

Media Fill (APS) Report

Write the aseptic process simulation report: units filled, incubated and contaminated in each run, the interventions simulated and the outcome against EU Annex 1 and the FDA aseptic processing guidance.

WRITES

GMP 3.2.P.3.5
3.2.A.1

PRODUCT TYPE

Small molecule and
biologics

GUIDANCE IT FOLLOWS

EU GMP Annex 1
(2022) 9.32–9.49;
FDA Sterile Drug
Products Produced
by Aseptic
Processing (2004)
IX; PIC/S PI 007-6;
ISO 13408-1; USP
<1116>; 21 CFR
211.113(b)

TIME TO LEARN

About 20 minutes
with the example

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

1. What this module does

You enter each run with the units filled, removed and incubated, contaminated units, duration and operators, and the interventions performed. The tool applies the criteria for the regions you choose.

EU: any contaminated unit fails the run. FDA: under 5,000 units no contaminated unit is allowed; above that, one unit means investigation and two mean revalidation. It also checks duration, interventions, incubation and growth promotion.

What you get

- A Word or PDF report: Aseptic process simulation report.

2. Before you start

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

- Run data: units filled, removed with justification, incubated and contaminated.
- Interventions required and performed in each run.
- Incubation conditions, growth promotion and EM results during the runs.

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/media-fill.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 line

Enter the line, the container and fill, the medium, and whether these runs are initial qualification or periodic requalification.

CMCfy Media Fill (APS) Report 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.

GMP 3.2.P.3.5 3.2.A.1 [Save project](#) [Open project](#) [Start blank](#) [Load example](#)

Write the aseptic process simulation (media fill) report. For each run the tool reconciles the units, applies the EU Annex 1 and FDA criteria to the contaminated units, checks the interventions simulated, the duration, incubation, growth promotion and personnel, and concludes whether the line is qualified.

Guidance: EU GMP Annex 1 (2022) 9.32-9.49; FDA Sterile Drug Products Produced by Aseptic Processing (2004) IX; PIC/S PI 007-6; ISO 13408-1; USP <1116>; 21 CFR 211.113(b)

1 - LINE AND DESIGN

Filling line and process

Vial filling line FL-2 (isolator), room 2.105; liquid fill of 10R via

Regulations: Both US and EU Report number: APS-R-2026-02

Type of runs: Periodic requalification Longest commercial batch duration (h): 36

Largest commercial batch (units): 60000

RESULT

2 runs · 20,615 units · no contaminated units

0 contaminated units in 20,615 incubated. The line remains qualified.

RUNS	UNITS INCUBATED	CONTAMINATED
2	20,615	0

LONGEST RUN: 38 h

RUNS

Reconciliation = filled - removed - incubated (should be 0).

2 Enter runs and interventions

One row per run. One row per intervention with the number required and the number performed in each run, separated by ";".

3 Read the result

The headline gives the outcome: "2 runs · 20,615 units · no contaminated units".

RUNS							
Reconciliation = filled – removed – incubated (should be 0).							
RUN	DATE	SHIFT	FILLED	REMOVED	INCUBATED	RECONCILIATION	CONTAMINATED
APS- 2026- 03	2026- 03-11	A	10450	120	10330	0	0
APS- 2026- 04	2026- 04-08	B	10380	95	10285	0	0

Runs and interventions.

4 Resolve alerts and download

A contaminated unit is critical. Runs shorter than the longest batch, interventions not performed, short incubation and too few runs for initial qualification are flagged. Then preview and download.

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.

1 recommended

MISSING INFORMATION (1)

"Identification of any contaminants and investigation" is empty.

Enter it in the tool, or confirm it does not apply. Empty inputs show as placeholders or gaps in the report.

recommended · Runs Ignore

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 shown.

Aseptic process simulation report

Vial filling line FL-2 (isolator), room 2.105; liquid fill of 10R vials · APS-R-2026-02 · US (FDA) and EU (EMA)

Line	Vial filling line FL-2 (isolator), room 2.105; liquid fill of 10R vials
Report number	APS-R-2026-02
Type	Periodic requalification
Medium	Tryptic soy broth, growth promotion passed (≤ 100 cfu; compendial organisms plus EM isolates)
Incubation	7 days at 20–25 °C then 7 days at 30–35 °C
Regulations	US (FDA) and EU (EMA)

1. Objective

To show that the aseptic process on Vial filling line FL-2 (isolator), room 2.105; liquid fill of 10R vials can be performed without microbial contamination, by simulating it with a growth medium under worst-case conditions.

2. Runs

Run	Date	Shift	Filled	Removed	Incubated	Contaminated	Duration (h)
APS-2026-03	2026-03-11	A	10450	120	10330	0	38
APS-2026-04	2026-04-08	B	10380	95	10285	0	37

3. Interventions

Intervention	Type	Required per run	Performed
Stopper bowl replenishment	inherent	6	6; 6
Weight check sampling	inherent	20	22; 21
Removal of fallen vials	corrective	2	3; 2

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Download PDF

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 · Line and design

FIELD	WHAT TO ENTER
Filling line and process	Type it in.
Regulations	Choose one: US: FDA aseptic guidance (2004); EU: EU GMP Annex 1 (2022); Both US and EU.
Report number	Type it in.
Type of runs	Choose one: Initial qualification (three consecutive runs); Periodic requalification.
Longest commercial batch duration (h)	Type a number.

FIELD	WHAT TO ENTER
Largest commercial batch (units)	Type a number.
Medium and growth promotion	Type it in.
Incubation	Type it in.

2 · Runs

One row per run. Units removed must be justified (for example non-integral units) in the protocol.

FIELD	WHAT TO ENTER
Runs	A table. Columns: Run Date Shift Units filled Units removed (justified) Units incubated Contaminated units Duration (h) Operators. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
Interventions	List the count for each run in the same order as the runs table. A table. Columns: Intervention Type (inherent/corrective) Required per run Performed in each run (";"). Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
Identification of any contaminants and investigation	Type or paste text.

3 · Personnel and environment

FIELD	WHAT TO ENTER
All operators authorised for aseptic work took part in an APS in the last 12 months	Tick the box if it applies.
Environmental and personnel monitoring during the runs	Type or paste text.

FIELD	WHAT TO ENTER
Inspection of incubated units by trained staff, with defect and positive controls	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:

- Contaminated units against EU and FDA criteria.
- Run duration against the longest commercial batch; interventions at routine frequency.
- Incubation, growth promotion, inspection and operator participation.

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: Results and 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
Report	Aseptic process simulation 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

EU follows EU GMP Annex 1 (2022) 9.32–9.49: the target is zero and any contaminated unit fails. US follows the FDA aseptic processing guidance (2004) section IX.

8. Working with other modules

- Environmental monitoring during the runs is trended in the Environmental Monitoring Trend Report report.

9. Common pitfalls

- Simulating fewer interventions than happen in routine production.
- Runs shorter than the longest commercial batch.

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. **Find a contaminated unit**

Change the contaminated units in run APS-2026-03 from 0 to 1.

EXPECTED RESULT

The headline shows one run failed.

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.