



Data Integrity (ALCOA+) & Computer System Validation Kit (Part 11)

System inventory with GxP risk, Part 11 checklist, audit trail review log and risk-based validation plan.

What's inside

File	What it is / how to use it
01_Data_Integrity_CSV_Workbook.xlsx	System inventory, Part 11 checklist, audit trail and access review logs.
02_Validation_Plan.docx	Plan template (CSV/CSA style).
03_Test_Script.docx	Test script template.
04_Data_Integrity_Policy.docx	Policy template.

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GMP decisions (batch release, validation acceptance, OOS conclusions) belong to your quality unit. Confirm requirements against current 21 CFR 210/211, Part 11 and FDA/ICH guidance for your products.

About the author

Built by Matt Norman, US Navy veteran and former SpaceX Falcon 9 quality inspector and QA supervisor. (Not affiliated with or endorsed by SpaceX.) Norman Quality Tools is Veteran-Owned & Operated. Contains no SpaceX, government, or customer proprietary information; all example data is made up.

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Risk-Based Computer System Validation Plan

Data Integrity (ALCOA+) & Computer System Validation Kit (Part 11) - Document 02 - Rev A (2026-10)

System		Version	
Owner		Plan no.	

1. Intended use and GxP impact

Intended use; records and signatures it holds; risk to product quality, patient safety and data integrity

2. Approach

Scale testing to risk. Use supplier documentation where it is adequate; focus scripted testing on high-risk functions and unscripted/exploratory testing on lower-risk functions (in line with FDA's Computer Software Assurance thinking).

3. Deliverables

Deliverable	Required? (Y/N)	Owner

4. Acceptance

Release criteria