EPA AND USDA · TRAINING GUIDE

Veterinary Serial Release

Write the release summary for a serial of a USDA-licensed veterinary biologic: each 9 CFR 113 test checked against the Outline of Production, potency margin, dating, retests and sampling, ready for APHIS Form 2008.

WRITES	PRODUCT TYPE	GUIDANCE IT FOLLOWS	TIME TO LEARN
`9 CFR 113` `APHIS 2008`	EPA and USDA	9 CFR 113 (standard requirements: 113.3 sampling, 113.5 general testing, 113.6 APHIS testing, 113.8 in vitro potency, 113.26/113.27 bacteria and fungi, 113.30 Salmonella, 113.33 mouse safety, 113.38 guinea pig safety, 113.200 killed virus vaccines); 9 CFR 114.13 (expiration date); 9 CFR 116.7 (APHIS Form 2008)	About 20 minutes with the example

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

1. What this module does

You give the serial, its dates, the release and expiry potency minimums and the samples taken, then list each test with its criterion and result.

The tool evaluates each result, flags failures and results it cannot evaluate, retests with no reason, a release minimum that does not cover the dating period, an expiration date beyond the approved dating and too few samples.

What you get

- A Word or PDF file: serial release summary with the APHIS Form 2008 data.

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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.

- The Outline of Production test list and criteria.
- The serial test results.
- The approved dating period.

> **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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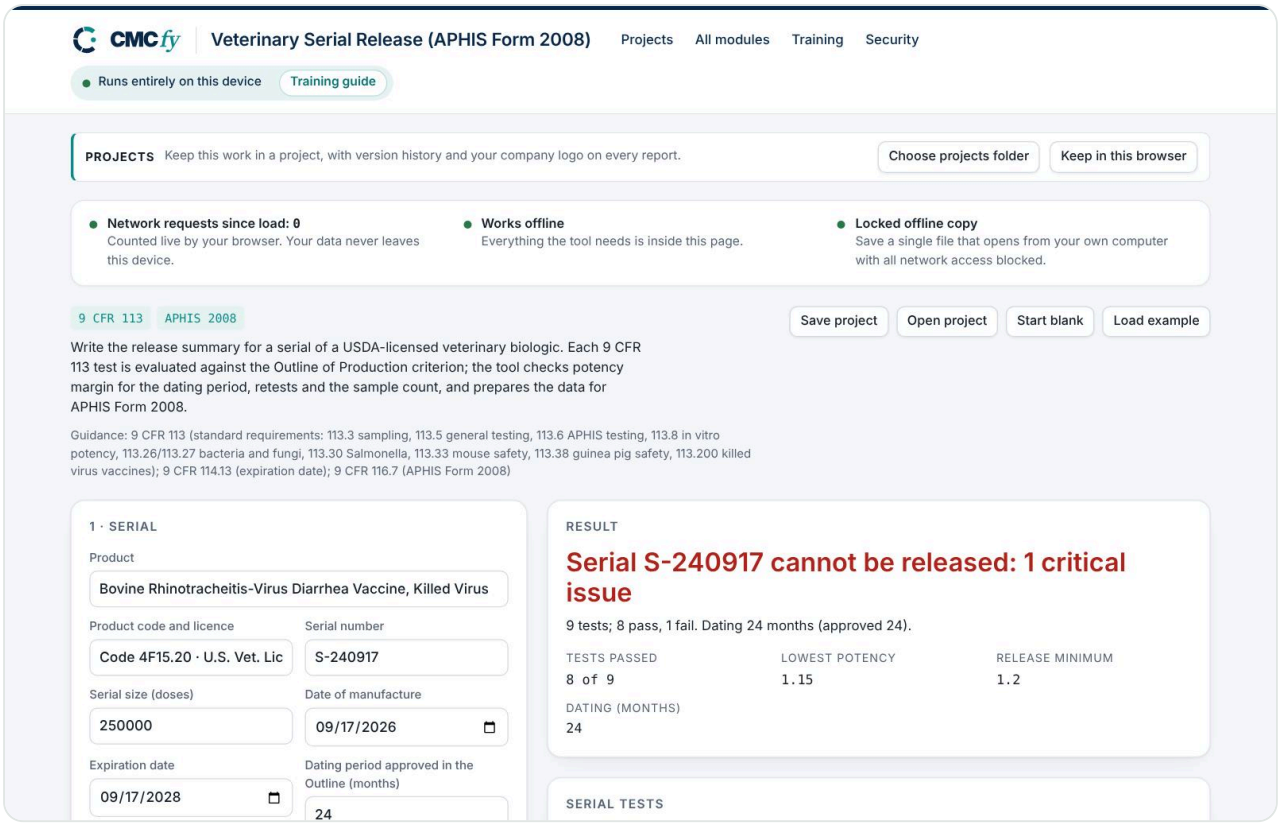
3. Step by step with the example

Open the tool at app.cmcfy.com/app/veterinary-serial-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 serial

Serial number, size, manufacture and expiration dates, the potency minimums and the samples taken.

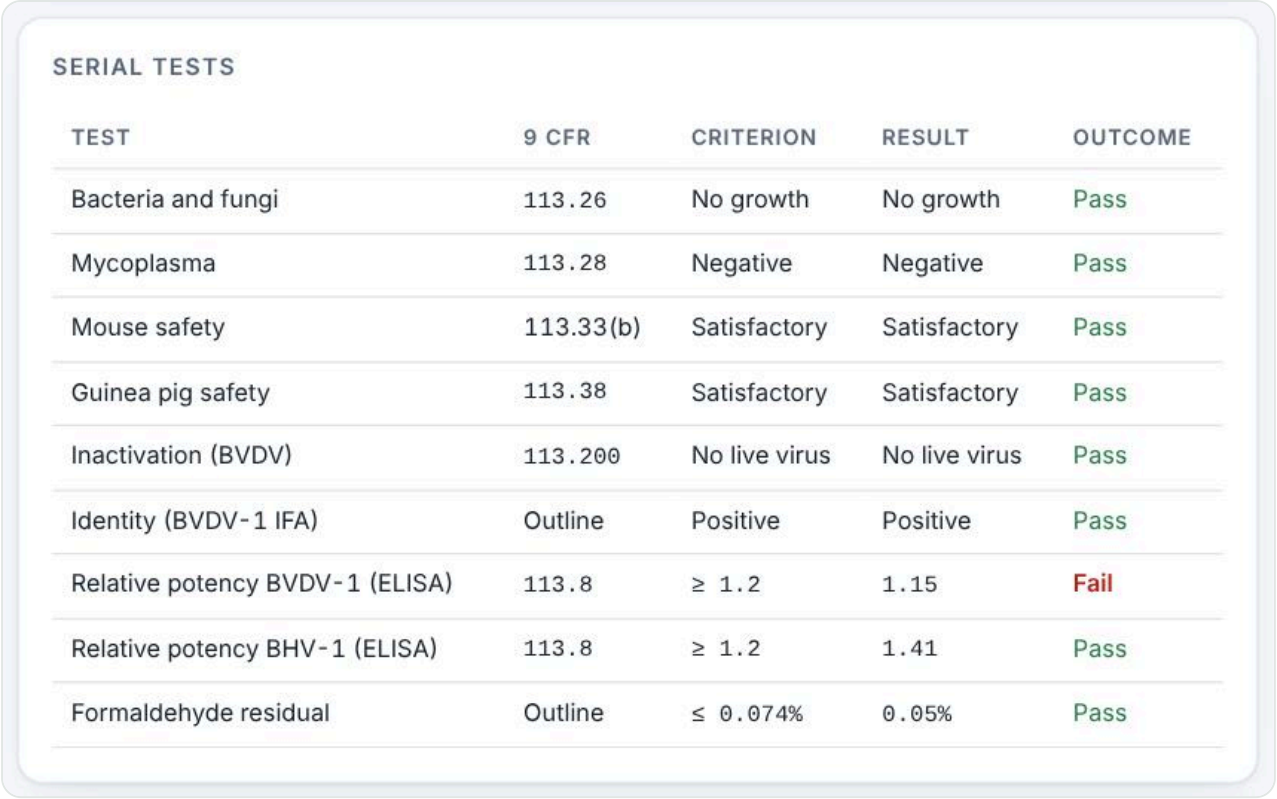


2 Enter the tests

One row per test with the 9 CFR section, the criterion and the result. Mark retests and give the reason.

3 Read the result

The headline says whether the serial meets the release requirements.



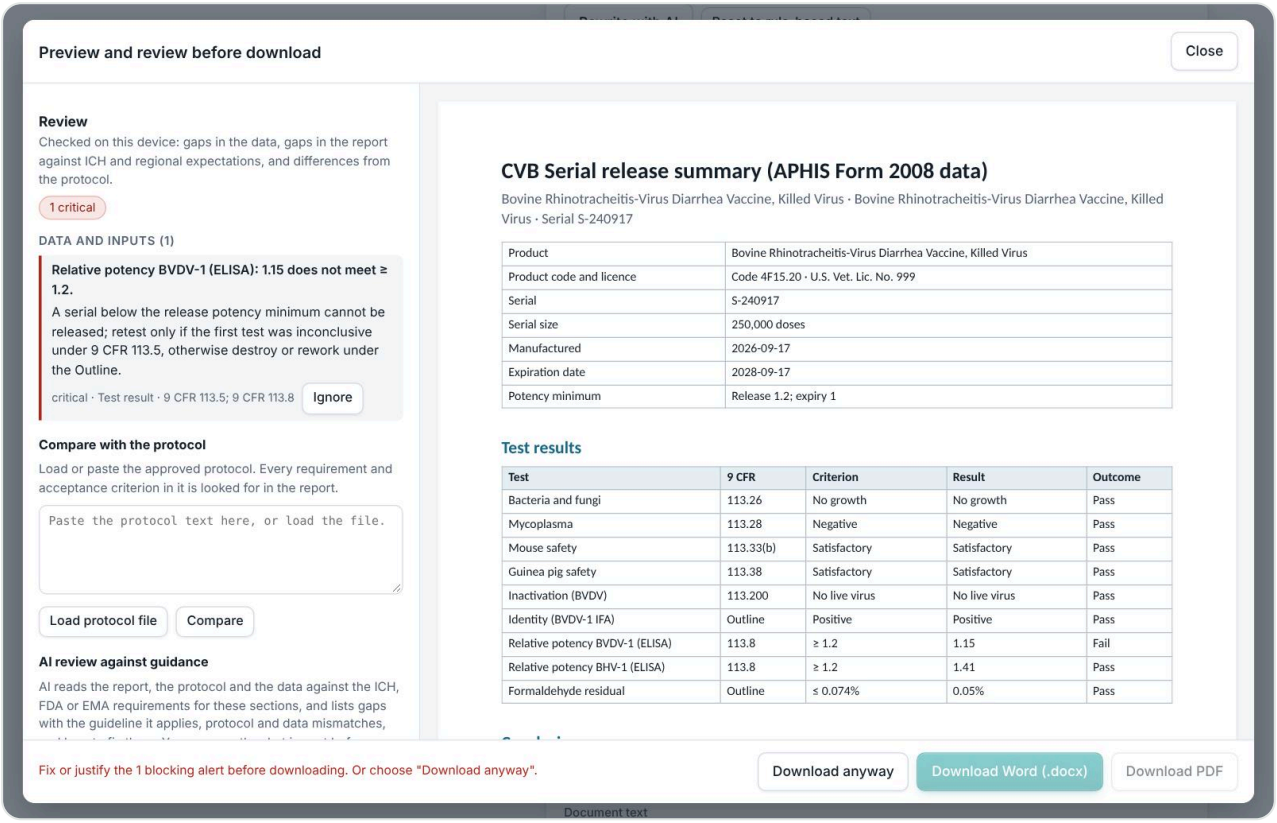
SERIAL TESTS

TEST	9 CFR	CRITERION	RESULT	OUTCOME
Bacteria and fungi	113.26	No growth	No growth	Pass
Mycoplasma	113.28	Negative	Negative	Pass
Mouse safety	113.33(b)	Satisfactory	Satisfactory	Pass
Guinea pig safety	113.38	Satisfactory	Satisfactory	Pass
Inactivation (BVDV)	113.200	No live virus	No live virus	Pass
Identity (BVDV-1 IFA)	Outline	Positive	Positive	Pass
Relative potency BVDV-1 (ELISA)	113.8	≥ 1.2	1.15	Fail
Relative potency BHV-1 (ELISA)	113.8	≥ 1.2	1.41	Pass
Formaldehyde residual	Outline	≤ 0.074%	0.05%	Pass

Each test with its outcome.

4 Resolve alerts and download

A failed test or an expiration date beyond the approved dating is 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 · Serial

FIELD	WHAT TO ENTER
Product	Type it in.
Product code and licence	Type it in.
Serial number	Type it in.
Serial size (doses)	Type a number.
Date of manufacture	Type it in.
Expiration date	Type it in.
Dating period approved in the Outline (months)	Type a number.
Release potency minimum (relative potency)	Type a number.
Expiry potency minimum (relative potency)	Type a number.
Final container samples taken	Type a number.
Samples required by the Outline (9 CFR 113.3)	Type a number.

2 · Tests

One row per test in the Outline of Production. Retest: yes when this is a repeat of an earlier test, with the reason.

FIELD	WHAT TO ENTER
Serial tests	Write criteria as "≥ 1.2", "≤ 0.074%", "No growth" or "Satisfactory". A table. Columns: Test | 9 CFR | Criterion | Result | Retest (yes/no) | Retest reason. Paste rows from Excel, type comma-separated rows, or press `Load file` (Excel, CSV, Word, PDF or a scan).

5. Checks and alerts

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

- Each test against its criterion.
- Potency margin and dating.
- Retests and sampling.

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 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
CVB	Serial release summary (APHIS Form 2008 data)

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.

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7. US and EU submissions

US only: 9 CFR 113 and APHIS Form 2008.

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8. Working with other modules

- The tests and criteria come from the Outline of Production filed with the Veterinary Biologics Licence.

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9. Common pitfalls

- Retesting a failed serial without an inconclusive first test.
- A release potency minimum equal to the expiry minimum.

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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. **Use the valid retest result**

   The first BVDV-1 potency test was inconclusive (reference out of range); enter the retest result 1.32.

   EXPECTED RESULT

   The serial meets the release requirements.

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.