EPA AND USDA · TRAINING GUIDE

Veterinary Biologics Licence

Plan a US veterinary biological product licence for the USDA APHIS Center for Veterinary Biologics: the content your product type needs, and the host-animal efficacy challenge analysed for preventable fraction, significance and challenge validity.

WRITES	PRODUCT TYPE	GUIDANCE IT FOLLOWS	TIME TO LEARN
`9 CFR 102` `APHIS 2001`	EPA and USDA	Virus-Serum-Toxin Act (21 U.S.C. 151–159); 9 CFR 101–118 (veterinary biologics), in particular 102 (licences), 112 (labeling), 113 (standard requirements), 114 (production requirements, outline of production 114.8–114.9), 116 (records); CVB Veterinary Services Memoranda 800.201, 800.202, 800.204	About 20 minutes with the example

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

1. What this module does

You give the product, its type and label claim, the status of each application item, and the counts from the efficacy challenge and field safety study.

The tool lists the items the product type needs (backpassage and shedding for live vaccines, master cell stock for cell-line products), calculates the preventable fraction and a one-sided Fisher exact test, checks the controls were validly challenged, and flags open items and field safety gaps.

What you get

- A Word or PDF file: licence application summary with the efficacy summary.

---

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.
- Master seed and master cell stock reports.
- The efficacy study report with vaccinate and control counts.
- The field safety study report.

> **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.

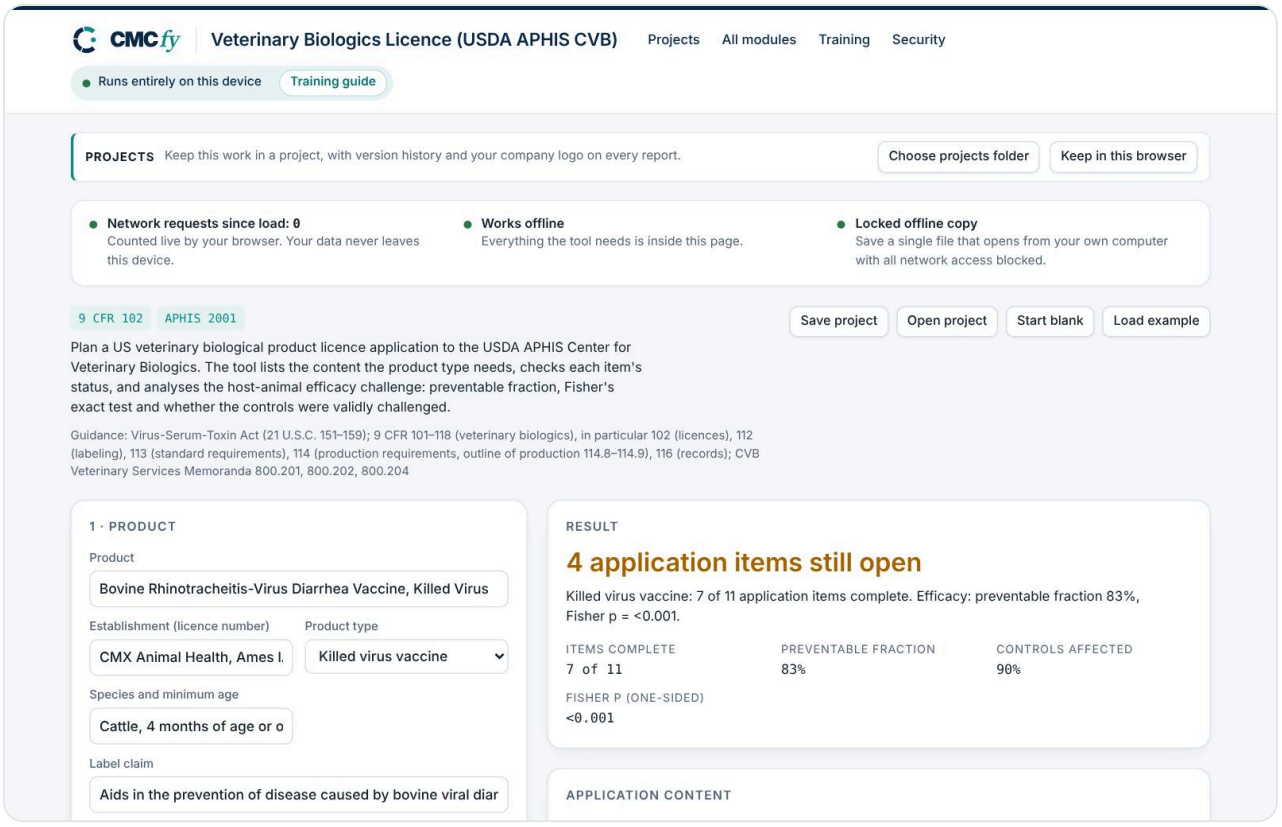
---

3. Step by step with the example

Open the tool at app.cmcfy.com/app/veterinary-biologics-licence.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 product

Choose the product type and give the species and the label claim. Tick the cell line box if the product is grown in cells.



2 Track the content

One row per item with its status: complete, in progress, not started or not applicable.

3 Enter the challenge

Vaccinates and controls challenged and affected, the minimum proportion of controls affected, and the preventable fraction your claim needs.

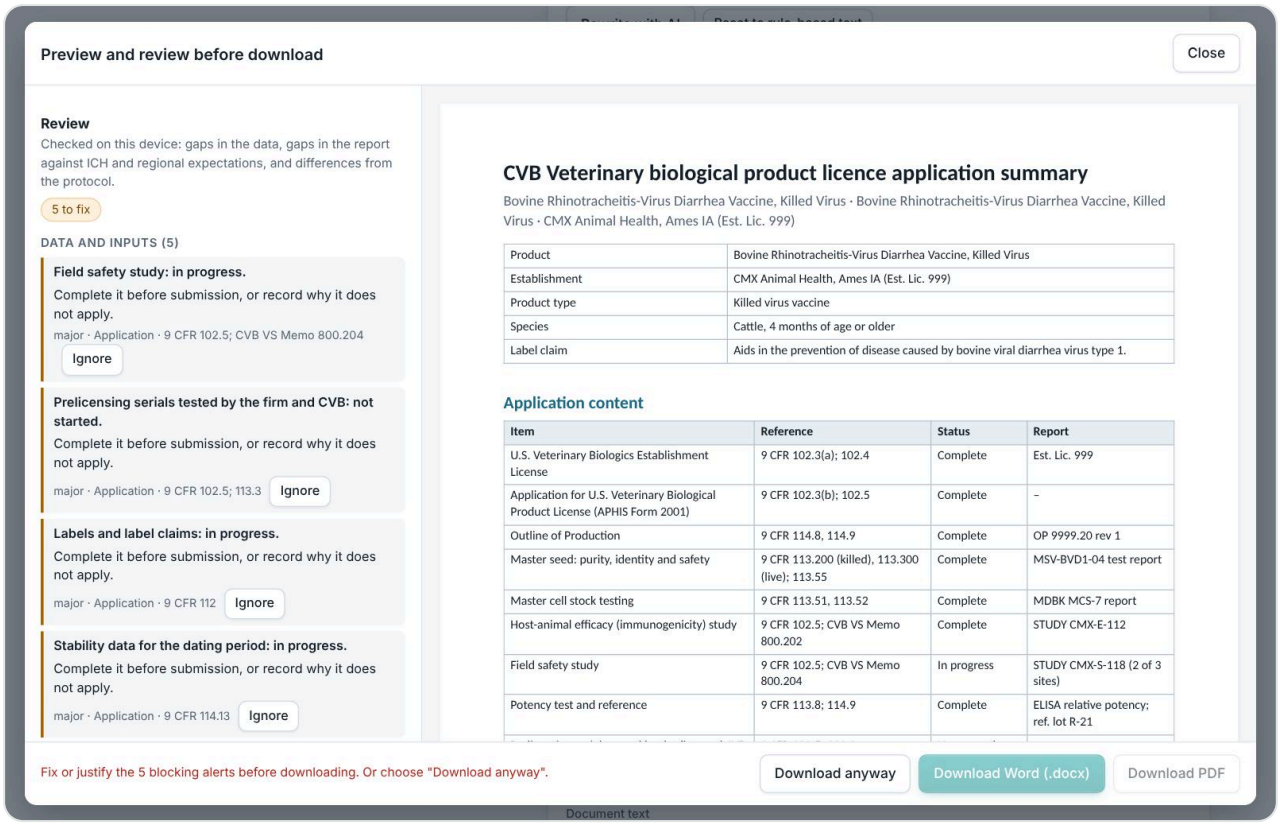
APPLICATION CONTENT

ITEM	REFERENCE	STATUS	REPORT
U.S. Veterinary Biologics Establishment License	9 CFR 102.3(a); 102.4	Complete	Est. Lic. 999
Application for U.S. Veterinary Biological Product License (APHIS Form 2001)	9 CFR 102.3(b); 102.5	Complete	–
Outline of Production	9 CFR 114.8, 114.9	Complete	OP 9999.20 rev 1
Master seed: purity, identity and safety	9 CFR 113.200 (killed), 113.300 (live); 113.55	Complete	MSV-BVD1-04 test report
Master cell stock testing	9 CFR 113.51, 113.52	Complete	MDBK MCS-7 report
Host-animal efficacy (immunogenicity) study	9 CFR 102.5; CVB VS Memo 800.202	Complete	STUDY CMX-E-112
Field safety study	9 CFR 102.5; CVB VS Memo 800.204	In progress	STUDY CMX-S-118 (2 of 3 sites)
Potency test and reference	9 CFR 113.8; 114.9	Complete	ELISA relative potency; ref. lot R-21
Prelicensing serials tested by the firm and CVB	9 CFR 102.5; 113.3	Not started	–
Labels and label claims	9 CFR 112	In progress	–
Stability data for the dating period	9 CFR 114.13	In progress	24-month data at 12 months

Application content and the efficacy challenge.

4 Resolve alerts and download

An invalid challenge, a non-significant difference, or a missing Outline of Production or efficacy study 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 · Product

FIELD	WHAT TO ENTER
Product	Type it in.
Establishment (licence number)	Type it in.
Product type	Choose one: Killed virus vaccine; Bacterin; Modified live vaccine; Subunit or recombinant; Toxoid; Antibody product.
Species and minimum age	Type it in.
Label claim	Type it in.
Produced in a cell line (master cell stock)	Tick the box if it applies.

FIELD	WHAT TO ENTER
Planned submission date	Type it in.

2 · Application content

Status: complete, in progress, not started or not applicable. Rows the tool does not recognise are kept as extra items.

FIELD	WHAT TO ENTER
Content	The tool recognises items by name, for example "Outline of production" or "Field safety study". A table. Columns: Item | Status | Reference or report. Paste rows from Excel, type comma-separated rows, or press `Load file` (Excel, CSV, Word, PDF or a scan).

3 · Efficacy challenge

Counts of animals affected after challenge (the protocol's primary outcome, for example clinical disease or viraemia).

FIELD	WHAT TO ENTER
Vaccinates challenged	Type a number.
Vaccinates affected	Type a number.
Controls challenged	Type a number.
Controls affected	Type a number.
Minimum proportion of controls affected for a valid challenge (%)	Take it from your protocol or the 9 CFR standard requirement for the product. Type a number.
Preventable fraction needed to support the claim (%)	Type a number.
Field safety: animals vaccinated	Type a number.
Field safety: sites	Type a number.

FIELD	WHAT TO ENTER
Field safety: animals with a serious adverse event	Type a number.

5. Checks and alerts

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

- Content by product type.
- Preventable fraction, Fisher exact test and challenge validity.
- Field safety sites and serious adverse events.

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: Efficacy 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
CVB	Veterinary biological product licence application 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 only: USDA APHIS Center for Veterinary Biologics under the Virus-Serum-Toxin Act.

---

8. Working with other modules

- Release each serial with the Veterinary Serial Release module.

---

9. Common pitfalls

- Claiming efficacy from a challenge that did not affect enough controls.
- Running field safety at too few sites.

---

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. **Close the open items**

   Mark field safety, prelicensing serials, labels and stability complete, and enter 3 field safety sites.

   EXPECTED RESULT

   Ready to submit to CVB.

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.