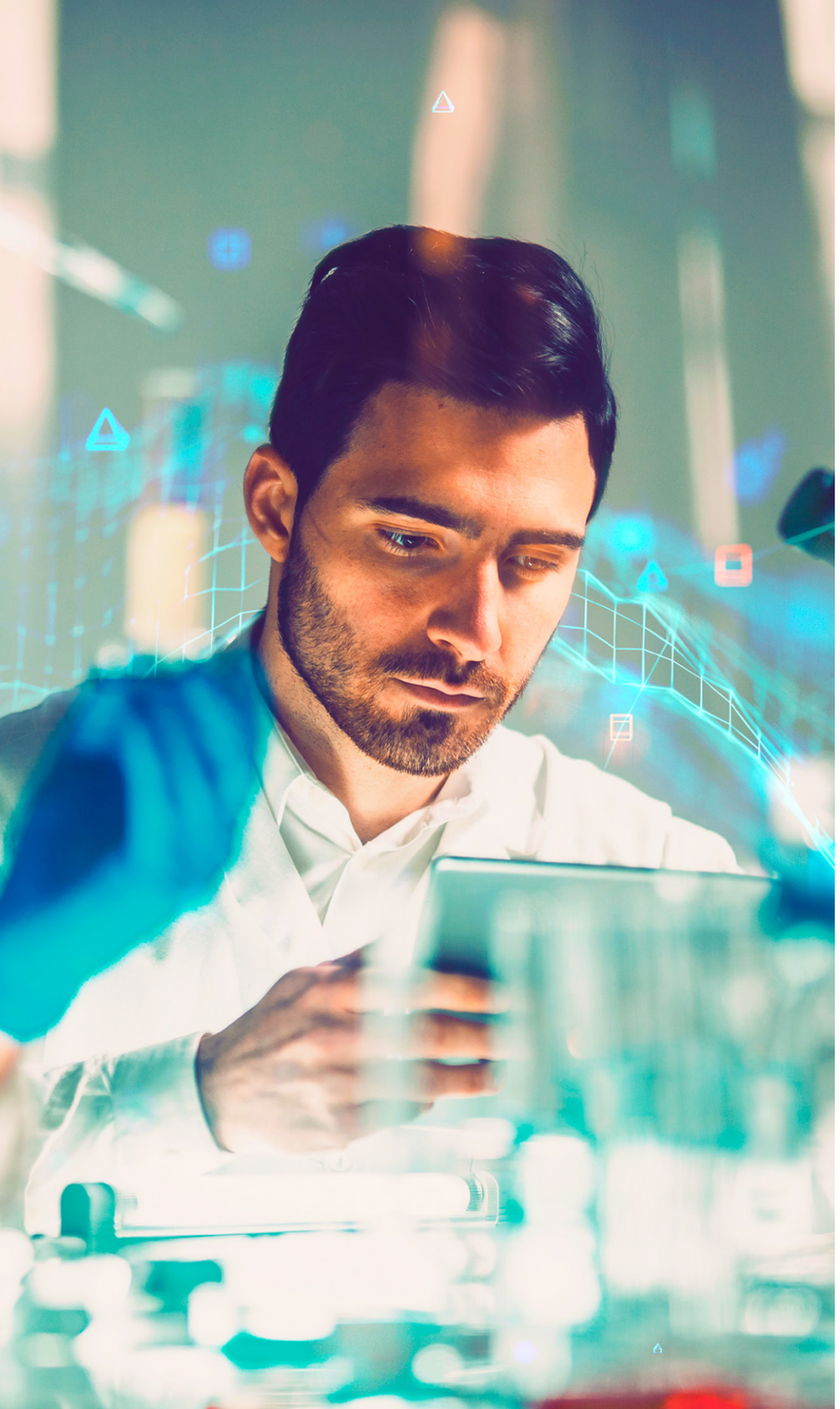
Chapter 3:

Focusing on the future

New technologies, applications, and AI/ML solutions are dramatically reshaping the biopharmaceutical lab's digital landscape. As data becomes more complex, regulatory compliance becomes more difficult to maintain—forcing us to evolve lab infrastructure as we undergo our digital transformation.

And the more we connect our instruments and systems, the more we automate our workflows, the more we digitize our labs—the more we need to focus on data integrity.

Because without *that*, we can't safely advance scientific discovery.



Chapter 4:

Meet the modern lab

Scitara' DLX, the first iPaaS for Science, connects every instrument, application, and system in the lab to an independent, peer-to-peer platform—and provides the tools and technologies you need to ensure data integrity.

The platform's monitoring system provides unprecedented insight into lab operations, ensuring that every data transaction can be captured in an audit trail that facilitates analysis and accelerates decision-making.

Scitara DLX enables you to:

- Apply calculations and logic for data in flight
- Establish secure in-process review gates for data in flight
- Establish an auditable chain of custody for simple instrument outputs
- Capture transactional information and reconstruct data flow at any time

Learn more about data integrity and compliance

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