

Supplier Qualification Report

Write the supplier qualification report: risk rating, audit outcome and findings, quality agreement, CoA verification by in-house testing and the requalification date.

WRITES

GMP 3.2.S.2.3

3.2.P.4

PRODUCT TYPE

Small molecule and
biologics

GUIDANCE IT FOLLOWS

ICH Q7 7.1 and 13;
ICH Q10 2.7
Management of
outsourced
activities and
purchased
materials; ICH
Q9(R1); EU GMP
Chapter 5 (5.27–
5.36) and Chapter
7; EU Guidelines on
the formalised risk
assessment for
excipients (2015/C
95/02); 21 CFR
211.84(d), 211.80;
FDA Contract
Manufacturing
Arrangements for
Drugs: Quality
Agreements (2016);
IPEC-PQG GMP
Guide

TIME TO LEARN

About 20 minutes
with the example

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

1. What this module does

You choose the material type and risk, enter the audit and its findings, and the supplier and in-house results for each lot tested. The tool checks the results and the agreement between them.

It decides whether the supplier is approved, conditionally approved or not approved, and sets the next audit date by risk.

What you get

- A Word or PDF report: Supplier qualification report.

2. Before you start

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

- The material, supplier and risk rationale.
- The audit report and CAPA status of findings.
- Supplier CoA and in-house results for the verification lots.

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/supplier-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 supplier

Enter the supplier, the material and its type, the risk and its rationale.

CMCfy | Supplier Qualification Report | 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 3.2.S.2.3 3.2.P.4

[Save project](#) [Open project](#) [Start blank](#) [Load example](#)

Write the supplier qualification report and approval decision. The tool sets the risk from the material type and use, checks the audit outcome and findings, the quality agreement and certificates, compares the supplier's certificate of analysis with in-house results on the first lots, and sets the requalification date.

Guidance: ICH Q7 7.1 and 13; ICH Q10 2.7 Management of outsourced activities and purchased materials; ICH Q9(R1); EU GMP Chapter 5 (5.27–5.36) and Chapter 7; EU Guidelines on the formalised risk assessment for excipients (2015/C 95/02); 21 CFR 211.84(d), 211.80; FDA Contract Manufacturing Arrangements for Drugs: Quality Agreements (2016); IPEC-PQG GMP Guide

1 - SUPPLIER AND MATERIAL

Supplier and site

Excipia Chemicals Ltd., Plant 2, Ahmedabad, India

Regulations Report number

Both US and EU SQ-R-044

Material Material type

Croscarmellose sodium (dis Excipient

Risk

Medium

Risk rationale

RESULT

Excipia Chemicals Ltd.: approved

Croscarmellose sodium (disintegrant), Ph. Eur./USP-NF. On-site audit 2026-06-18: acceptable; 2 findings (0 open). CoA verified on 3 lots. Next audit by 2029-06-18.

RISK	AUDIT	LOTS VERIFIED
medium	acceptable	3

NEXT AUDIT
2029-06-18

COA VERIFICATION

Difference = |in-house – supplier| ÷ supplier.

2 Enter the audit and CoA verification

Choose the assessment type and outcome, list the findings, and enter one row per lot and test.

3 Read the result

The headline gives the decision: "Excipia Chemicals Ltd.: approved".

COA VERIFICATION

$$\text{Difference} = |\text{in-house} - \text{supplier}| \div \text{supplier}.$$

LOT	TEST	SPECIFICATION	SUPPLIER	IN-HOUSE	DIFFERENCE	OUTCOME
EX2604	Loss on drying (%)	≤ 10.0	6.1	6.3	3.3%	agree
EX2604	Degree of substitution	0.60–0.85	0.72	0.71	1.4%	agree
EX2604	Settling volume (mL)	10.0–30.0	18	19	5.6%	agree
EX2605	Loss on drying (%)	≤ 10.0	5.8	6.0	3.4%	agree
EX2605	Degree of substitution	0.60–0.85	0.74	0.73	1.4%	agree
EX2605	Settling volume (mL)	10.0–30.0	17	17	0.0%	agree
EX2606	Loss on drying (%)	≤ 10.0	6.4	6.2	3.1%	agree
EX2606	Degree of substitution	0.60–0.85	0.70	0.71	1.4%	agree
EX2606	Settling volume (mL)	10.0–30.0	19	20	5.3%	agree

CoA verification.

4

Resolve alerts and download

An unacceptable audit, open critical findings or an out-of-specification result is critical. Questionnaire-only assessment of a high-risk supplier, a missing quality agreement and poor CoA agreement are flagged. Then preview and download.

Maximum relative difference

Preview and review before download Close

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 preview 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 file Compare

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

Supplier qualification report

Excipia Chemicals Ltd., Plant 2, Ahmedabad, India · SQ-R-044 · US (FDA) and EU (EMA)

Supplier	Excipia Chemicals Ltd., Plant 2, Ahmedabad, India
Material	Croscarmellose sodium (disintegrant), Ph. Eur./USP-NF
Risk	medium
Audit	2026-06-18 (onsite): acceptable
Certificates	EXCIPACT certificate EXC-2025-117 (valid to 2028-03); ISO 9001:2015
Status	approved
Next audit	2029-06-18
Regulations	US (FDA) and EU (EMA)

1. Audit findings

Finding	Classification	CAPA
Change control does not require customer notification for site changes	major	Closed
Calibration label missing on one balance	minor	Closed

2. CoA verification

Lot	Test	Specification	Supplier	In-house	Difference
EX2604	Loss on drying (%)	≤ 10.0	6.1	6.3	3.3%
EX2604	Degree of substitution	0.60–0.85	0.72	0.71	1.4%
EX2604	Settling volume (mL)	10.0–30.0	18	19	5.6%
EX2605	Loss on drying (%)	≤ 10.0	5.8	6.0	3.4%
EX2605	Degree of substitution	0.60–0.85	0.74	0.73	1.4%

Download Word (.docx) Download PDF

Paste the text here, or load a file

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 · Supplier and material

FIELD	WHAT TO ENTER
Supplier and site	Type it in.
Regulations	Choose one: US: 21 CFR 211.84; EU: EU GMP Chapter 5 and the excipient risk guideline; Both US and EU.
Report number	Type it in.
Material	Type it in.
Material type	Choose one: Active substance; Excipient; Primary packaging; Contract service or testing; Other material.
Risk	Choose one: High; Medium; Low.

FIELD	WHAT TO ENTER
Risk rationale	Type or paste text.

2 · Audit and documents

FIELD	WHAT TO ENTER
Audit date	Type it in.
Assessment type	Choose one: On-site audit; Remote audit; Questionnaire only; Third-party audit report.
Audit outcome	Choose one: Acceptable; Acceptable with conditions; Not acceptable.
Findings	A table. Columns: Finding Classification (critical/major/minor) CAPA status (open/closed). Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
Quality agreement signed	Tick the box if it applies.
Certificates (GMP, ISO, CEP)	Type it in.

3 · CoA verification

One row per lot and test: the supplier's result and your in-house result, with the specification.

FIELD	WHAT TO ENTER
CoA verification	Use the same test names as the specification. A table. Columns: Lot Test Specification Supplier result In-house result. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
Maximum relative difference between supplier and in-house results (%)	Type a number.

5. Checks and alerts

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

- Risk and assessment type: audit for active substances and high-risk materials.
- Findings and CAPA, quality agreement.
- CoA results within specification and in agreement with in-house testing.

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: Assessment and decision. 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	Supplier 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 211.84(d). EU follows EU GMP Chapter 5 (5.27–5.36) and the excipient risk assessment guideline (2015/C 95/02). ICH Q7 7.1 applies to API suppliers.

8. Working with other modules

- Excipient suppliers are described in Excipients Writer.

9. Common pitfalls

- Reduced testing before the CoA has been verified.
- A high-risk supplier approved on a questionnaire alone.

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 the audit

Set the audit outcome to Not acceptable.

EXPECTED RESULT

The headline shows the supplier is not approved.

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.