NONCLINICAL · TRAINING GUIDE

Pathology Report

Write the anatomic pathology report of a toxicity study: incidence and severity of the microscopic findings by dose and sex, their interpretation, the pathology NOAEL, the tissues examined and the peer review.

WRITES	PRODUCT TYPE	GUIDANCE IT FOLLOWS	TIME TO LEARN
4.2.3.2	Small molecule and biologics	21 CFR Part 58 (58.185); OECD Principles of GLP; OECD GLP Advisory Document No. 16 (pathology peer review, 2014); OECD Guidance Document 116; STP recommendations for tissue sampling (Bregman et al. 2003) and organ weights (Sellers et al. 2007); STP best practices for pathology peer review (Morton et al. 2010); INHAND nomenclature	About 20 minutes with the example

Open the tool at https://app.cmcfy.com/app/pathology-report.html. This guide is also online at https://cmcfy.com/guides/pathology-report.html

1. What this module does

You enter the study, the dose groups, the tissues examined, the peer review and one row per finding, sex and dose with the incidence, mean severity and whether it is test item related and adverse.

The tool builds the incidence table against the control, flags findings whose incidence or severity rises with dose but are called not test item related, sets the pathology NOAEL, and checks the core tissue

list, the grading scale, the peer review and the pathologist's GLP statement.

What you get

- A Word or PDF report: pathology report (Module 4.2.3.2).

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2. Before you start

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

- Incidence and severity of each finding by dose and sex, including the control.
- The tissue list examined.
- The peer review statement.

> **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.

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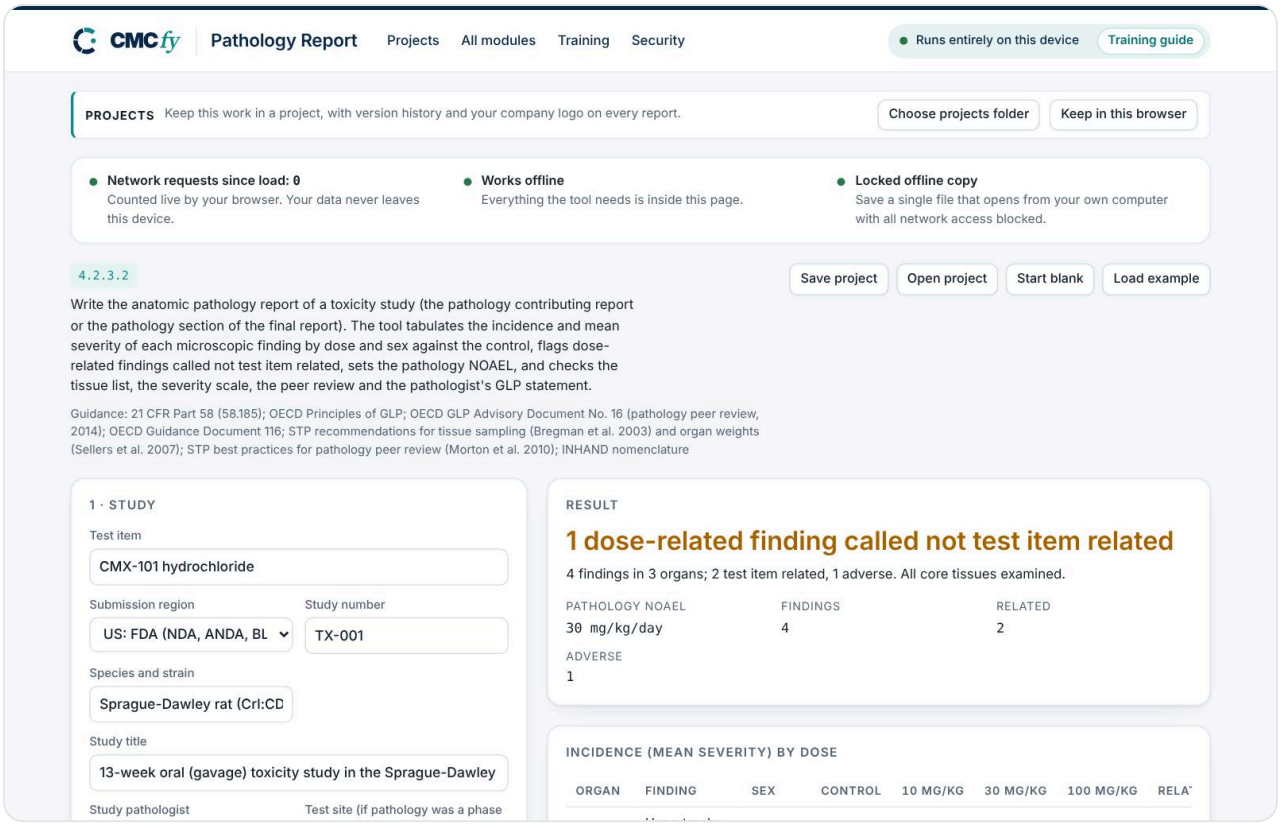
3. Step by step with the example

Open the tool at app.cmcfy.com/app/pathology-report.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 study

Enter the study, species, pathologist, dose groups and the number of animals examined per sex.

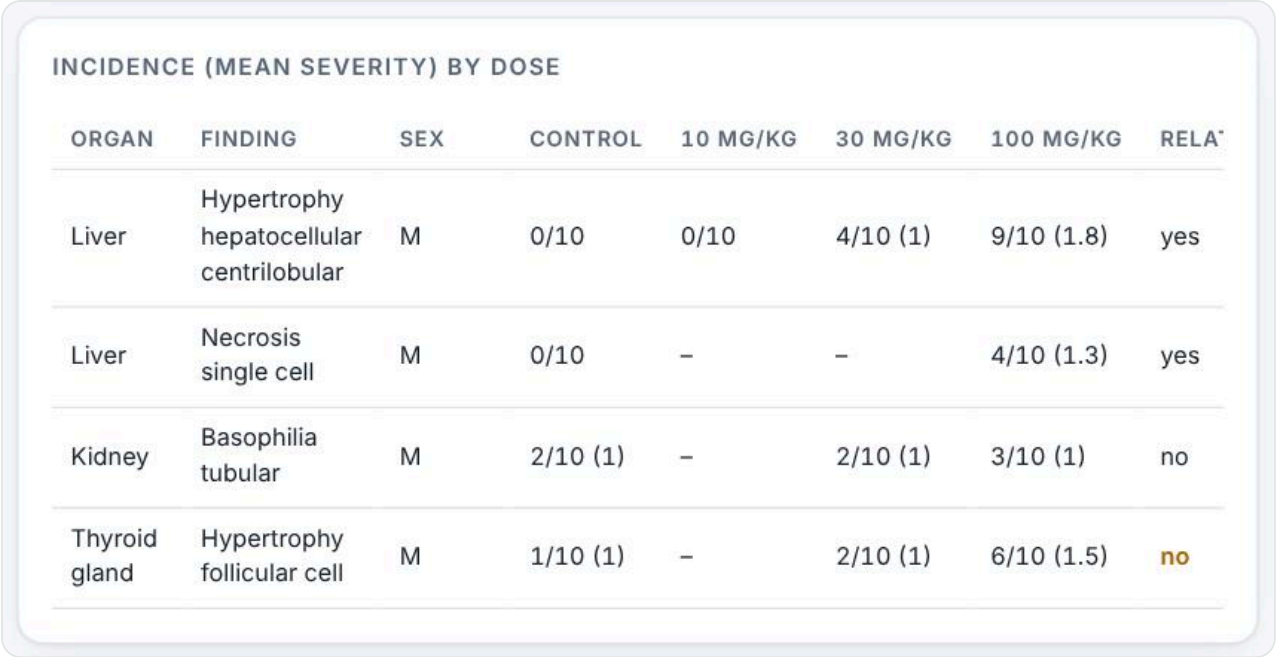


2 Enter tissues and findings

List the tissues examined. Enter one row per finding, sex and dose, with a control row (incidence 0 when absent).

3 Read the result

The headline gives the outcome, for example "1 dose-related finding called not test item related".



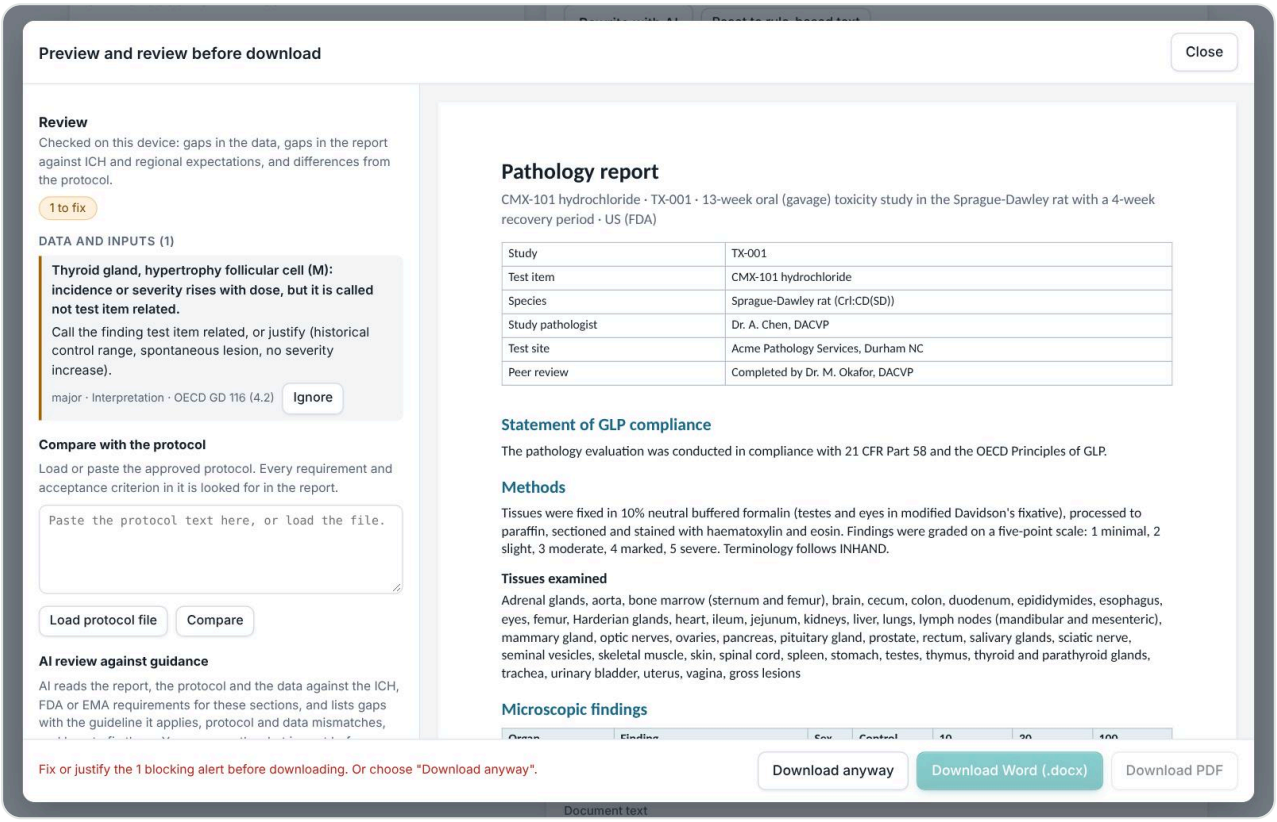
INCIDENCE (MEAN SEVERITY) BY DOSE

ORGAN	FINDING	SEX	CONTROL	10 MG/KG	30 MG/KG	100 MG/KG	RELA
Liver	Hypertrophy hepatocellular centrilobular	M	0/10	0/10	4/10 (1)	9/10 (1.8)	yes
Liver	Necrosis single cell	M	0/10	–	–	4/10 (1.3)	yes
Kidney	Basophilia tubular	M	2/10 (1)	–	2/10 (1)	3/10 (1)	no
Thyroid gland	Hypertrophy follicular cell	M	1/10 (1)	–	2/10 (1)	6/10 (1.5)	no

Incidence (mean severity) by dose.

4 Resolve alerts and download

A missing GLP statement and an incidence above the number examined are critical. Dose-related findings called unrelated, a missing peer review and core tissues not examined are flagged. Then preview and download.



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 · Study

FIELD	WHAT TO ENTER
Test item	Type it in.
Submission region	Choose one: US: FDA (NDA, ANDA, BLA, IND); EU: EMA and national agencies (MAA); Both US and EU.
Study number	Type it in.
Species and strain	Type it in.
Study title	Type it in.
Study pathologist	Type it in.
Test site (if pathology was a phase at another site)	Type it in.
Dose groups (mg/kg/day, control first)	Type it in.
Animals examined per sex per group	Type a number.
Severity grading scale stated in the methods	Tick the box if it applies.
INHAND nomenclature used	Tick the box if it applies.
Signed pathologist statement of GLP compliance	Tick the box if it applies.

2 · Tissues and peer review

FIELD	WHAT TO ENTER
Tissues examined microscopically (all animals of the control and high dose groups)	Type or paste text.
Peer review	Choose one: Completed, with a signed peer review statement; In progress; Not performed.
Peer review pathologist when it applies	Type it in.
Diagnoses changed after the peer review when it applies	Type it in.

3 · Microscopic findings

One row per finding, sex and dose, including the control (dose 0). Incidence is the number of animals affected; mean severity is for affected animals.

FIELD	WHAT TO ENTER
Findings	Mean severity is for affected animals, on the 1 (minimal) to 5 (severe) scale. A table. Columns: Organ | Finding | Sex | Dose (mg/kg/day) | Incidence | Mean severity | Test item related (yes/no) | Adverse (yes/no). Paste rows from Excel, type comma-separated rows, or press `Load file` (Excel, CSV, Word, PDF or a scan).
Recovery animals (end of recovery)	Type or paste text.
Macroscopic findings and organ weights	Type or paste text.

5. Checks and alerts

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

- Dose response against the control.

- Pathology NOAEL from the adverse findings.
- Core tissues, grading scale, nomenclature and peer review.

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: Pathology 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.

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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
4.2.3.2	Pathology 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: 21 CFR Part 58. EU: OECD Principles of GLP. The OECD guidance on pathology peer review applies to both.

8. Working with other modules

- The pathology NOAEL feeds the GLP Toxicology Study Report and the Nonclinical Overview & Summaries.

9. Common pitfalls

- Calling a finding with a clear dose response spontaneous without historical control data.
- Leaving out the control row, so the incidence cannot be compared.

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. **Accept the thyroid finding as related**

   Mark the thyroid follicular cell hypertrophy at 100 mg/kg/day as test item related.

   EXPECTED RESULT

   The headline gives the pathology NOAEL with no open interpretation issue.

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.