

Equipment Qualification Report

Write the IQ, OQ and PQ report for a piece of equipment or a utility, with every test traced to the user requirements and a conclusion on release for GMP use.

WRITES

GMP 3.2.A.1

PRODUCT TYPE

Small molecule and biologics

GUIDANCE IT FOLLOWS

EU GMP Annex 15 (Qualification and validation, 2015) sections 3–4; EU GMP Annex 11; 21 CFR 211.63, 211.67, 211.68; FDA Process Validation guidance (2011) stage 2 facility and equipment qualification; ASTM E2500; ISPE Baseline Guide Vol. 5 Commissioning and Qualification (2nd ed.); USP <1058> Analytical Instrument Qualification; ICH Q9(R1)

TIME TO LEARN

About 20 minutes with the example

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

1. What this module does

You list the user requirements and the tests at each stage with their acceptance criteria and results. The tool checks each result, builds the traceability matrix and shows which requirements are verified.

It also checks deviations, procedures, training, calibration and computerised-system functions before the equipment is released for use.

What you get

- A Word or PDF report: Equipment qualification report (IQ/OQ/PQ).

2. Before you start

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

- The user requirement specification with critical requirements marked.
- IQ, OQ and PQ tests with acceptance criteria and results.
- Deviations and their status.

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/equipment-qualification.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 equipment

Enter the equipment, its ID and location, the protocol and report numbers, and choose the regulations.

CMCfy Equipment Qualification Report Projects All modules Training Security

Runs entirely on this device Training guide Protocol builder

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 3.2.A.1 [Save project](#) [Open project](#) [Start blank](#) [Load example](#)

Write the equipment qualification report. Each IQ, OQ and PQ test is checked against its acceptance criterion and traced to the user requirements. The tool finds requirements with no passing test, failures and open deviations, and concludes whether the equipment is released for GMP use.

Guidance: EU GMP Annex 15 (Qualification and validation, 2015) sections 3–4; EU GMP Annex 11; 21 CFR 211.63, 211.67, 211.68; FDA Process Validation guidance (2011) / EMA process validation guideline (EMA/CHMP/CVMP/QWP/BWP/70278/2012 Rev1) stage 2 facility and equipment qualification; ASTM E2500; ISPE Baseline Guide Vol. 5 Commissioning and Qualification (2nd ed.); USP <1058> Analytical Instrument Qualification; ICH Q9(R1)

1 · EQUIPMENT

Equipment and asset number

Tablet press TP-05 (Fette 2090i), asset 100345

Regulations Report number

Both US and EU QR-TP05-01

Protocol number User requirement specification

QP-TP05-01 URS-TP05 v2

Risk assessment Stages covered

RA-TP05 (FMEA, 2026-03) IQ, OQ and PQ

RESULT

11 tests passed · released for GMP use

IQ 3 tests, OQ 6 tests, PQ 2 tests. 7 of 7 requirements verified.

STAGES	REQUIREMENTS	TESTS
IQ, OQ, PQ	7	11

DEVIATIONS

1 (0 open)

TRACEABILITY TO THE URS

2 Enter requirements and tests

One row per user requirement. One row per test with its stage (IQ, OQ or PQ), the requirement IDs it verifies, the criterion and the result.

3 Read the result

The headline says whether every test passed and the equipment can be released: "11 tests passed · released for GMP use".

TRACEABILITY TO THE URS				
ID	REQUIREMENT	CRITICAL	TESTS	OUTCOME
URS-01	Product-contact parts 316L stainless steel or approved polymers	yes	IQ: Materials of construction certificates	verified
URS-02	Turret speed 20–120 rpm	yes	OQ: Turret speed at 20 rpm; OQ: Turret speed at 120 rpm	verified
URS-03	Compression force control $\pm 5\%$ of set point	yes	IQ: Calibration of critical instruments; OQ: Compression force control at 10 kN; PQ: Three consecutive placebo batches: weight RSD (%)	verified
URS-04	Automatic rejection of out-of-weight tablets	yes	OQ: Weight reject function (challenge tablets $\pm 10\%$); PQ: Three consecutive placebo batches: weight RSD (%)	verified
URS-05	Audit trail and user access levels (Part 11 / Annex 11)	yes	OQ: Audit trail and access levels	verified
URS-06	Dust extraction connected and interlocked	no	IQ: Installation against drawings and utilities; OQ: Alarms and interlocks (door; dust extraction)	verified
URS-07	Output at least 200 000 tablets per hour	no	PQ: Throughput (tablets per hour)	verified

Tests and traceability.

4

Resolve alerts and download

A failed test is critical. Requirements with no test, open deviations, missing stages and missing calibration or training 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

Equipment qualification report

Tablet press TP-05 (Fette 2090i), asset 100345 · QR-TP05-01 · US (FDA) and EU (EMA)

Equipment	Tablet press TP-05 (Fette 2090i), asset 100345
Report number	QR-TP05-01
Protocol	QP-TP05-01
URS	URS-TP05 v2
Risk assessment	RA-TP05 (FMEA, 2026-03)
Stages	IQ, OQ and PQ
Regulations	US (FDA) and EU (EMA)

1. Objective

To document that Tablet press TP-05 (Fette 2090i), asset 100345 is installed correctly, operates as intended across its operating ranges and performs consistently, meeting URS-TP05 v2.

2. Test results

Stage	Test	Acceptance criterion	Result	Outcome
IQ	Materials of construction certificates	Certificates for all product-contact parts	pass	Pass
IQ	Installation against drawings and utilities	As built matches approved drawings	pass	Pass
IQ	Calibration of critical instruments	All critical instruments calibrated	pass	Pass
OQ	Turret speed at 20 rpm	18–22 rpm	20.3	Pass
OQ	Turret speed at 120 rpm	114–126 rpm	119.1	Pass
OQ	Compression force control at 10 kN	9.5–10.5 kN	10.2	Pass

Download Word (.docx)Download PDF

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 · Equipment

FIELD	WHAT TO ENTER
Equipment and asset number	Type it in.
Regulations	Choose one: US: 21 CFR 211.63/68; EU: EU GMP Annex 15; Both US and EU.
Report number	Type it in.
Protocol number	Type it in.
User requirement specification	Type it in.
Risk assessment	Type it in.

FIELD	WHAT TO ENTER
Stages covered	Type it in.
Computerised system (Annex 11 / Part 11 assessed)	Tick the box if it applies.

2 · Requirements and tests

Requirements: one row each, critical yes or no. Tests: stage (IQ, OQ, PQ), the requirement IDs it covers (";"), the criterion and the result. A result can be a number, pass or fail.

FIELD	WHAT TO ENTER
User requirements	Mark a requirement critical with "yes". A table. Columns: ID Requirement Critical (yes/no). Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
Tests	Separate several requirement IDs with ";". A table. Columns: Stage Test Requirement IDs Acceptance criterion Result Deviation. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
Deviations and their status	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).

3 · Release for use

FIELD	WHAT TO ENTER
Operating, cleaning and maintenance procedures approved	Tick the box if it applies.
Operators trained	Tick the box if it applies.
Equipment in the calibration and maintenance programme	Tick the box if it applies.

FIELD	WHAT TO ENTER
Periodic review or requalification interval (months)	Type a number.

5. Checks and alerts

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

- Each result against its acceptance criterion.
- Every requirement verified by at least one test.
- IQ, OQ and PQ present; deviations closed; calibration, procedures and training in place.

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	Equipment qualification 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 211.63 and 211.68. EU follows EU GMP Annex 15 (and Annex 11 for computerised functions). ASTM E2500 gives a risk-based approach.

8. Working with other modules

- Qualified equipment is referenced in the Process Validation Report and the Facilities & Equipment Writer section.

9. Common pitfalls

- Tests that do not trace to a requirement, or requirements nobody tested.
- Releasing the equipment with a deviation still open.

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. **Fail an OQ test**

Change the turret speed result at 20 rpm from 20.3 to 23.1.

EXPECTED RESULT

The headline shows one test failed.

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.