

Computerised System Validation Summary

Write the validation summary report for a GxP computerised system: the deliverables expected for its GAMP 5 category, test results and deviations, requirement traceability and the Part 11 / Annex 11 controls.

WRITES

GMP

PRODUCT TYPE

Small molecule and biologics

GUIDANCE IT FOLLOWS

21 CFR Part 11; FDA Data Integrity and Compliance with Drug CGMP (2018); FDA Computer Software Assurance for Production and Quality System Software (2025); EU GMP Annex 11 (2011) and the draft revision (2025); ISPE GAMP 5 Second Edition (2022); PIC/S PI 041-1 Data Integrity (2021)

TIME TO LEARN

About 20 minutes with the example

Open the tool at <https://app.cmcfy.com/app/computerised-system-validation.html>. This guide is also online at <https://cmcfy.com/guides/computerised-system-validation.html>

1. What this module does

You choose the GAMP 5 category and GxP impact, list the deliverables with their status, and enter the tests, the requirements they verify and any deviations.

The tool checks every expected deliverable, every test and requirement, open deviations and the data-integrity controls before release.

What you get

- A Word or PDF report: Computerised system validation summary report.

2. Before you start

Have these ready. You can still start with the example data and replace it piece by piece.

- The validation deliverables and their document numbers.
- Test results with the requirement IDs.
- Deviations and the data-integrity control checks.

Your data stays on your computer. The bar under the title counts every network request the page makes; it stays at 0 because your data never leaves your computer. [Download offline](#) [copy](#) saves a single file that opens from your own computer with all network access blocked, for air-gapped PCs.

3. Step by step with the example

Open the tool at app.cmcfy.com/app/computerised-system-validation.html. The example is loaded when the page opens, so every panel already has realistic data. Follow the steps to see how it works, then replace the example with your own data.

1

Describe the system

Enter the system, choose the GAMP 5 category and the GxP impact, and say whether electronic records or data migration are involved.

CMCfy Computerised System Validation Summary Projects All modules Training Security

Runs entirely on this device Training guide

PROJECTS Keep this work in a project, with version history and your company logo on every report. Choose projects folder Keep in this browser

- Network requests since load: 0**
Counted live by your browser. Your data never leaves this device.
- Works offline**
Everything the tool needs is inside this page.
- Locked offline copy**
Save a single file that opens from your own computer with all network access blocked.

GMP Save project Open project Start blank Load example

Write the computerised system validation summary report. Choose the GAMP 5 category and GxP impact; the tool lists the deliverables expected, checks their status, every test result and requirement trace, and the Part 11 / Annex 11 controls before the system is released for GxP use.

Guidance: 21 CFR Part 11; FDA Data Integrity and Compliance with Drug CGMP (2018); FDA Computer Software Assurance for Production and Quality System Software (2025); EU GMP Annex 11 (2011) and the draft revision (2025); ISPE GAMP 5 Second Edition (2022); PIC/S PI 041-1 Data Integrity (2021)

1 · SYSTEM

System

Chromatography data system (Empower 3 FR5), QC laboratc

Regulations Both US and EU GAMP 5 category 4: configured product

GxP impact High (direct impact on pr Report number CSV-VSR-018

☒ Electronic records and signatures used (Part 11 / Annex 11 applies)

☐ Data migrated from a legacy system

RESULT

Validated · released for GxP use

GAMP category 4, high GxP impact. 10 of 10 deliverables approved; 7 tests (1 failed first time); 10 of 10 requirements traced.

GAMP CATEGORY	TESTS	DEVIATIONS
4	7	1 (0 open)
REQUIREMENTS		
10		

DELIVERABLES

2 Enter deliverables and tests

One row per deliverable, test and deviation. Separate requirement IDs with ";".

3 Read the result

The headline gives the decision: "Validated · released for GxP use".

DELIVERABLES

Expected for GAMP category 4.

DELIVERABLE	DOCUMENT	STATUS	OUTCOME
User requirements specification	URS-CDS-01	approved	complete
Risk assessment (GxP and functional)	RA-CDS-01	approved	complete
Supplier assessment	SA-WAT-2025	approved	complete
Functional or configuration specification	CS-CDS-01	approved	complete
Installation qualification	IQ-CDS-01	approved	complete
Operational qualification	OQ-CDS-01	approved	complete
Performance qualification / user acceptance testing	PQ-CDS-01	approved	complete
Traceability matrix	TM-CDS-01	approved	complete
Procedures (use; administration; backup; incident)	SOP-QC-110 to 114	approved	complete
Training records	TR-CDS-2026	approved	complete

Deliverables and tests.

4 Resolve alerts and download

A failed test with no deviation is critical, as is an open deviation at release. Missing deliverables, untested requirements and unverified controls are flagged. Then preview and download.

Preview and review before download

Review

Checked on this device: gaps in the data, gaps in the report against ICH and regional expectations, and differences from the protocol.

No open gaps

No open gaps: the data, the report and the protocol (if given) match every rule checked, or you accepted the rest. Read the review before you sign.

Compare with the protocol

Load or paste the approved protocol. Every requirement and acceptance criterion in it is looked for in the report.

Paste the protocol text here, or load the file.

Load protocol fileCompare

AI review against guidance

AI reads the report, the protocol and the data against the ICH, FDA or EMA requirements for these sections, and lists gaps with the guideline it applies, protocol and data mismatches, and how to fix them. You see exactly what is sent before anything leaves this device. Results and pass/fail are not changed.

Run AI review

Computerised system validation summary report

CSV-VSR-018 · US (FDA) and EU (EMA)

System	Chromatography data system (Empower 3 FR5), QC laboratory
Report number	CSV-VSR-018
GAMP 5 category	4
GxP impact	high
Regulations	US (FDA) and EU (EMA)

1. Deliverables

Deliverable	Document	Status
User requirements specification	URS-CDS-01	approved
Risk assessment (GxP and functional)	RA-CDS-01	approved
Supplier assessment	SA-WAT-2025	approved
Functional or configuration specification	CS-CDS-01	approved
Installation qualification	IQ-CDS-01	approved
Operational qualification	OQ-CDS-01	approved
Performance qualification / user acceptance testing	PQ-CDS-01	approved
Traceability matrix	TM-CDS-01	approved
Procedures (use; administration; backup; incident)	SOP-QC-110 to 114	approved
Training records	TR-CDS-2026	approved

2. Test summary

Test	Requirements	Result	Deviation
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4. Field reference

Every input in the tool, panel by panel. Tables accept rows pasted straight from Excel, comma-separated text, or a loaded file; check the columns after loading a file. Fields marked “when it applies” appear only for the choices that need them.

1 · System

FIELD	WHAT TO ENTER
System	Type it in.
Regulations	Choose one: US: 21 CFR Part 11; EU: EU GMP Annex 11; Both US and EU.
GAMP 5 category	Choose one: 3: non-configured product; 4: configured product; 5: custom application.
GxP impact	Choose one: High (direct impact on product quality or release data); Medium; Low.
Report number	Type it in.

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FIELD	WHAT TO ENTER
Electronic records and signatures used (Part 11 / Annex 11 applies)	Tick the box if it applies.
Data migrated from a legacy system	Tick the box if it applies.

2 · Deliverables

Status: approved, draft or n/a (with a reason).

FIELD	WHAT TO ENTER
Deliverables	A table. Columns: Deliverable Document number Status (approved/draft/n/a). Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).

3 · Testing

FIELD	WHAT TO ENTER
Test results	A table. Columns: Test ID Requirement IDs Result (pass/fail) Deviation. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
Requirement IDs	Write a range such as "URS-01 to URS-10", or list the IDs. Type it in.
Deviations	A table. Columns: Deviation Description Status (open/closed) Impact. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).

4 · Data integrity controls

FIELD	WHAT TO ENTER
Audit trail on, secure and reviewed	Tick the box if it applies.
Unique user accounts and role-based access	Tick the box if it applies.

FIELD	WHAT TO ENTER
Electronic signatures linked to records (name, date, meaning)	Tick the box if it applies.
Backup and restore tested	Tick the box if it applies.
System clock controlled	Tick the box if it applies.
Business continuity and disaster recovery	Tick the box if it applies.
Periodic review scheduled	Tick the box if it applies.
Release decision	Choose one: Released for GxP use; Released with restrictions; Not released.

5. Checks and alerts

Calculations and pass/fail outcomes always come from fixed rules, never from AI. The tool checks:

- Deliverables for the GAMP category.
- Tests, deviations and traceability.
- Audit trail, access, e-signatures, backup and periodic review.

How to resolve alerts

- **Critical** alerts block the download and must be fixed in the data. A failing result can instead be linked to an investigation: type the investigation reference and outcome and press **Record**.
- **Major** alerts block the download until you fix them or type a justification and press **Accept justification**.
- **Minor** alerts do not block anything. They are listed in the documents so the reviewer sees them.
- Some alerts have an **Apply fix** button that makes the change for you. **Reopen** undoes a justification.

Narratives

This module writes: Summary and conclusion. Each narrative is written by fixed rules from your data. You can edit it in the box. **Rewrite with AI** (where your plan includes AI) rewrites it in regulatory style; every number in the text is checked against your data, and a number that does not match is

flagged under the box and blocks the download until you correct it. [Reset to rule-based text](#) brings back the original.

6. Preview, gap review and download

1. Press [Preview](#) next to a section, or [Preview and download all](#). The document opens in a preview window, exactly as the Word file will read.
2. The left side lists the review, run on your device: **gaps in the data** (missing values, open alerts), **gaps in the report** (missing content the guidance expects, placeholders such as [site] or TBD left in the text) and, if you load the approved protocol under [Compare with the protocol](#), **differences from the protocol** (requirements, criteria, batches or time points it plans that the report does not show).
3. Click a finding to jump to the place in the preview. Fix it in the tool, then preview again.
4. Optional [AI review](#): a second read for contradictions, claims without data and vague wording. The report text is sent to Claude only when you press it, and only where your plan includes AI. Check every AI finding; AI can be wrong.
5. Press [Download Word \(.docx\)](#) or [Download PDF](#). With several documents open, [All as Word \(.zip\)](#) and [All as PDF \(.zip\)](#) download the set. The download buttons stay disabled while a blocking alert is open; the preview still works.

Documents this module produces

SECTION	DOCUMENT
Report	Computerised system validation summary report

Use [Save project](#) to keep your work as a file on your computer, and [Open project](#) to continue later. [Start blank](#) clears every field; [Load example](#) brings the example back. Nothing is stored on CMCfy servers.

7. US and EU submissions

US follows 21 CFR Part 11 and the FDA data integrity guidance. EU follows EU GMP Annex 11. ISPE GAMP 5 applies to both.

8. Working with other modules

- Equipment with embedded software is qualified in Equipment Qualification Report.

9. Common pitfalls

- Releasing with an open deviation.
- Audit trail configured but never reviewed.

10. Practice exercises

Each exercise starts from the example (press [Load example](#) to reset). We run these on every update of this guide, so the result you see should match.

1. **Reopen the deviation**

Change the status of DEV-CDS-03 from closed to open.

EXPECTED RESULT

The headline shows one open test failure or deviation.

Guide updated 28 October 2026 for the current version of the tool. CMCfy drafts are for review by a qualified person before use in a submission.