CORVANE
BIOLOGICS

GMP TRAINING · MODULE AT-04 · REVISION 6

Aseptic gowning and behaviour in Grade A and B areas

Filling lines FL-3 and FL-5 · Industriezone Rottenmatte, Visp

Based on EU GMP Annex 1 (2022) and SOP-QA-0112



90 minutes

10 quiz questions

Pass mark 80%

Valid from 1 November 2026

Corvane Biologics AG · Quality Academy

Learning objectives and contents

After this module you can

- explain why people are the main contamination risk
- name the grades A to D and their limits
- gown for Grade B in the validated sequence
- protect first air and classify interventions
- perform a corrective intervention step by step

Contents

1 Why aseptic behaviour matters

2 Clean-room grades and airflow

3 Gowning for Grade B

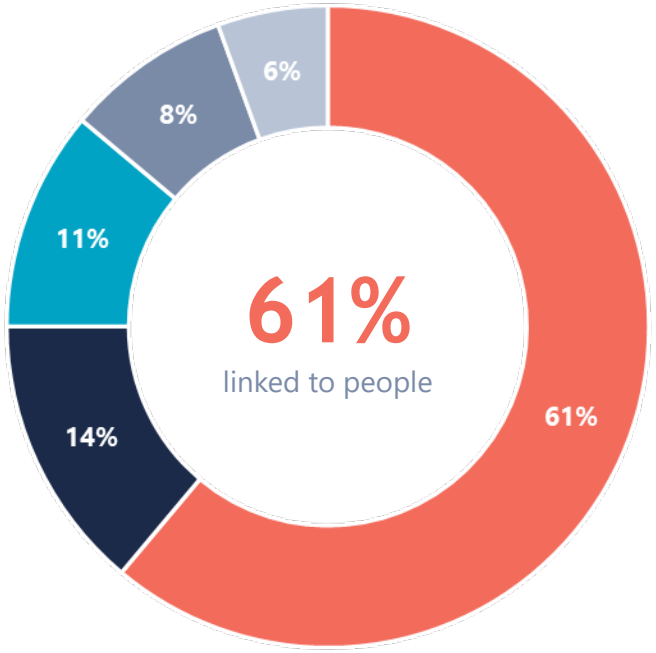
4 Behaviour and interventions

5 Quiz and key rules

6 Glossary and certificate

Why it matters: people are the main risk

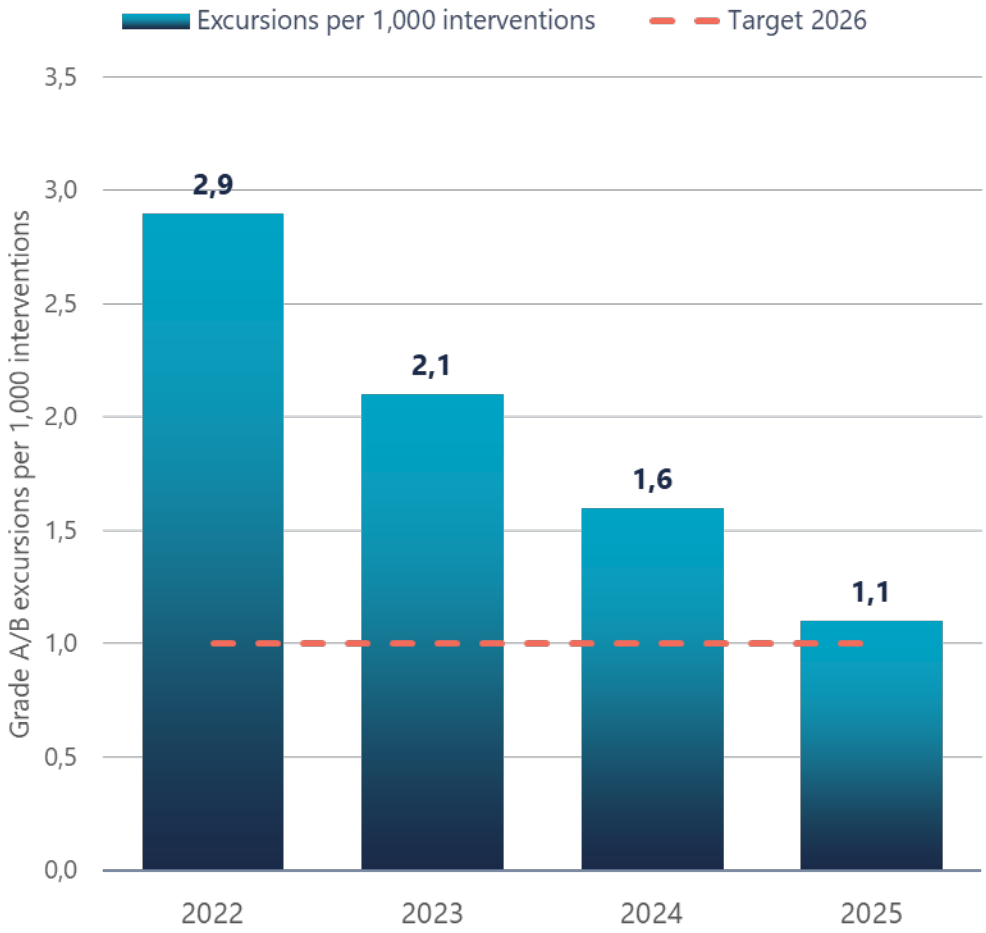
Viable environmental monitoring excursions in Grade A and B, FL-3 and FL-5, 2025 (n = 36)



- Personnel: gowning and behaviour **22**
- Materials and transfers **5**
- Equipment **4**
- HVAC and environment **3**
- Undetermined **2**

One contaminated unit

in an aseptic process simulation (media fill) fails the run and stops the line until the investigation is closed.



Source: Corvane EM database, trend report QA-TR-2025-12. Interventions counted from electronic batch records.

1

Clean-room grades and airflow

What the grades mean, how unidirectional airflow protects the product, and why the pressure cascade matters.

Grades A to D: limits and typical activities

Grade	Particles per m³, ≥ 0.5 µm / ≥ 5.0 µm		Viable limits (CFU)			Typical activities at Corvane
	At rest	In operation	Air, per m³	Settle plate, 4 h	Contact plate	
A	3,520 / n.s.	3,520 / n.s.	**No growth**	**No growth**	**No growth**	Open vials and stoppers inside the FL-3 and FL-5 isolators; aseptic connections
B	3,520 / n.s.	352,000 / 2,930	**10**	**5**	**5**	Background of the FL-3 RABS; airlocks to Grade A; transfer of sterilised parts
C	352,000 / 2,930	3,520,000 / 29,300	**100**	**50**	**25**	Compounding and filtration of bulk drug substance; gowning rooms
D	3,520,000 / 29,300	Not predetermined	**200**	**100**	**50**	Component washing, autoclave loading, first change rooms

Reading the table

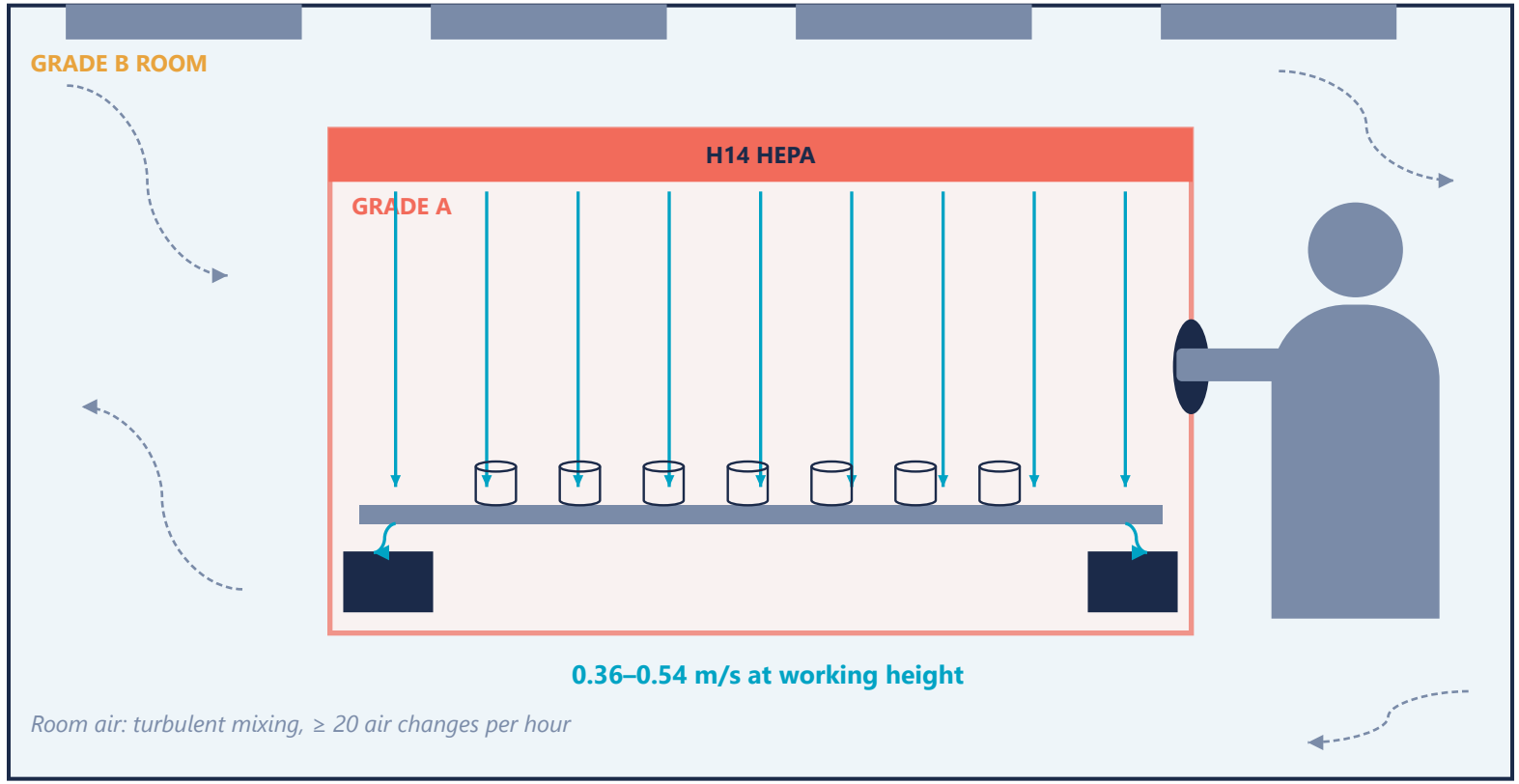
n.s. = not specified. The ≥ 5.0 µm count in Grade A is still monitored continuously: any trend is an early warning of a gowning or equipment problem.

Grade A means zero

Any growth in Grade A is an excursion and triggers an investigation, whatever the count. Gloves are tested at the end of every session.

Limits per SOP-QA-0112 Rev. 9, aligned with EU GMP Annex 1 (2022), tables 1 and 6.

Unidirectional airflow and the pressure cascade



Pressure cascade relative to the corridor (Pa)

Corridor **0** → Grade D **+15** → Grade C **+30** → Grade B **+45** → Isolator A **+60**

What this means for you

First air
Air leaving the HEPA filter is sterile until it touches something. Keep it that way.

Hands outside
Never place a gloved hand or tool between the filter and an open vial.

Slow movements
Fast arm movements create eddies that lift particles into the flow.

Doors closed
An open door collapses the cascade within seconds.

2

Gowning for Grade B

The validated ten-step sequence, glove integrity, and what to do and not to do once you are gowned.

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The ten-step gowning sequence

1 · Grade D



Wash and prepare

No jewellery, make-up or watches; wash hands 60 s

2 · Grade D



Undergarments

Dedicated clean-room underwear and socks

3 · Grade C



Cross the bench

Step over; first overshoes on the clean side

4 · Grade C



First gloves

Sanitise hands, put on sterile inner gloves

5 · Grade C



Hood

All hair and neck covered, no gaps

6 · Grade C



Mask and goggles

No skin visible between hood and mask

7 · Grade C



Coverall

Don without touching the floor or walls

8 · Grade B



Boots

Over the coverall legs, crossing the second bench

9 · Grade B



Second gloves

Over the coverall cuffs; check for damage

10 · Grade B



Mirror check

Full-length check, sanitise gloves, enter

Sequence per SOP-PR-0457 Rev. 12. Zone colours: grey Grade D change room, cyan Grade C gowning room, amber Grade B airlock.

Glove integrity: your last barrier

- Sanitise gloves after every intervention and at least every 30 minutes
- Let the sanitiser dry: 30 seconds, no wiping
- Check for punctures and stretched cuffs before each intervention
- Isolator gloves: leak test before every batch and after every glove change
  - Pressure-decay test at 500 Pa for 10 minutes
  - Visual check of the cuff ring and clamping band
- Report any damage at once; never tape a glove



0.3% of isolator gloves failed the pressure-decay test in 2025, all detected before use.

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Once gowned: do and don’t

Do ✓

- Move slowly and deliberately in Grade A and B
- Keep hands above the waist and in view
- Sanitise gloves after every intervention
- Use sterile tools for every contact with Grade A
- Report gown damage immediately and leave to re-gown
- Stay out of the path of first air

Don’t ×

- Lean or reach over open vials or stoppers
- Touch your mask, goggles or hood
- Talk unnecessarily in Grade A and B
- Walk fast, run or make sudden movements
- Crouch, sit or kneel on the floor
- Re-use a garment that touched the floor

How you are assessed

Observed gowning
Three successful observed gownings before the first unsupervised entry

Glove and gown plates
Contact plates on gloves, sleeves and chest within Grade B limits

Every 12 months
Requalification with participation in at least one media fill

3

Behaviour and interventions

First air, inherent and corrective interventions, and how to perform them without risk to the product.

Protect first air



1 **Know where the air comes from**
In the isolators it comes from the ceiling filter; follow it down to the product.

2 **Work from the side**
Reach in from the side of the open container, never from above it.

3 **One hand, sterile tool**
Use forceps for anything near an open vial or stopper.

4 **Pause and check**
Before moving, look up: is anything between the filter and the product?

Inherent and corrective interventions

Type		Examples on FL-3 and FL-5	Rules
Inherent	**Routine**	Stopper bowl top-up every 45 min; settle plate change at 4 h; weight check every 15 min	Part of the batch record; simulated in every media fill; no approval needed
Inherent	**Set-up**	Aseptic assembly of filling needles and tubing; loading the first RTU tub	
Corrective	**Process recovery**	Removing a fallen or broken vial; clearing a stopper jam in the feeder track	Line stop; supervisor approval in the eBR; only interventions on the validated list; maximum number per batch; containers in the zone rejected
Corrective	**Equipment**	Replacing a broken needle; adjusting a guide rail; resetting a star-wheel sensor	



Why the difference matters

Inherent interventions are expected and designed into the process. Corrective interventions are not: each one is a risk to sterility and must be justified, approved and recorded.

6.2

inherent interventions per batch, 2025 average

0.8

corrective interventions per batch, 2025 average

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Performing a corrective intervention

Five steps, every time, whatever the pressure on the batch

1 Stop and assess

Line stop; note the time and the position of the fallen item.

2 Request approval

Supervisor approval in the eBR before any hand enters the glove port.

3 Perform with sterile tools

Forceps only, slow moves, hands kept out of first air.

4 Sanitise and reset

Gloves sanitised; containers in the zone are rejected.

5 Record in the eBR

Type, duration, glove port and operator, signed off by QA.

Time limits

Approval within 10 min; intervention completed within 15 min of the line stop, otherwise the zone is cleared.

Who approves

Line supervisor in the eBR; QA on the floor for any intervention not on the validated list.

What is recorded

Type, start and end time, operator, glove port, containers rejected, sanitisation done.

Know your line: FL-5 isolator at a glance



1 H14 HEPA filters and air plenum
2 Glove ports, leak-tested before each batch
3 HMI: batch status and intervention log
4 Window: watch first air before you reach in
5 Rapid transfer port for sterile parts
6 Technical area: return air ducts

Quiz 1: a vial falls over

A vial tips over inside the FL-5 isolator, right next to the filling needles. What is the correct response?

A Reach in quickly through the nearest glove port and set the vial upright before it causes a jam

B Stop the line, request a corrective intervention, remove the vial with sterile forceps and record it

C Leave it: the vial will be rejected automatically at visual inspection

D Open the isolator door briefly to remove the vial; the airflow will protect the product

Select an answer card to see the trainer key.

Quiz 2: true or false?



1. Gloves need sanitising only after a corrective intervention.

True | False

2. A stopper jam in the feeder track is a corrective intervention.

True | False

3. Settle plates may be moved during an intervention if they are in the way.

True | False

4. After a gown tear you leave Grade B and re-gown completely.

True | False

Three key rules in our seven site languages

English

- Move slowly and deliberately
- Never block or break first air
- Sanitise gloves after every intervention

FR Français

- Se déplacer lentement et calmement
- Ne jamais couper le premier air
- Désinfecter les gants après chaque intervention

Deutsch

- Langsam und überlegt bewegen
- Die Erstluft nie unterbrechen
- Handschuhe nach jedem Eingriff desinfizieren

IT Italiano

- Muoversi lentamente e con calma
- Non interrompere mai l'aria primaria
- Disinfettare i guanti dopo ogni intervento

Português

- Mover-se devagar e com calma
- Nunca interromper o ar primário
- Higienizar as luvas após cada intervenção

العربية AR

- تحرّك ببطء وبهدوء
- لا تقطع أبدًا تدفّق الهواء الأول
- عقّم القفازات بعد كل تدخّل

中文

- 缓慢、平稳地移动
- 切勿阻断第一空气
- 每次干预后对手套进行消毒



Glossary

Airlock Room with interlocked doors between two grades, used to transfer people or materials.

APS Aseptic process simulation (media fill): the process run with growth medium instead of product.

At rest Clean-room state with installation complete and equipment running, but no people present.

CCS Contamination control strategy: the site-wide plan describing all controls and their links.

CFU Colony-forming unit: a viable microorganism counted on a plate after incubation.

Corrective intervention Unplanned intervention to correct or adjust the process; requires approval.

eBR Electronic batch record; every intervention is recorded here.

First air Filtered air that has not touched any surface before reaching the product.

HEPA filter High-efficiency particulate air filter; H14 retains at least 99.995% of the most penetrating particles.

Inherent intervention Planned intervention that is an integral part of the process, such as set-up or sampling.

In operation Clean-room state with the process running and the usual number of people present.

Isolator Sealed enclosure with a decontaminated interior, operated through glove ports.

RABS Restricted access barrier system: rigid walls and glove ports in a Grade B background.

RTP Rapid transfer port: double-door system for transfers without breaking the barrier.

RTU Ready-to-use: pre-sterilised containers delivered in sealed tubs.

Settle plate Agar plate exposed for up to four hours to collect particles falling from the air.

Unidirectional airflow Air moving in one direction at uniform speed across the critical zone.

VHP Vaporised hydrogen peroxide, used for biodecontamination of isolators and transfer hatches.

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Certificate of completion

This certifies that

_____

Name and personnel number

has successfully completed the GMP training module

AT-04 · Aseptic gowning and behaviour in Grade A and B areas · Revision 6

Date: _____



Score: ____ / 10

_____

Lea Zurbriggen
Trainer, Sterility Assurance

_____

Dr Pascal Imesch
Head of Quality Assurance, Visp

Requalification due 12 months after the date above · record in the learning management system, course code QA-AT04-R6