

Facilities & Equipment Writer

Describe the facility for 3.2.A.1: room classifications and pressure cascade, flows, shared and dedicated equipment, and cleaning validation with limits calculated from the PDE of each product on shared equipment.

WRITES

3.2.A.1

PRODUCT TYPE

Small molecule and
biologics

**GUIDANCE IT
FOLLOWS**

ICH M4Q(R1)
3.2.A.1; EU GMP
Annex 1 (2022),
Chapter 3 and
Chapter 5; FDA
Sterile Drug
Products Produced
by Aseptic
Processing (2004);
21 CFR 211.42,
211.67;
EMA/CHMP/CVMP/SWP
(health-based
exposure limits)

TIME TO LEARN

About 20 minutes
with the example

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

1. What this module does

Biotechnology products, and sterile products in many cases, need a facilities and equipment appendix (3.2.A.1). This module writes it from your room list, equipment list and cleaning validation data.

It calculates the maximum allowable carryover (MACO) for every pair of products that share equipment, from the PDE of the previous product, the minimum batch size of the next one and its maximum daily intake, and converts the worst case to a swab limit from the shared surface area and swab area.

What you get

- A Word or PDF file for 3.2.A.1 Facilities and equipment.

- 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.

- Site and building, type of operation, and whether the facility is multi-product.
- Descriptions of flows (people, materials, product, waste), HVAC and environmental monitoring, and the contamination control strategy reference.
- Rooms with activity, grade or ISO class, pressure difference and air changes.
- Major equipment, dedicated or shared, and the cleaning method; the shared product-contact surface area and swab area.
- Every product made on the shared equipment with PDE, minimum batch size and maximum daily intake; the cleaning validation summary and hold times.

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/facilities-equipment.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 facility

Enter the site, choose the [Type of operation](#) (aseptic, terminally sterilised, biologic drug substance, or non-sterile) and tick [Multi-product facility](#) if it applies. Describe flows, HVAC and the contamination control strategy.

CMCfy

Facilities & Equipment

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.A.1

Save project

Open project

Start blank

Load example

Describe the facility for 3.2.A.1: room classifications and pressure cascade, flows, shared and dedicated equipment, and cleaning validation. Cleaning limits are calculated from the permitted daily exposure (PDE) of each product made on shared equipment.

Guidance: ICH M4Q(R1) 3.2.A.1; EU GMP Annex 1 (2022), Chapter 3 and Chapter 5; FDA Sterile Drug Products Produced by Aseptic Processing (2004); 21 CFR 211.42, 211.67; EMA/CHMP/CVMP/SWP/169430/2012 (health-based exposure limits)

1 · FACILITY

Product this filling is for

CMB-201 Injection (monoclonal antibody), aseptically filled

Submission region

US: FDA (NDA, ANDA, BL)

Site and building

BioCMX Manufacturing Inc., Building 2, 400 Bioreactor Drive

Type of operation

Aseptic processing (sterile)

☒ Multi-product facility

RESULT

Worst-case swab limit 43.2 µg per swab

Worst case: residue of CMB-305 Injection carried into CMB-201 Injection, MACO 320.0 mg over 185000 cm².

ROOMS

6

SHARED EQUIPMENT

5

PRODUCTS SHARING

3

OPERATION

Aseptic

ROOMS

ROOM	ACTIVITY	GRADE	ΔP (PA)	ACH
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2 List rooms and equipment

Enter each room with its grade and pressure difference. For aseptic processing, the filling room must be Grade A with a Grade B background, and pressure differences should be at least 10 Pa.

ROOMS				
ROOM	ACTIVITY	GRADE	ΔP (PA)	ACH
2.10	Buffer and solution preparation	Grade C (ISO 8 in operation)	15	30
2.11	Compounding before sterile filtration	Grade C (ISO 8 in operation)	15	30
2.12	Aseptic filling line (RABS)	Grade A (ISO 5 in operation)	15	–
2.13	Background to filling	Grade B (ISO 7 in operation)	15	50
2.14	Capping	Grade A (ISO 5 in operation)	12	30
2.15	Visual inspection and labelling	Grade D (ISO 8 at rest)	10	20

Rooms with grades and pressure cascade.

3 Enter cleaning validation data

List every product on the shared equipment, including this one, with PDE, minimum batch size and maximum daily intake. Enter the shared surface area and swab area.

4 Read the cleaning limits

The headline gives the worst-case swab limit: 43.2 µg per swab, for residue of CMB-305 Injection carried into CMB-201 Injection (MACO 320.0 mg over 185,000 cm²).

RESULT

Worst-case swab limit 43.2 µg per swab

Worst case: residue of CMB-305 Injection carried into CMB-201 Injection, MACO 320.0 mg over 185000 cm².

ROOMS
6

SHARED EQUIPMENT
5

PRODUCTS SHARING
3

OPERATION
Aseptic

5 Preview and download

The example has no alerts. Preview 3.2.A.1, read the review 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.

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.A.1 Facilities and equipment

CMB-201 Injection (monoclonal antibody), aseptically filled · US (FDA)

CMB-201 Injection (monoclonal antibody), aseptically filled is manufactured at BioCMX Manufacturing Inc., Building 2, 400 Bioreactor Drive, Durham, NC 27709, USA. The facility is multi-product.

Room classification. Room 2.10 (buffer and solution preparation) is Grade C (ISO 8 in operation), at 15 Pa above the adjacent lower grade. Room 2.11 (compounding before sterile filtration) is Grade C (ISO 8 in operation), at 15 Pa above the adjacent lower grade. Room 2.12 (aseptic filling line (RABS)) is Grade A (ISO 5 in operation), at 15 Pa above the adjacent lower grade. Room 2.13 (background to filling) is Grade B (ISO 7 in operation), at 15 Pa above the adjacent lower grade. Room 2.14 (capping) is Grade A (ISO 5 in operation), at 12 Pa above the adjacent lower grade. Room 2.15 (visual inspection and labelling) is Grade D (ISO 8 at rest), at 10 Pa above the adjacent lower grade.

Flows. Unidirectional flows. Personnel enter Grade B through a Grade D and C airlock sequence; materials enter through pass-through hatches with decontamination; waste leaves through a separate corridor.

HVAC and monitoring. Dedicated AHUs per grade with terminal HEPA filters; continuous particle monitoring in Grade A; viable monitoring by settle plates, contact plates and active air per the contamination control strategy.

Equipment. Formulation vessel 500 L (shared; CIP); Sterilising-grade filter housing (shared; single-use filters; housing CIP); Filling machine with RABS (shared; manual clean and VHP of RABS); Freeze-dryer (shared; CIP and SIP); Capping machine (shared; manual).

Cleaning. Cleaning limits are based on health-based exposure limits. The worst case is CMB-305 Injection followed by CMB-201 Injection: MACO 320.0 mg, or 43.24 µg per 25 cm² swab over 185000 cm² of shared surface. Three consecutive runs per product changeover with worst-case soil and hold times; TOC swab and rinse sampling, visually clean criterion, bioburden and endotoxin limits; protein degradation by low pH and heat during CIP confirmed by SDS-PAGE.

Room classification

Room	Activity	Grade	Pressure difference (Pa)	Air changes/h
2.10	Buffer and solution preparation	Grade C (ISO 8 in operation)	15	30
2.11	Compounding before sterile filtration	Grade C (ISO 8 in operation)	15	30

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 · Facility

FIELD	WHAT TO ENTER
Product this filing is for	Type it in.
Submission region	Choose one: US: FDA (NDA, ANDA, BLA, IND); EU: EMA and national agencies (MAA); Both US and EU.
Site and building	Type it in.
Type of operation	Choose one: Aseptic processing (sterile); Terminally sterilised; Biologic drug substance (cell culture and purification); Non-sterile (oral, topical).
Multi-product facility	Tick the box if it applies.
Flows of people, materials, product and waste	Type it in.
HVAC and environmental monitoring	Type it in.
Contamination control strategy reference	Type it in.

2 · Rooms and classifications

FIELD	WHAT TO ENTER
Rooms	A table. Columns: Room Activity Grade or ISO class Pressure difference to adjacent lower grade (Pa) Air changes per hour. Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).

3 · Equipment

FIELD	WHAT TO ENTER
Major equipment	A table. Columns: Equipment Dedicated or shared Product contact Cleaning (CIP, manual, single-use). Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
Shared product-contact surface area of the train (cm ²)	Total product-contact surface area of the shared equipment train. Type a number.
Swab area (cm ²)	Area sampled by one swab, usually 25 or 100 cm ² . Type a number.

4 · Cleaning validation

List every product made on the shared equipment, including this one. PDE values come from the toxicology assessment.

FIELD	WHAT TO ENTER
Products on shared equipment	PDE from the toxicology assessment; maximum daily intake of the next product in mg/day. A table. Columns: Product PDE (mg/day) Minimum batch size (kg) Maximum daily intake of the product (mg/day). Paste rows from Excel, type comma-separated rows, or press Load file (Excel, CSV, Word, PDF or a scan).
Cleaning validation summary	Type it in.
Dirty hold time validated	Type it in.
Clean hold time validated	Type it in.

5. Checks and alerts

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

- Flows, HVAC and environmental monitoring described; a contamination control strategy referenced (major in EU mode, per EU GMP Annex 1).
- Rooms listed with recognised grades; for aseptic processing a Grade A filling room with a Grade B background and a compounding room; pressure differences of at least 10 Pa.
- Equipment listed with cleaning methods.

- Cleaning validation: more than one product listed when equipment is shared, PDE for each, surface area given, a summary present, visually clean as a criterion, microbial and endotoxin limits, dirty and clean hold times.
- Segregation: beta-lactams in a shared facility are critical; highly potent products on shared equipment, and segregation before and after viral clearance for biologics, are flagged.

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: Facility description. 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.A.1	Facilities and equipment

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 21 CFR 211 subparts C and D and the FDA aseptic processing guidance (2004), and ISO 14644 classes. EU mode cites EU GMP Annex 1 (2022) grades A to D, requires a contamination control strategy, and the EMA guideline on setting health-based exposure limits (PDE) for shared facilities.

8. Working with other modules

- Process steps and equipment should match the Process & Controls Writer, Biologics Process Writer or Biologics Drug Product Writer.
- Viral safety segregation links to the Viral Safety Studio module.

9. Common pitfalls

- Listing only this product in the cleaning table when equipment is shared. The MACO needs every product that can follow another.
- Using ISO class and grade inconsistently. Write "Grade A" or "ISO 5" as your site documents do.
- Forgetting to update the swab limit when the swab area changes.
- No hold times: reviewers ask how long equipment may stay dirty or clean before use.

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. Change the swab area

Change **Swab area (cm²)** from 25 to 100.

EXPECTED RESULT

The headline reads "Worst-case swab limit 173.0 µg per swab".

2. Remove the dirty hold time

Clear **Dirty hold time validated**.

EXPECTED RESULT

A minor alert says the dirty hold time is not validated.

3. Downgrade the filling room

In the rooms table, change the aseptic filling line from Grade A to Grade B.

EXPECTED RESULT

A critical alert says no aseptic filling room is in Grade A.

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.