

# DSCSA readiness checkpoints

What leaders should be able to answer with confidence

**As DSCSA enforcement tightens, readiness is no longer just about meeting deadlines, it's about operational confidence.**

While many organizations have addressed visible requirements like serialization, data exchange, and procedures, the real test lies in whether these capabilities hold up under stress: investigations, partner exceptions, audits, or rapid scaling.

From a leadership perspective, DSCSA readiness can be assessed through these critical checkpoints. These are not technical checklists but indicators of alignment between operations and regulatory intent.

## 1. Traceability is immediate, not reconstructed

### Key question

Can your team trace a serialized unit from manufacturing through distribution without manual reconciliation?

### What good looks like

- Traceability is achieved through a single query, not an extensive project.
- Serialization events, batch genealogy, warehouse movements, and shipment records are integrated in one system (e.g., SAP), providing immediate insight and traceability without manual intervention.

### Why it matters

Immediate traceability is essential for timely responses to verification or investigation requests. Reliance on manual reconciliation indicates operational fragility and risk of non-compliance. Using SAP as the transactional anchor supports both inspections and partner inquiries.

## 2. Serialized data and physical movement are tightly coupled

### Key question

Are serialized data updates exclusively triggered by executed operations, rather than manual corrections?

### What good looks like

- Serialized units cannot be shipped without accurate system recording.
- Status changes are enforced by system logic, preventing unauthorized manual adjustments.
- Exceptions are flagged in real time, enabling proactive management.

### Why it matters

SAP's value here is governance. Real-time integration of serialization, inventory status, and warehouse execution preserves data integrity and ensures the digital record matches physical movement, supporting compliance and accuracy.

## 3. Investigation and verification workflows are operational, not exceptional

### Key question

Are investigation and verification workflows embedded as routine operating procedures instead of being ad hoc responses?

### What good looks like

- Investigation workflows are standardized, system-defined, and directly linked to serialized and batch data.
- Execution does not require manual data gathering or bespoke reporting.
- Consistent, repeatable responses are delivered with minimal disruption to operations.

### Why it matters

When SAP supports investigation workflows using live transactional data, responses are consistent and repeatable. This reduces both regulatory risk and internal disruption.



## 4. Data integrity is enforced across system boundaries

### Key question

Are data exchanges between internal and external systems validated and monitored as rigorously as internal transactions?

### What good looks like

- All relevant system interfaces are validated and continuously monitored for failures or discrepancies.
- Clear data lineage is maintained from the original source through to the ERP.
- Issues are visible and actionable in real time.

### Why it matters

When SAP is integrated with packaging, manufacturing, and logistics systems through controlled interfaces, data integrity becomes demonstrable rather than assumed. This is increasingly important as FDA scrutiny expands beyond individual systems to the relationships between them.

## 5. Quality status and DSCSA controls are aligned

### Key question

Are quality decisions automatically governing the movement and release of serialized inventory?

### What good looks like

- Only products with released quality status enter the supply chain.
- Systematic prevention ensures quarantined, rejected, or recalled batches cannot be distributed.
- Recall scopes are accurate and defensible, based on integrated quality and serialization data.

### Why it matters

Alignment between quality control and serialization minimizes ambiguity during audits, strengthens trading partner trust, and reduces risk of non-compliant distribution.

## 6. Trading partner data exchange is predictable

### Key question

Are trading partner data exchanges automated, monitored, and reliably managed for immediate exception handling?

### What good looks like

- Automated and monitored data exchanges with trading partners are the norm.
- Failures are detected at the earliest opportunity, with clear accountability for resolution.
- Exceptions are surfaced and resolved rapidly to prevent compliance risks.

### Why it matters

SAP's role here is not to eliminate partner variability, but to provide visibility and control. When exchanges are integrated into core order and shipment processes, exceptions surface quickly and can be resolved before they escalate into compliance risks.

## 7. Audit readiness is continuous

### Key question

Is audit readiness designed as an ongoing operational state, not a last-minute activity?

### What good looks like

- Traceability, audit trails, and necessary approvals are embedded in day-to-day operations.
- The organization maintains a continuous state of readiness, reducing the burden of audit preparation.
- Leaders focus resources on driving business growth, not crisis management.

### Why it matters

A continuous audit-ready posture ensures regulatory responsiveness, mitigates executive distraction, and supports a robust compliance culture. This posture reduces executive distraction and allows teams to focus on growth rather than defense.

## Closing perspective

DSCSA readiness is not a single milestone. It is an indicator of how well an organization's operating model supports transparency, control, and trust at scale.

For mid-market pharma and biotech manufacturers, the most resilient approach is to align DSCSA requirements with core execution—using SAP not as a compliance overlay, but as the structural foundation that keeps serialized data, physical movement, and decision-making in sync.

Organizations that do this well tend to find that DSCSA compliance becomes quieter over time. Exceptions decrease. Responses accelerate. Confidence grows.

That is ultimately what readiness looks like: not just meeting regulatory expectations, but doing so in a way that strengthens the business.



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