

Biologics Drug Product Writer

Write the drug product sections for a protein injectable: composition, formulation development, fill volume and overfill, compatibility, devices, the fill-finish process with a flow diagram, and sterility assurance.

WRITES

3.2.P.1
3.2.P.2
3.2.P.3.2
3.2.P.3.3
3.2.P.3.4
3.2.P.3.5

PRODUCT TYPE

Biologics
(biotechnology
products)

GUIDANCE IT FOLLOWS

ICH M4Q(R1) 3.2.P;
ICH Q8(R2), Q6B;
EU GMP Annex 1
(2022); FDA Sterile
Drug Products
Produced by
Aseptic Processing
(2004); USP <697>,
USP <1151>, USP
<1207>; 21 CFR
Part 4; Regulation
(EU) 2017/745
Article 117

TIME TO LEARN

About 20 minutes
with the example

Open the tool at <https://app.cmcfy.com/app/biologics-drug-product.html>. This guide is also online at <https://cmcfy.com/guides/biologics-drug-product.html>

1. What this module does

The module writes 3.2.P.1, 3.2.P.2 and 3.2.P.3.2 to 3.2.P.3.5 for vials (liquid or lyophilised), prefilled syringes, autoinjectors and pens.

It checks overfill against USP <1151>, compatibility with diluents and infusion sets, the device information for combination products, the fill-finish steps, and sterility assurance: filter validation, PUPSIT, media fills, depyrogenation and container closure integrity.

What you get

- Word or PDF files for 3.2.P.1, 3.2.P.2, 3.2.P.3.2, 3.2.P.3.3 (with flow diagram), 3.2.P.3.4 and 3.2.P.3.5.
- A summary file for the QOS Composer & Dossier Assembler.

2. Before you start

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

- Presentation, protein concentration, labelled and target fill volume, route and any reconstitution.
- Composition per mL with function and quality standard, pH, formulation development summary and compatibility data.
- For devices: description, dose accuracy and functional tests, human factors study and the EU notified body opinion or US device constituent information.
- Batch size, fill-finish steps with parameters and controls, maximum time from compounding to end of filling.
- Filter validation, PUPSIT status, media fill runs, depyrogenation and container closure integrity.

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/biologics-drug-product.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 Choose the presentation

Choose the [Presentation](#). The device panel appears for syringes, autoinjectors and pens; the reconstitution field for lyophilised vials. The headline for the example reads "Vial (liquid) · 500 mg per unit".

CMCfy | **Biologics Drug Product** | Projects | All modules | Training | Security

Runs entirely on this device | **Training guide** | Protocol builder

PROJECTS Keep this work in a project, with version history and your company logo on every report. Choose projects folder Keep in this browser

- 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.

3.2.P.1 | 3.2.P.2 | 3.2.P.3.2 | 3.2.P.3.3 | 3.2.P.3.4 | 3.2.P.3.5 Save project Open project Start blank Load example

Write the drug product sections for a protein injectable: composition, formulation development, fill volume and overfill, compatibility, devices, the fill-finish process with a flow diagram, and sterility assurance (filtration, media fills, container closure integrity).

Guidance: ICH M4Q(R1) 3.2.P; ICH Q8(R2), Q6B; EU GMP Annex 1 (2022); FDA Sterile Drug Products Produced by Aseptic Processing (2004); USP <697>, USP <1151>, USP <1207>; 21 CFR Part 4; Regulation (EU) 2017/745 Article 117

1 · PRODUCT AND PRESENTATION

Product
CMB-201 Injection

Submission region
US: FDA (NDA, ANDA, BL)

Presentation
Vial (liquid)

Protein concentration (mg/mL)
100

Labelled volume (mL)
5

Target fill volume (mL)
5.5

☒ Viscous solution (over about 10 cP)

RESULT

Vial (liquid) · 500 mg per unit

Fill 5.5 mL for a labelled 5 mL: overfill 0.50 mL against 0.50 mL recommended (USP <1151>, viscous).

STEPS 8	CRITICAL STEPS 4	MEDIA FILL RUNS 3
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PROTEIN PER BATCH
6.60 kg

FILL-FINISH FLOW DIAGRAM

```

graph LR
    A[Drug substance] --> B["1. Thaw of drug substance  
Controlled-rate thaw station"]
    B --> C["IPC: Appearance"]
  
```

2 Check fill volume

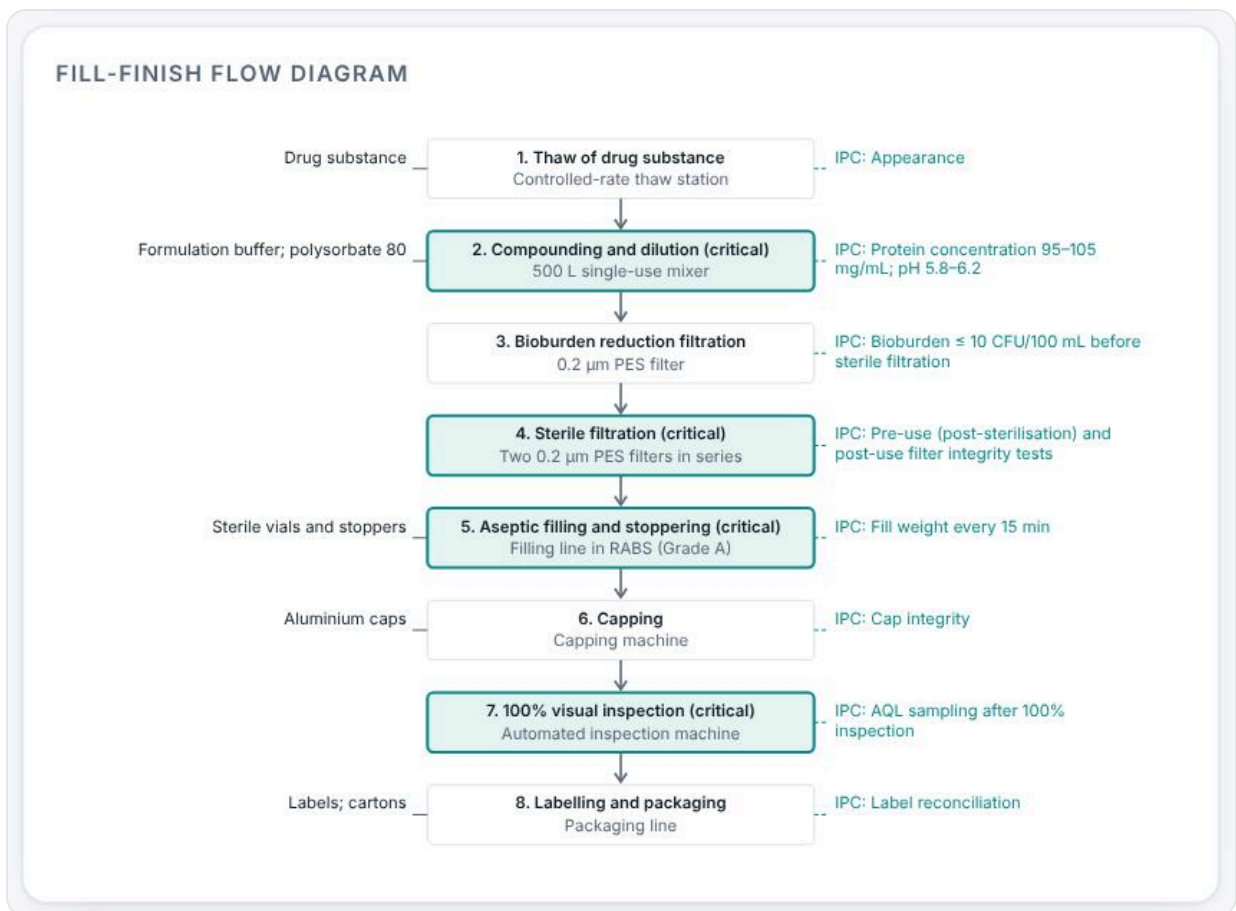
Enter labelled and target fill volume and tick **Viscous solution** if it applies. The note compares the overfill with the USP <1151> recommendation: 0.50 mL against 0.50 mL for a viscous 5 mL fill.

3 Enter composition and compatibility

Enter the composition per mL, pH and development summary, and the compatibility of diluted product with bags, sets and in-line filters.

4 Enter the fill-finish process

One row per step from thaw to inspection. The flow diagram is drawn from the table, and the facts show 8 steps, 4 critical, 3 media fill runs and 6.60 kg of protein per batch.



Fill-finish flow diagram.

5 Enter sterility assurance

Summarise filter validation, choose the PUPSIT status, and list media fills with units filled and contaminated. The example has no alerts.

6 Preview and download

Preview each section, read the review and download.

Columns: Run, Units filled, Contaminated units, Date

Preview and review before download Close

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

3.2.P.1 Description and composition of the drug product

CMB-201 Injection · US (FDA)

CMB-201 Injection is a sterile solution of 100 mg/mL presented as a vial (liquid) with a labelled volume of 5 mL (500 mg). Intravenous infusion after dilution in 0.9% sodium chloride. No reconstitution diluent is supplied.

Component	Quantity per mL	Function	Quality standard
CMB-201	100 mg	Active substance	In-house
L-Histidine	1.55 mg	Buffer	Ph. Eur. / USP
L-Histidine hydrochloride monohydrate	2.10 mg	Buffer	Ph. Eur. / USP
Sucrose	80 mg	Stabiliser (tonicity)	Ph. Eur. / USP-NF
Polysorbate 80	0.2 mg	Surfactant	Ph. Eur. / USP-NF
Water for injections	to 1 mL	Solvent	Ph. Eur. / USP

pH	6.0
Fill volume	5.5 mL (labelled 5 mL)

Draft prepared with CMCfy Biologics Drug Product on 2026-10-29. Guidance applied: ICH M4Q(R1) 3.2.P; ICH Q8(R2), Q6B; EU GMP Annex 1 (2022); FDA Sterile Drug Products Produced by Aseptic Processing (2004); USP <697>, USP <1151>, USP <1207>; 21 CFR Part 4; Regulation (EU) 2017/745 Article 117. 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 presentation

FIELD	WHAT TO ENTER
Product	Type it in.
Submission region	Choose one: US: FDA (NDA, ANDA, BLA, IND); EU: EMA and national agencies (MAA); Both US and EU.
Presentation	Choose one: Vial (liquid); Vial (lyophilised powder); Prefilled syringe; Autoinjector; Pen or cartridge.
Protein concentration (mg/mL)	Type a number.
Labelled volume (mL)	Type a number.
Target fill volume (mL)	Type a number.

FIELD	WHAT TO ENTER
Viscous solution (over about 10 cP)	Over about 10 cP; uses the larger USP <1151> overfill recommendation. Tick the box if it applies.
Route and administration	Type it in.
Reconstitution (lyophilised only) when it applies	Type it in.

2 · Composition and formulation development

FIELD	WHAT TO ENTER
Composition per mL	A table. Columns: Component Quantity per mL Function Quality standard. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
pH	Type it in.
Formulation development summary	Type or paste text.
Compatibility (diluent, infusion bags, sets, in-line filters)	A table. Columns: Material Conditions Result. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).

3 · Device (combination product) shown when it applies

FIELD	WHAT TO ENTER
Device description	Type it in.
Dose accuracy and functional testing (ISO 11608 / ISO 11040)	Type it in.
Human factors (usability) study	Type it in.
EU notified body opinion (Article 117) or US device constituent information (21 CFR Part 4)	Type it in.

4 · Fill-finish process

FIELD	WHAT TO ENTER
Batch size (units)	Type a number.
Steps	A table. Columns: Step Operation Materials added Equipment Critical (yes/no) Process parameters In-process controls. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
Maximum time from compounding to end of filling	Type it in.

5 · Sterility assurance

FIELD	WHAT TO ENTER
Sterilising filter validation	Type it in.
Pre-use post-sterilisation integrity test (PUPSIT)	Pre-use post-sterilisation integrity test of the sterilising filter. Choose one: Performed; Not performed; risk assessment justifies; Not performed.
Media fills	A table. Columns: Run Units filled Contaminated units Date. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
Depyrogenation and component sterilisation	Type it in.
Container closure integrity	Type it in.

5. Checks and alerts

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

- Every component has a function; a surfactant is present and polysorbate degradation is discussed; a formulation development summary is given.
- Fill volume not below the labelled volume (critical); overfill compared with USP <1151>.
- Compatibility data when the product is diluted; reconstitution described for lyophilised products.
- Combination products: device description, dose accuracy and functional testing, human factors (major in EU mode), syringe siliconisation.

- A sterile filtration step with a bioburden limit before it; a time limit from compounding to end of filling; 100% visual inspection; critical steps with parameters or controls.
- Filter validation summarised; PUPSIT performed or justified (major in EU mode under Annex 1); at least three media fill runs with no contaminated units (critical) and enough units; depyrogenation and container closure integrity addressed.

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: Pharmaceutical development; Description of the fill-finish process; Sterility assurance and process validation. 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
3.2.P.1	Description and composition of the drug product
3.2.P.2	Pharmaceutical development
3.2.P.3.2	Batch formula
3.2.P.3.3	Description of manufacturing process and process controls
3.2.P.3.4	Controls of critical steps and intermediates
3.2.P.3.5	Process validation and/or evaluation

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 mode cites the FDA aseptic processing guidance, 21 CFR Part 4 for combination products and USP <1151>, <790>, <1207>. EU mode cites EU GMP Annex 1 (2022), which expects PUPSIT or a documented risk assessment, Article 117 of the Medical Devices Regulation (notified body opinion) and Ph. Eur. methods.

8. Working with other modules

- The drug substance comes from the Biologics Process Writer.
- Shelf life and in-use stability go in the Biologics Stability Studio module.
- Container closure components and extractables are covered by the Container Closure & E&L.
- Cleanroom grades and shared equipment belong in the Facilities & Equipment Writer module.

9. Common pitfalls

- Target fill equal to the labelled volume: the patient cannot withdraw the full dose.
- No compatibility data for the infusion bags and in-line filters named on the label.
- Media fills with a contaminated unit left unexplained.

- Choosing "Not performed" for PUPSIT without a risk assessment in an EU filing.

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. Under-fill the vial

Change `Target fill volume (mL)` to 4.9.

EXPECTED RESULT

A critical alert says the fill volume is below the labelled volume.

2. Record a contaminated media fill unit

In the media fills table, change the contaminated units of MF-02 from 0 to 1.

EXPECTED RESULT

A critical alert says media fill MF-02 has a contaminated unit.

3. Skip PUPSIT in an EU filing

Set the region to EU and `Pre-use post-sterilisation integrity test (PUPSIT)` to "Not performed".

EXPECTED RESULT

A major alert says PUPSIT is not performed and not justified.

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.