BIOLOGICS · TRAINING GUIDE

Vaccine Lot Release Summary

Prepare the lot release summary for a vaccine: the release tests expected for the platform, each result against its specification, residual DNA and adjuvant limits, and US (CBER) and EU (OCABR) official release.

WRITES	PRODUCT TYPE	GUIDANCE IT FOLLOWS	TIME TO LEARN

`3.2.P.5.1`
`3.2.P.5.4`
`Lot release`
	Vaccines	21 CFR 600, 610 (610.2 lot release, 610.10–610.15); FDA Guidance on content and format of CMC for vaccines (1999); WHO TRS 978 Annex 3 (lot release); Directive 2001/83/EC Art. 114 and the EDQM OCABR guidelines; Ph. Eur. 0153 Vaccines for human use; EMA Guideline on quality aspects of mRNA vaccines (draft, 2024); WHO TRS 1039 Annex 3 (mRNA vaccines)	About 20 minutes with the example

Open the tool at https://app.cmcfy.com/app/vaccine-lot-release.html. This guide is also online at https://cmcfy.com/guides/vaccine-lot-release.html

1. What this module does

You choose the platform (inactivated, live attenuated, subunit, conjugate, mRNA-LNP or viral vector) and enter the release results. The tool lists the tests expected for that platform and shows any that are missing.

It checks each result, the aluminium content and residual DNA for continuous cell lines, and whether the lot release protocol (US) and OCABR (EU) are in place.

What you get

- A Word or PDF summary: Vaccine lot release summary (3.2.P.5.4).

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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.

- Final lot release results with specifications.
- The production substrate and any adjuvant content.
- The status of official release.

> **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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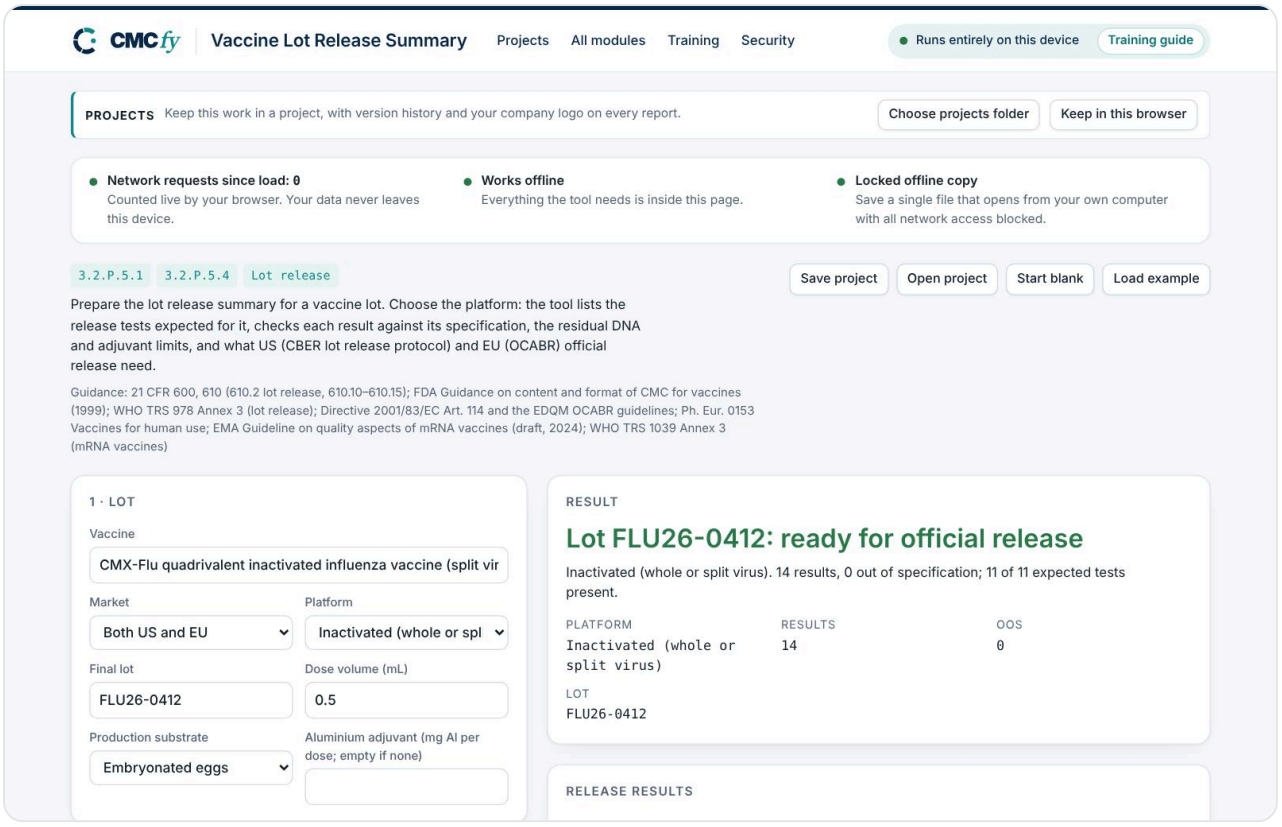
3. Step by step with the example

Open the tool at app.cmcfy.com/app/vaccine-lot-release.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 lot

Enter the vaccine, the lot and dose, and choose the platform and the production substrate.



2 Enter the results

One row per test with its specification and result. Write pass results as "Conforms" or "No growth".

3 Read the result

The headline gives the outcome: "Lot FLU26-0412: ready for official release".

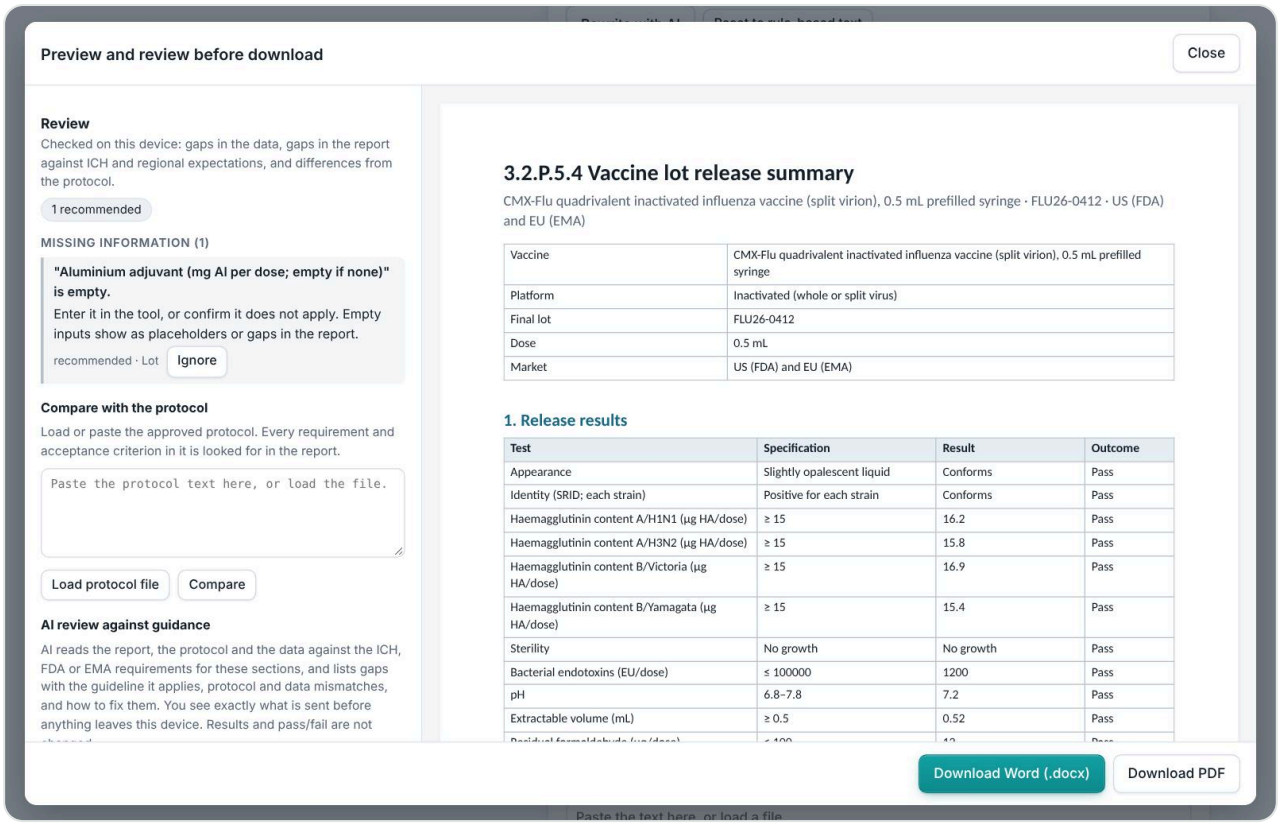
RELEASE RESULTS

TEST	SPECIFICATION	RESULT	OUTCOME
Appearance	Slightly opalescent liquid	Conforms	pass
Identity (SRID; each strain)	Positive for each strain	Conforms	pass
Haemagglutinin content A/H1N1 (µg HA/dose)	≥ 15	16.2	pass
Haemagglutinin content A/H3N2 (µg HA/dose)	≥ 15	15.8	pass
Haemagglutinin content B/Victoria (µg HA/dose)	≥ 15	16.9	pass
Haemagglutinin content B/Yamagata (µg HA/dose)	≥ 15	15.4	pass
Sterility	No growth	No growth	pass
Bacterial endotoxins (EU/dose)	≤ 100000	1200	pass
pH	6.8–7.8	7.2	pass
Extractable volume (mL)	≥ 0.5	0.52	pass
Residual formaldehyde (µg/dose)	≤ 100	12	pass
Ovalbumin (µg/dose)	≤ 1	0.08	pass
Residual infectivity (inactivation test)	No residual infectious virus	Conforms	pass
Residual host DNA (ng/dose)	≤ 10	0.4	pass

Release results.

4 Resolve alerts and download

Out-of-specification results and missing potency, sterility or identity tests are critical. 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 · Lot

FIELD	WHAT TO ENTER
Vaccine	Type it in.
Market	Choose one: US: CBER lot release; EU: OCABR; Both US and EU.
Platform	Choose one: Inactivated (whole or split virus); Live attenuated; Recombinant or purified subunit; Polysaccharide conjugate; mRNA-LNP; Viral vector.
Final lot	Type it in.
Dose volume (mL)	Type a number.
Production substrate	Choose one: Embryonated eggs; Primary or diploid cells; Continuous cell line; Cell-free (in vitro transcription, synthesis).

FIELD	WHAT TO ENTER
Aluminium adjuvant (mg Al per dose; empty if none)	Type a number.

2 · Release results

FIELD	WHAT TO ENTER
Results	Name tests in the usual way (for example "Haemagglutinin content", "Encapsulation efficiency") so the expected-test check finds them. A table. Columns: Test | Specification | Result. Paste rows from Excel, type comma-separated rows, or press `Load file` (Excel, CSV, Word, PDF or a scan).

3 · Official release

FIELD	WHAT TO ENTER
Lot release protocol submitted to CBER with samples when it applies	Tick the box if it applies.
OCABR by an OMCL (EU official control authority batch release certificate) when it applies	Tick the box if it applies.
Stability at release (potency at end of shelf life predicted above the minimum)	Tick the box if it applies.

5. Checks and alerts

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

- Expected tests for the platform.
- Each result against its specification.
- Residual DNA, aluminium and official release.

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: Release 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.

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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
3.2.P.5.4	Vaccine lot release summary

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: CBER lot release on a lot release protocol (21 CFR 610.2). EU: official control authority batch release (OCABR) by an OMCL (Directive 2001/83/EC Art. 114).

8. Working with other modules

- Stability of the vaccine is evaluated in Biologics Stability Studio.

9. Common pitfalls

- Potency tested only on the bulk and not reported for the final lot.
- Placing an EU lot on the market before OCABR.

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 a strain**

   Change the B/Yamagata haemagglutinin result from 15.4 to 14.2 µg.

   EXPECTED RESULT

   The headline shows one result out of specification.

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.