7 Ways to Know If Your GxP Workflow Is Ready for AI/Automation

This quick-reference checklist helps you assess if a workflow is suitable for AI/automation in a GxP-regulated environment.

1 Digitally Documented & Repeatable

- SOPs clearly define task flow, inputs/outputs, and owners.
- Minimal variation and exceptions are tracked.

2 ALCOA+ Data Principles Are in Practice

- Data is Attributable, Legible, Contemporaneous, Original, and Accurate.
- Ideally managed electronically, not paper-based.

3 Risk and Impact Are Well Understood

- A documented risk assessment classifies the workflow as automation-ready.
- Workflow does not introduce high patient safety or product quality risk.

4 Data Sources Are Reliable and Integrated

- Even if pulling from multiple systems (ERP, LIMS, QMS), data is harmonized and auditable.
- Interfaces or integrations are validated and traceable.

5 Inputs and Outputs Can Be Structured

- Data is collected through standard forms, logs, or digital fields.
- No excessive OCR/NLP required just to access basic data.

6 Workflow Has Measurable Metrics

- KPIs like cycle time, error rate, or compliance rate are already tracked.
- There is a baseline to measure improvement post-automation.

7 Change Control Path for Validation Exists

- QMS includes CSV/CSA approach for validating automation tools.
- You have a defined path for change management and re-validation.

Not there yet? A data capture strategy is probably right for you.

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