Life sciences

What do you need to consider when integrating SAP with other GxP systems?

Risk	Solution	Impact if ignored
Manual data transfers Re-keying lab or batch results breaks traceability and introduces transcription errors.	**Automate data flow** Use SAP Cloud ERP's integration capabilities to connect LIMS, MES, and QA systems with validated interfaces.	Incorrect batch release data → product recalls and audit citations.
Paper-to-digital gaps Hybrid documentation leads to missing timestamps and unverifiable signatures.	**Digitize records** Enable Part 11-compliant e-signatures and workflow logs in SAP Cloud ERP.	Delayed QA release, incomplete audit trails, inspection findings.
Siloed systems Batch, QA, and supply data live in separate systems with inconsistent master data	**Centralize data** Implement SAP Cloud ERP's master data governance and synchronized process mapping.	Costly rework during inspections, inconsistent product genealogy.
Unvalidated interfaces Data transfers between systems lack verification or audit documentation.	**Validate integrations** Treat every interface as a GxP system—validate, document, and monitor performance using SAP tools.	Failed FDA audit → "system not validated" finding and CAPA.
Shadow IT workarounds Excel trackers and Access databases operate outside IT governance.	**Standardize workflows** Migrate ad hoc tools into SAP-controlled environments with robust audit trails.	Hidden data loss, uncontrolled versioning, and noncompliance risk.
Weak change control Spec or method changes fail to cascade across connected systems.	**Automate Change Management** Use SAP Cloud ERP's change control features to propagate updates across quality, production, and supply chain.	Data mismatches in submissions, rejected lots, loss of regulatory confidence.

> " If data moves, it must be controlled. If it changes, it must be traceable. If it's reported, it must be defensible.
> — GxP validation principle

How SAP Cloud ERP strengthens compliance

- **Centralized master data governance:** Ensures consistency across systems, reducing errors and improving traceability.
- **Built-in audit trails and e-signatures:** Supports ALCOA+ principles for data integrity and compliance with FDA 21 CFR Part 11.
- **Validated integration frameworks:** Seamlessly connect LIMS, MES, and other GxP systems, ensuring secure data flow.
- **Automated change propagation:** Synchronizes updates across production and QA systems, reducing manual errors.
- **Hybrid system support:** SAP Cloud ERP accommodates hybrid systems, ensuring compliance for both digital and paper-based records.