

Environmental Monitoring Trend Report

Write the periodic environmental monitoring trend report: results by grade and sample type against Annex 1 action limits and your alert levels, recovery rates, organisms and adverse trends.

WRITES

GMP 3.2.A.1

PRODUCT TYPE

Small molecule and biologics

GUIDANCE IT FOLLOWS

EU GMP Annex 1 (2022) 9.4–9.31 and Table 6; FDA Sterile Drug Products Produced by Aseptic Processing (2004) X and Table 1; USP <1116>; PIC/S PI 007-6; ISO 14644-1/-2; 21 CFR 211.42(c)(10)(iv), 211.113

TIME TO LEARN

About 20 minutes with the example

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

1. What this module does

You enter each result with the date, room, grade, sample type, location, count and organism. The tool applies the Annex 1 action limits for each grade and sample type and your alert level.

It calculates recovery rates by grade, finds repeat recoveries at a location and flags spore-formers and objectionable organisms in grade A and B.

What you get

- A Word or PDF report: Environmental monitoring trend report.

2. Before you start

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

- All EM results for the period, with organisms identified.
- Alert levels and the rule for an adverse trend.
- Investigations and the cleaning and disinfection review.

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/environmental-monitoring.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 area

Enter the area, the period and choose the regulations. Set the alert level and the number of repeat recoveries that make a trend.

The screenshot shows the 'Environmental Monitoring Trend Report' interface. At the top, there's a navigation bar with 'Projects', 'All modules', 'Training', and 'Security'. Below it, a status bar indicates 'Runs entirely on this device' and 'Training guide'. The main content area is divided into sections. The 'PROJECTS' section has a note about version history and buttons for 'Choose projects folder' and 'Keep in this browser'. Below that, three status indicators are shown: 'Network requests since load: 0', 'Works offline', and 'Locked offline copy'. The 'GMP' section shows '3.2.A.1' and buttons for 'Save project', 'Open project', 'Start blank', and 'Load example'. The '1 - PERIOD AND AREA' section contains input fields for 'Facility and area' (Sterile filling suite, building 2 (filling line FL-2 isolator, grade), 'Regulations' (Both US and EU), 'Report number' (EM-TR-2026-Q3), 'Period' (2026-07-01 to 2026-09-30), and 'Alert level as % of the action limit (grades B-D)' (50). A 'RESULT' section shows 'No action-level excursions · 8 recoveries' and a summary of results entered (12), recoveries (8), and alerts (1). A 'RECOVERY RATE BY GRADE' section is also visible.

2 Enter results

One row per sample. Sample types are settle, active air, contact and glove.

3 Read the result

The headline gives the excursions: "No action-level excursions · 8 recoveries".

RECOVERY RATE BY GRADE				
GRADE	SAMPLES	WITH GROWTH	RECOVERY RATE	GRADE A EXPECTATION
A	624	0	0.00%	any growth investigated
B	410	4	0.98%	
C	180	3	1.67%	
D	96	1	1.04%	

Results by grade.

4 Resolve alerts and download

An action-level result is critical, and any growth in grade A is an action. Alert-level results, repeat locations and missing investigations 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)
 "Investigations and CAPA for excursions" is empty.
 Enter it in the tool, or confirm it does not apply. Empty inputs show as placeholders or gaps in the report.

recommended · Actions 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 changed.

Environmental monitoring trend report
 Sterile filling suite, building 2 (filling line FL-2 isolator, grade B background) · EM-TR-2026-Q3 · US (FDA) and EU (EMA)

Area	Sterile filling suite, building 2 (filling line FL-2 isolator, grade B background)
Report number	EM-TR-2026-Q3
Period	2026-07-01 to 2026-09-30
Alert level	50% of the action limit (grades B-D); grade A any growth
Regulations	US (FDA) and EU (EMA)

1. Recovery rates

Grade	Samples	With growth	Recovery rate
A	624	0	0.00%
B	410	4	0.98%
C	180	3	1.67%
D	96	1	1.04%

2. By month

Month	Recoveries	Alert	Action
2026-07	2	0	0
2026-08	3	0	0
2026-09	3	1	0

3. Recoveries

Download Word (.docx)

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 - Period and area

FIELD	WHAT TO ENTER
Facility and area	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.
Period	Type it in.
Alert level as % of the action limit (grades B–D)	Type a number.
Repeat recoveries at one location that make an adverse trend	Type a number.

2 - Results

One row per sample with growth or a summary row per location and month. Grade A, B, C or D. Sample type: air, settle, contact or glove. Count in cfu. Organism if identified.

FIELD	WHAT TO ENTER
Results	Leave the organism empty when the count is 0. A table. Columns: Date Room Grade Sample type Location Count (cfu) Organism. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
Samples taken in the period by grade (A;B;C;D)	Type it in.

3 · Actions

FIELD	WHAT TO ENTER
Investigations and CAPA for excursions	Type or paste text.
Cleaning and disinfection effectiveness	Type or paste text.

5. Checks and alerts

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

- Each result against the action limit and alert level for its grade.
- Recovery rates, repeat recoveries and organisms.
- Investigations and disinfection effectiveness.

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: Trend discussion 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	Environmental monitoring trend 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) Tables 6 and 7. US follows the FDA aseptic processing guidance (2004) section X and USP <1116>.

8. Working with other modules

- EM during media fills is reported in Media Fill (APS) Report; excursions are investigated in Investigation Studio (OOS, deviation, CAPA).

9. Common pitfalls

- Treating 1 cfu in grade A as within limits.
- Looking only at individual results, not trends.

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. **Add a grade A recovery**

Change the last filling-needle settle plate from 0 to 1 cfu with *Micrococcus luteus*.

EXPECTED RESULT

The headline shows one action-level excursion.

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.