

IND & IMPD Quality

Write the quality part of an IND or an EU investigational medicinal product dossier (IMPD), appropriate to the phase: drug substance and drug product summaries, impurities compared with the toxicology batch, the specification, and a shelf life that covers the trial.

WRITES

IND/IMPD 2.1.S

IND/IMPD 2.1.P

PRODUCT TYPE

Small molecule and biologics

GUIDANCE IT FOLLOWS

21 CFR 312.23(a)(7); FDA Content and Format of INDs for Phase 1 Studies (1995) and INDs for Phase 2 and Phase 3 Studies: CMC Information (2003); FDA CGMP for Phase 1 Investigational Drugs (2008); EMA Guideline on the requirements for the chemical and pharmaceutical quality documentation concerning investigational medicinal products in clinical trials (EMA/CHMP/QWP/5455 Rev. 2); EMA/CHMP/BWP/5348 Rev. 2 (biological IMPs); Regulation (EU) No 536/2014; ICH Q3A, Q3B, M7

TIME TO LEARN

About 20 minutes with the example

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

1. What this module does

You enter the phase, dosage form, maximum clinical dose and trial duration, the impurity levels in the toxicology batch and the clinical batch, the specification and the stability data.

The tool qualifies each impurity: covered by the toxicology batch, covered by the daily intake at the NOAEL, or below the ICH Q3A threshold. It checks the tests expected for the phase, form and product type, the EU shelf-life extrapolation rule, and that the shelf life covers the trial.

What you get

- US: IND 312.23(a)(7) drug substance and drug product sections.
- EU: IMPD 2.1.S and 2.1.P quality sections, with placebo where supplied.
- A Word or PDF file for each.

2. Before you start

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

- Phase, dosage form, maximum daily dose and trial duration including supply.
- Toxicology batch number and NOAEL.
- Impurity levels in the toxicology and clinical batches, with mutagenic alerts.
- Composition, specification, method suitability, stability data and extension plan.

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/ind-impd-quality.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 trial

Choose the region, phase, product type and dosage form, and enter the maximum daily dose and the trial duration.

The screenshot shows the CMCfy web application interface for 'IND & IMPD Quality'. The top navigation bar includes 'IND & IMPD Quality', 'Projects', 'All modules', 'Training', and 'Security'. A status bar indicates 'Runs entirely on this device' and provides a 'Training guide' link.

The main content area is titled 'PROJECTS' and includes instructions: 'Keep this work in a project, with version history and your company logo on every report.' It offers buttons for 'Choose projects folder' and 'Keep in this browser'.

Below this, there are three status indicators:

- 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.

The tool version is 'IND/IMPD 2.1.S' and 'IND/IMPD 2.1.P'. Action buttons include 'Save project', 'Open project', 'Start blank', and 'Load example'.

The main instruction reads: 'Write the quality part of an IND (21 CFR 312.23(a)(7)) or an EU IMPD for a clinical trial, appropriate to the phase. The tool compares the impurity profile of the clinical batches with the batch used in toxicology, checks the shelf life covers the trial (with the EU extrapolation rule), and checks the tests a reviewer expects for the phase, dosage form and product type.'

Guidance text is provided: 'Guidance: 21 CFR 312.23(a)(7); FDA Content and Format of INDs for Phase 1 Studies (1995) and INDs for Phase 2 and Phase 3 Studies: CMC Information (2003); FDA CGMP for Phase 1 Investigational Drugs (2008); EMA Guideline on the requirements for the chemical and pharmaceutical quality documentation concerning investigational medicinal products in clinical trials (EMA/CHMP/QWP/545525/2017 Rev. 2); EMA/CHMP/BWP/534898/2008 Rev. 2 (biological IMPs); Regulation (EU) No 536/2014; ICH Q3A, Q3B, M7'.

The '1 · PRODUCT AND TRIAL' section contains the following input fields:

- Investigational product: CMX-205 capsules, 25 mg and 100 mg
- Submission region: US: FDA (NDA, ANDA, BL)
- Phase: Phase 1 (first in human)
- Product type: Small molecule
- Dosage form: Oral solid
- Maximum clinical daily dose (mg): 400
- Planned trial duration including supply (months): 18

The 'RESULT' section displays:

- Phase 1 · impurities qualified · specification complete**
- Shelf life 12 months on 6 months of real-time data. Trial supply needs 18 months.
- QUALIFICATION THRESHOLD: 0.15% (dose 400 mg/day)
- TESTS IN SPECIFICATION: 8
- SUPPORTED SHELF LIFE: 12 months
- TRIAL DURATION: 18 months

The bottom section is titled 'IMPURITY QUALIFICATION'.

2 Enter impurities and the specification

One row per impurity with the level in the toxicology batch and in the clinical batch, the clinical batch number, and yes if it has a mutagenic alert. One row per test in the specification.

3 Read the result

The headline gives the phase, whether every impurity is qualified and whether the specification has the expected tests: "Phase 1 · impurities qualified · specification complete".

IMPURITY QUALIFICATION

Daily intake = level × dose. Tox intake uses the NOAEL scaled to a 60 kg adult.

IMPURITY	TOX BATCH	CLINICAL	TOX INTAKE (MG/DAY)	CLINICAL INTAKE (MG/DAY)
Impurity A (des-methyl)	0.32%	0.18%	19.20	0.720
Impurity B (dimer)	0.12%	0.21%	7.20	0.840
Impurity C (aryl amine)	not detected	0.04%	—	0.160
Unspecified (each)	0.08%	0.07%	4.80	0.280

Impurity qualification.

4

Resolve alerts and download

Unqualified impurities, uncontrolled mutagenic impurities, missing tests and a shelf life beyond the EU rule 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 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

IND 2.1.5 Drug substance
CMX-205 capsules, 25 mg and 100 mg - Phase 1 - US (FDA)

Chem Dev Ltd., Cambridge UK. Five-step synthesis from commercially available starting materials; final step crystallisation from ethanol/water. Starting materials, intermediates and the final step are described with in-process controls. Structure confirmed by NMR, MS, IR and elemental analysis.

Impurities: the clinical batch impurity profile was compared with that of the toxicology batch (Batch TOX-01; rat 4-week NOAEL 100 mg/kg/day). Impurity A (des-methyl) (0.18%) is present at or below the level in the toxicology batch; Impurity B (dimer) (0.21%) is covered by the daily intake in toxicology; Impurity C (aryl amine) (0.04%) is below the qualification threshold; Unspecified (each) (0.07%) is present at or below the level in the toxicology batch. Impurity C (aryl amine) has a structural alert for mutagenicity and is controlled in the specification in line with ICH M7.

Retest period: 12 months; 6 months real-time at 25 °C/60% RH and 6 months at 40 °C/75% RH.

Impurities: toxicology and clinical batches

Impurity	Toxicology batch	Clinical batch	Status
Impurity A (des-methyl)	0.32%	0.18%	Qualified
Impurity B (dimer)	0.12%	0.21%	Qualified
Impurity C (aryl amine)	not detected	0.04%	Mutagenic alert: controlled in the specification (ICH M7)
Unspecified (each)	0.08%	0.07%	Qualified

Draft prepared with CMCfy IND & IMPD Quality on 2026-10-29. Guidance applied: 21 CFR 312.23(a)(7); FDA Content and Format of INDs for Phase 1 Studies (1995) and INDs for Phase 2 and Phase 3 Studies; CMC Information (2003); FDA CGMP for Phase 1 Investigational Drugs (2008); EMA Guideline on the requirements for the chemical and pharmaceutical quality documentation concerning investigational medicinal products in clinical trials (EMA/CHMP/QWP/545525/2017 Rev. 2); EMA/CHMP/BWP/534898/2008 Rev. 2 (biological IMPs); Regulation (EU) No 536/2014; ICH Q3A, Q3B, M7. To be reviewed and approved by a qualified person before submission.

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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 · Product and trial

FIELD	WHAT TO ENTER
Investigational product	Type it in.
Submission region	Choose one: US: FDA (NDA, ANDA, BLA, IND); EU: EMA and national agencies (MAA); Both US and EU.
Phase	Choose one: Phase 1 (first in human); Phase 2; Phase 3.
Product type	Choose one: Small molecule; Biological.
Dosage form	Choose one: Oral solid; Oral liquid; Parenteral (sterile); Other.
Maximum clinical daily dose (mg)	Type a number.
Planned trial duration including supply (months)	Type a number.
Placebo or comparator supplied	Tick the box if it applies.

2 · Drug substance

FIELD	WHAT TO ENTER
Manufacturer, route and controls	Type or paste text.
Drug substance retest period and real-time data (months)	Type it in.

3 · Impurities: toxicology batch against clinical batches

Levels in % of the drug substance. The tox dose is the NOAEL dose in the most sensitive species in mg/kg/day; human dose uses 60 kg.

FIELD	WHAT TO ENTER
Toxicology batch and NOAEL	Type it in.
NOAEL (mg/kg/day)	From the pivotal toxicology study in the most sensitive species. Type a number.
Impurities	Leave a level empty if the impurity was not detected in that batch. A table. Columns: Impurity Toxicology batch (%) Clinical batch (%) Clinical batch Mutagenic alert (yes/no). Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).

4 · Drug product

FIELD	WHAT TO ENTER
Composition and manufacture	Type or paste text.
Specification	A table. Columns: Test Method Acceptance criterion. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
Placebo when it applies	Type or paste text.
Method suitability	Type it in.
Proposed shelf life (months)	Type a number.
Real-time stability data on the clinical batch or a representative batch (months)	Real-time months on the clinical batch or a representative batch. Type a number.
Stability programme and extension plan	Type or paste text.

5. Checks and alerts

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

- Qualification threshold min(0.15%, 1.0 mg/day) (0.05% above 2 g/day). Tox intake = level × NOAEL × 60 kg; clinical intake = level × dose.
- Mutagenic impurities named in the specification count as controlled per ICH M7.
- Expected tests for the phase, dosage form and product type (for example sterility and endotoxin for parenterals, potency for biologics).
- EU: shelf life no more than twice the real-time data and no more than 12 months beyond it.

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: Drug substance summary; Drug product summary. 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
2.1.S / IND DS	Drug substance summary, impurity comparison
2.1.P / IND DP	Composition, specification, stability, placebo

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 312.23(a)(7) and the FDA guidances on content and format of Phase 1 INDs (1995) and Phase 2 and 3 CMC information (2003). EU follows EMA/CHMP/QWP/545525/2017 Rev. 2 (chemical IMPs) or EMA/CHMP/BWP/534898/2008 Rev. 2 (biological IMPs) under Regulation (EU) No 536/2014.

8. Working with other modules

- Stability data come from the Stability Studio.
- At marketing application, write the full Module 3 sections with the QOS Composer & Dossier Assembler.

9. Common pitfalls

- Comparing percentages without the dose: an impurity at a higher percentage can still be covered by the daily intake in toxicology.
- Proposing a shelf life longer than the EU rule allows without a stability commitment.

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. Lower the NOAEL

Set `NOAEL (mg/kg/day)` to 5.

EXPECTED RESULT

The headline shows one impurity not qualified.

2. Extend the shelf life in the EU

Set the region to EU and `Proposed shelf life` to 18.

EXPECTED RESULT

The note says the EU rule supports up to 12 months.

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.