

# Method Transfer Report

Write the analytical method transfer report: the receiving laboratory's results compared with the sending laboratory's against the criteria set in the protocol, with the statistics done for you.

## WRITES

Report

3.2.S.4.3

3.2.P.5.3

## PRODUCT TYPE

Small molecule and  
biologics

## GUIDANCE IT FOLLOWS

USP <1224>  
Transfer of  
Analytical  
Procedures; ICH  
Q2(R2); FDA  
Analytical  
Procedures and  
Methods Validation  
for Drugs and  
Biologics (2015),  
section VIII; EU  
GMP Chapter 6  
(6.37–6.41); WHO  
TRS 961 Annex 7

## TIME TO LEARN

About 20 minutes  
with the example

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

## 1. What this module does

You enter the acceptance criteria from the protocol (maximum difference of means and maximum %RSD for each test) and the replicate results of both laboratories for each batch and analyst.

For each test and batch the tool calculates the means, the difference (relative or absolute), each laboratory's %RSD and the 90% confidence interval of the difference, and decides whether the receiving laboratory is qualified.

## What you get

- A Word or PDF report: Analytical method transfer report, with criteria, results, discussion and sign-off.

## 2. Before you start

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

- The approved transfer protocol and its criteria.
- Both laboratories' replicate results for each test and batch.
- Training, instrument qualification and gap analysis records.

**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/method-transfer.html](https://app.cmcfy.com/app/method-transfer.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 transfer

Enter the procedure, the sending and receiving units and the approach (comparative testing, co-validation, revalidation or waiver). For a waiver, give the justification.

**CMCfy** Method Transfer 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.

Report 3.2.S.4.3 3.2.P.5.3 Save project Open project Start blank Load example

Write the analytical method transfer report. Enter the predefined criteria and both laboratories' results; the tool compares the means of the receiving and sending units, checks each laboratory's precision, gives the 90% confidence interval of the difference, and concludes whether the receiving laboratory is qualified.

Guidance: USP <1224> Transfer of Analytical Procedures; ICH Q2(R2); FDA Analytical Procedures and Methods Validation for Drugs and Biologics (2015), section VIII; EU GMP Chapter 6 (6.37–6.41); WHO TRS 961 Annex 7

**1 · TRANSFER**

Product  
CMX-101 tablets 50 mg

Regulations Report number  
Both US and EU TR-R-031

Protocol number  
TR-P-031

Procedure transferred  
AM-0142 v2, assay and related substances of CMX-101 by H

Sending unit Receiving unit

**RESULT**

**4 comparisons · receiving laboratory qualified**

Assay (B2401): difference -0.37% (limit ±2%); Assay (B2402): difference -0.56% (limit ±2%); Impurity B (B2401-spiked): difference 0.018 (limit ±0.05); Total impurities (B2401-spiked): difference 0.030 (limit ±0.1).

| APPROACH            | TESTS | BATCHES |
|---------------------|-------|---------|
| Comparative testing | 3     | 3       |

RESULTS  
42

COMPARISON OF LABORATORIES

## 2 Enter criteria and results

One criteria row per test, with rel (% of the sending mean) or abs (absolute) difference. One result row per test, laboratory (SU or RU), batch and analyst, with the replicates separated by ", " .

## 3 Read the result

The headline says whether the receiving laboratory is qualified: "4 comparisons · receiving laboratory qualified". The table shows each difference with its 90% confidence interval.

## COMPARISON OF LABORATORIES

Difference = receiving – sending. The 90% interval within  $\pm$ limit shows equivalence (TOST).

| TEST             | BATCH        | SU MEAN (N) | RU MEAN (N) | SU %RSD | RU %RSD | DIFFERENCE | 90% CI      |
|------------------|--------------|-------------|-------------|---------|---------|------------|-------------|
| Assay            | B2401        | 100.02 (6)  | 99.65 (6)   | 0.3     | 0.4     | -0.37%     | -1.0 to 0.3 |
| Assay            | B2402        | 100.93 (3)  | 100.37 (3)  | 0.2     | 0.3     | -0.56%     | -1.0 to 0.3 |
| Impurity B       | B2401-spiked | 0.210 (6)   | 0.228 (6)   | 4.3     | 3.3     | 0.018      | 0.0 to 0.4  |
| Total impurities | B2401-spiked | 0.475 (6)   | 0.505 (6)   | 2.2     | 2.1     | 0.030      | 0.0 to 0.4  |

Comparison of laboratories.

## 4

## Resolve alerts and download

A difference or %RSD outside the criteria is critical. Results from one laboratory only, tests not done, a single analyst and undocumented prerequisites are flagged. Then preview and download.

One row per test, laboratory (SU or RU), batch and analyst. Put the

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 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 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

**Analytical method transfer report**

CMX-101 tablets 50 mg · TR-R-031 · US (FDA) and EU (EMA)

|                |                                                             |
|----------------|-------------------------------------------------------------|
| Product        | CMX-101 tablets 50 mg                                       |
| Report number  | TR-R-031                                                    |
| Protocol       | TR-P-031                                                    |
| Procedure      | AM-0142 v2, assay and related substances of CMX-101 by HPLC |
| Sending unit   | Acme Pharma Analytical Development, Raleigh NC              |
| Receiving unit | Contract QC laboratory, Dublin, Ireland                     |
| Approach       | Comparative testing                                         |
| Regulations    | US (FDA) and EU (EMA)                                       |

**1. Objective**

To qualify Contract QC laboratory, Dublin, Ireland to use AM-0142 v2, assay and related substances of CMX-101 by HPLC by demonstrating that it obtains results equivalent to those of Acme Pharma Analytical Development, Raleigh NC.

**2. Prerequisites**

Two receiving-unit analysts trained by the sending unit (training records TR-031-01/02); HPLC systems QC-HP-07 and QC-HP-09 qualified; gap analysis GA-031 found no gaps in columns, reagents or software.

**3. Acceptance criteria**

| Test             | Maximum difference | Maximum %RSD per laboratory |
|------------------|--------------------|-----------------------------|
| Assay            | ±2% (relative)     | 2%                          |
| Impurity B       | ±0.05 % (absolute) | 15%                         |
| Total impurities | ±0.1 % (absolute)  | 10%                         |

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 · Transfer

| FIELD                 | WHAT TO ENTER                                                                      |
|-----------------------|------------------------------------------------------------------------------------|
| Product               | Type it in.                                                                        |
| Regulations           | Choose one: US: USP <1224> and FDA guidance; EU: EU GMP Chapter 6; Both US and EU. |
| Report number         | Type it in.                                                                        |
| Protocol number       | Type it in.                                                                        |
| Procedure transferred | Type it in.                                                                        |
| Sending unit          | Type it in.                                                                        |
| Receiving unit        | Type it in.                                                                        |

| FIELD                                                             | WHAT TO ENTER                                                                  |
|-------------------------------------------------------------------|--------------------------------------------------------------------------------|
| Transfer approach                                                 | Choose one: Comparative testing; Co-validation; Revalidation; Transfer waiver. |
| Justification for the waiver<br>when it applies                   | Type or paste text.                                                            |
| Prerequisites met (training, qualified instruments, gap analysis) | Type or paste text.                                                            |

## 2 · Acceptance criteria

One row per test, from the approved protocol. Difference type: rel (% of the sending mean) or abs (absolute, in the result unit).

| FIELD    | WHAT TO ENTER                                                                                                                                                                                                                                                                                                                                           |
|----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Criteria | Use rel for assay (difference as % of the sending mean) and abs for impurities (difference in % points). A table. Columns: Test   Maximum difference of means   Difference type (rel/abs)   Maximum %RSD per laboratory   Unit. Paste rows from Excel, type comma-separated rows, or press <a href="#">Load file</a> (Excel, CSV, Word, PDF or a scan). |

## 3 · Results

One row per test, laboratory (SU or RU), batch and analyst. Put the replicate results in one cell separated by ", ".

| FIELD                               | WHAT TO ENTER                                                                                                                                                                                                                                                    |
|-------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Results                             | Laboratory: SU for the sending unit, RU for the receiving unit. A table. Columns: Test   Laboratory (SU/RU)   Batch   Analyst   Results. Paste rows from Excel, type comma-separated rows, or press <a href="#">Load file</a> (Excel, CSV, Word, PDF or a scan). |
| System suitability met in every run | Tick the box if it applies.                                                                                                                                                                                                                                      |
| Deviations and their impact         | Type or paste text.                                                                                                                                                                                                                                              |

## 5. Checks and alerts

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

- Difference of means within the limit and %RSD within the limit in each laboratory; a failure is critical.
- 90% confidence interval of the difference (Welch) within  $\pm$ limit (equivalence); a wide interval is noted.
- Both laboratories tested every sample; every test in the criteria was done; two receiving analysts where needed.
- Prerequisites (training, qualification, gap analysis) and system suitability.

### 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  | Analytical method transfer 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 USP <1224> and section VIII of the FDA guidance on analytical procedures and methods validation (2015). EU follows EU GMP Chapter 6 (6.37–6.41) on technical transfer of testing methods.

## 8. Working with other modules

- Write the protocol in the Protocol Builder (Analytical method transfer).
- The procedure's validation is in the Method Validation Studio.

## 9. Common pitfalls

- Comparing different samples in each laboratory.
- Setting the criteria after seeing the results.

## 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. **Introduce a bias in the receiving laboratory**

Change the receiving results for batch B2402 to 98.1;98.4;98.3.

**EXPECTED RESULT**

The headline shows one comparison outside criteria.

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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.