

Shipping Validation Report

Qualify shipping lanes and containers from logger data: summer and winter profiles, minimum and maximum loads, and excursions against the stability budget.

WRITES

GMP 3.2.P.3.5

3.2.P.8

PRODUCT TYPE

Small molecule and biologics

GUIDANCE IT FOLLOWS

EU Guidelines on Good Distribution Practice (2013/C 343/01) chapter 9; WHO TRS 961 Annex 9 Supplement 7 (Qualification of shipping containers) and Supplement 14 (Transport route profiling); USP <1079> and <1079.2>, <1079.4>; PDA Technical Report 39; ISTA 7D / 7E; 21 CFR 211.150; FDA guidance on biological product shipping (21 CFR 600.15)

TIME TO LEARN

About 20 minutes with the example

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

1. What this module does

You enter each shipment with its lane, season, load, logger position, duration and the minimum and maximum temperatures. The tool groups shipments into configurations and checks each has enough

successful shipments.

Excursions are compared with the time outside the range that your stability data supports. Freezing fails a shipment when the product must not freeze.

What you get

- A Word or PDF report: Shipping validation report.

2. Before you start

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

- The labelled range and the excursion budget from stability data.
- Logger data for each shipment.
- Mechanical stress and product testing results.

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/shipping-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 shipper

Enter the product, the shipper and its rating, the labelled range and the excursion budget.

CMCfy

Shipping Validation Report

ProjectsAll modulesTrainingSecurity

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 folderKeep 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.

GMP3.2.P.3.53.2.P.8

Save projectOpen projectStart blankLoad example

Write the shipping (transport) validation report. For each shipment the tool compares the logger minimum and maximum with the labelled range, compares any time outside it with the excursion budget from stability data, checks each lane is tested in summer and winter with minimum and maximum loads, and checks product testing after shipment.

Guidance: EU Guidelines on Good Distribution Practice (2013/C 343/01) chapter 9; WHO TRS 961 Annex 9 Supplement 7 (Qualification of shipping containers) and Supplement 14 (Transport route profiling); USP <1079> and <1079.2>, <1079.4>; PDA Technical Report 39; ISTA 7D / 7E; 21 CFR 211.150; FDA guidance / EMA guidance on biological product shipping (21 CFR 600.15)

1 · PRODUCT AND SHIPPERS

Product

CMX-mAb1 injection 100 mg/mL, vials

Regulations

Both US and EU

Report number

SV-R-006

Labelled temperature range

2-8 °C

Excursion budget supported by stability data (minutes outside the range)

720

Excursion budget applies up to (°C)

RESULT

1 lane qualified · 12 shipments

Range 2-8 °C; logged 2.0 to 8.4 °C. 1 excursion within the stability budget (S-03: 35 min).

LANES	SHIPMENTS	LONGEST
1	12	78 h
RANGE		
2-8 °C		

CONFIGURATIONS

2

Enter shipments

One row per shipment and logger, with the lane, season (summer or winter) and load (min or max).

3

Read the result

The headline says how many lanes are qualified: "1 lane qualified · 12 shipments".

CONFIGURATIONS

Each lane is tested in summer and winter with the minimum and maximum load; 3 successful shipments each.

LANE	SEASON	LOAD	SHIPMENTS	PASSED	OUTCOME
Raleigh-Dublin air	summer	min	3	3	qualified
Raleigh-Dublin air	summer	max	3	3	qualified
Raleigh-Dublin air	winter	min	3	3	qualified
Raleigh-Dublin air	winter	max	3	3	qualified

Configurations and shipments.

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 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

Shipping validation report

CMX-mAb1 injection 100 mg/mL, vials - SV-R-006 - US (FDA) and EU (EMA)

Product	CMX-mAb1 injection 100 mg/mL, vials
Report number	SV-R-006
Labelled range	2-8 °C
Shipper	Passive shipper with vacuum-insulated panels and phase-change material, rated 120 h at 2-8 °C
Excursion budget	720 min up to 25 °C
Regulations	US (FDA) and EU (EMA)

1. Objective

To show that CMX-mAb1 injection 100 mg/mL, vials stays within 2-8 °C and is not affected by transport on the lanes and in the shipper qualified.

2. Configurations tested

Lane	Season	Load	Shipments	Passed
Raleigh-Dublin air	summer	min	3	3
Raleigh-Dublin air	summer	max	3	3
Raleigh-Dublin air	winter	min	3	3
Raleigh-Dublin air	winter	max	3	3

3. Temperature results

Shipment	Lane	Season	Load	Duration (h)	Min °C	Max °C	Outside (min)	Outcome
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Download Word (.docx)

Download PDF

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.

FIELD	WHAT TO ENTER
Product	Type it in.
Regulations	Choose one: US: USP <1079>, 21 CFR 211.150; EU: EU GDP guidelines; Both US and EU.
Report number	Type it in.
Labelled temperature range	Type it in.

FIELD	WHAT TO ENTER
Excursion budget supported by stability data (minutes outside the range)	Type a number.
Excursion budget applies up to (°C)	Type a number.
Product must not freeze	Tick the box if it applies.
Successful shipments needed per configuration	Type a number.
Shipper	Type it in.

2 · Shipments

One row per shipment and logger. Season: summer or winter. Load: min or max. Time outside: minutes outside the labelled range.

FIELD	WHAT TO ENTER
Shipments	Write the time outside the range in minutes. A table. Columns: Lane Season Load Shipment Logger position Duration (h) Min °C Max °C Time outside (min). Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
Loggers calibrated and placed at worst-case positions (from thermal mapping)	Tick the box if it applies.
Mechanical stress (vibration, drop) assessed	Type or paste text.
Product testing after shipment	Type or paste text.

5. Checks and alerts

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

- Each shipment within the range or within the stability budget.
- Summer and winter, minimum and maximum load, with enough shipments each.
- Freeze protection, logger calibration, mechanical stress and product 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: Results 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	Shipping validation 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

EU follows the EU GDP guidelines (2013/C 343/01) section 9.2. US follows USP <1079> and 21 CFR 211.150. WHO TRS 961 Annex 9 gives the method.

8. Working with other modules

- The excursion budget comes from the Stability Studio or Biologics Stability Studio data.

9. Common pitfalls

- Testing only one season or one load.
- An excursion budget with no stability data behind it.

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. Exceed the budget

Change the time outside the range for shipment S-03 from 35 to 800 minutes.

EXPECTED RESULT

The headline shows one shipment 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.