Cleanroom Entry and Gowning Log

Sterile Manufacturing Campus – Building 4

Document ID
QA-LOG-CR-014

ISO CLASS 7
Cleanroom Suite B4 – at rest

ISO CLASS 8
Gowning Anteroom – at rest

Classification is maintained and monitored in accordance with [2] and is demonstrated equivalent to EU GMP Annex 1 Grade C for the cleanroom suite and Grade D for the gowning anteroom [1]. This log records every personnel entry/exit event, gowning-step completion, and viable/non-viable particle count taken during the shift covered below. Completion of this log is mandatory for all personnel prior to entry into Suite B4 regardless of duration of stay.

Facility Meridian Therapeutics – Sterile Manufacturing Campus	**Suite** B4 – Fill/Finish Support Suite
Classification Standard ISO 14644-1:2015, EU GMP Annex 1 (2022)	**Area Served** Vial fill line staging, component airlock
Log Period 22-Jul-2026, Day Shift 06:00 – 18:00	**Monitoring Frequency** Continuous (particles); per-event (entry/exit)
Gowning Room Monitor Priya Raman, EHS-114	**QA Reviewer** David Okafor, QA-208

Gowning Procedure

Gowning proceeds in two stages, separated by a physical interlock door. Each step must be initialled by the wearer and countersigned by the Gowning Room Monitor before advancing to the next stage. No step may be skipped or reordered.

Stage 1 – Change Room (Black/White)

- ☐ 1. Remove street shoes, jewellery, and personal outerwear at the black-line boundary.
- ☐ 2. Don hair cover and beard cover (if applicable); no hair may be exposed.
- ☐ 3. Perform a 30-second alcohol hand disinfection per SOP-EHS-021.
- ☐ 4. Don dedicated cleanroom undergarment (bunny suit base layer).
- ☐ 5. Don first pair of nitrile gloves; tuck cuffs under sleeve.
- ☐ 6. Don general-area cleanroom shoes; cross the white-line boundary.

Stage 2 – Gowning Room (White/White)

- ☐ 1. Don sterile coverall, closing all closures without touching the exterior surface.
- ☐ 2. Don sterile boot covers over coverall leg cuffs; overlap sealed with tape.
- ☐ 3. Don sterile hood, fully enclosing hair cover with no skin exposed at the collar.
- ☐ 4. Don safety goggles or full face shield per line assignment.
- ☐ 5. Perform second alcohol hand disinfection; don sterile outer gloves over cuffs.
- ☐ 6. Visual cross-check by Gowning Room Monitor; record result on entry log.

Materials Required Per Gowning Event

Sterile coverall (size-matched, lot-traceable), boot covers (2 pr.), sterile hood, nitrile gloves (2 pr.), sterile outer gloves, safety goggles or face shield, 70% IPA hand disinfectant, lint-free wipes. All sterile garments are single-use and discarded at exit; reusable goggles are wiped with disinfectant between uses per SOP-EHS-021.

Personnel Entry / Exit Log

Record every entry and exit to Suite B4 for the shift below. Time Out must be completed before the wearer's badge is reactivated for a subsequent entry.

Name	Role	Badge	Time In	Time Out	Gown Lot	Init.
Marcus Webb	Cleanroom Operator	B-4471	06:04	10:12	GK-2607A	MW
Aiko Tanaka	Cleanroom Operator	B-4488	06:07	10:15	GK-2607A	AT
Sofia Delgado	Line Supervisor	B-4402	06:15	14:30	GK-2607B	SD
Owen Bennett	QC Environmental Monitoring	B-4519	07:58	08:41	GK-2607B	OB
Farah Haddad	Maintenance Technician	B-4533	09:20	09:52	GK-2607B	FH
Marcus Webb	Cleanroom Operator	B-4471	10:40	14:22	GK-2607C	MW
Aiko Tanaka	Cleanroom Operator	B-4488	10:44	14:26	GK-2607C	AT
Owen Bennett	QC Environmental Monitoring	B-4519	13:58	14:40	GK-2607C	OB
Sofia Delgado	Line Supervisor	B-4402	14:35	18:02	GK-2607D	SD
David Okafor	QA Reviewer	B-4390	15:10	15:47	GK-2607D	DO

Gown Lot column records the sterile-garment lot number issued at the Stage 2 dispensing cabinet; lots rotate approximately every four hours per stockroom schedule.

Particle Count Monitoring

Non-viable particle counts are logged at four-hour intervals from fixed monitoring ports in the gowning anteroom and Suite B4, per the classification limits of [2] reproduced below (at-rest occupancy state).

Classification	≥0.5 µm (particles/m³)	≥5.0 µm (particles/m³)
ISO Class 7 (Suite B4)	352,000	2,930
ISO Class 8 (Gowning Anteroom)	3,520,000	29,300

Record Strip – 22 Jul 2026

Location	Time	0.5 µm	5.0 µm	Limit Basis	Status
Gowning Anteroom (ISO 8)	06:00	812,400	6,150	At-rest	PASS
Suite B4 (ISO 7)	06:00	94,200	640	At-rest	PASS
Gowning Anteroom (ISO 8)	10:00	1,102,800	8,920	At-rest	PASS
Suite B4 (ISO 7)	10:00	118,600	890	At-rest	PASS
Gowning Anteroom (ISO 8)	14:00	1,340,500	11,040	At-rest	PASS
Suite B4 (ISO 7)	14:00	341,700	3,410	At-rest	ALERT
Gowning Anteroom (ISO 8)	18:00	946,300	7,280	At-rest	PASS
Suite B4 (ISO 7)	18:00	87,950	510	At-rest	PASS

⚠ Exceedance Noted – 14:00 Reading, Suite B4

The 5.0 µm count of 3,410 particles/m³ exceeds the ISO Class 7 at-rest limit of 2,930 particles/m³ defined in [2]. Line Supervisor Sofia Delgado was notified at 14:07; entry into Suite B4 was suspended pending investigation. See Deviation DEV-2026-0148 in the following section for root cause and disposition, prepared in line with the excursion-handling guidance of [3].

Deviation Notes

DEV-2026-0148 – Particle Count Excursion, Suite B4, 14:00

Observation: 5.0 µm particle count of 3,410 particles/m³ recorded against an at-rest limit of 2,930 particles/m³. Entry suspended at 14:07; all personnel present withdrawn to the gowning anteroom without disrobing.

Investigation: Facilities review of the building management system showed the HVAC return-air differential pressure on AHU-B4-2 had drifted 18% below setpoint over the preceding six hours, consistent with a partially loaded HEPA filter bank. No product or open-container activity was in progress at the time of the excursion.

Immediate Action: HEPA filter bank F-3 on AHU-B4-2 replaced at 15:20 by Farah Haddad. Suite requalified by a 30-minute at-rest particle survey; results returned to baseline (0.5 µm: 91,400; 5.0 µm: 610) at 15:58. Suite re-opened for entry at 16:05 with QA concurrence from David Okafor.

CAPA Reference: CAPA-2026-0071 – preventive filter differential-pressure alarm threshold to be tightened from 25% to 15% drift, effective next PM cycle.

General Notes

No other deviations were recorded during this shift. Glove-integrity spot checks (n=6, random) all passed visual and tactile inspection per SOP-EHS-021. One gowning re-do was required at 09:15 (Farah Haddad, hood seal adjustment) and was completed without incident; no suite entry occurred prior to correction.

Sign-Off

Role	Printed Name / Signature	Date
Gowning Room Monitor	Priya Raman _____	_____
QA Reviewer	David Okafor _____	_____
Facility Manager	Lena Kowalski _____	_____

Completed logs are retained for seven years in the Meridian Therapeutics QA document control system per site retention policy and the record-keeping expectations of [5] and [4].

Regulatory References

[1] European Commission. EU GMP annex 1: Manufacture of sterile medicinal products. Technical report, European Commission, Directorate-General for Health and Food Safety, Brussels, Belgium, 2022.

[2] International Organization for Standardization. ISO 14644-1:2015 cleanrooms and associated controlled environments – part 1: Classification of air cleanliness by particle concentration. Technical Report ISO 14644-1:2015, International Organization for Standardization, Geneva, Switzerland, 2015.

[3] International Organization for Standardization. ISO 14644-2:2015 cleanrooms and associated controlled environments – part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration. Technical Report ISO 14644-2:2015, International Organization for Standardization, Geneva, Switzerland, 2015.

[4] United States Pharmacopeial Convention. *USP General Chapter <797> Pharmaceutical Compounding – Sterile Preparations*. USP, Rockville, MD, 2023.

[5] U.S. Food and Drug Administration. Guidance for industry: Sterile drug products produced by aseptic processing – current good manufacturing practice. Center for Drug Evaluation and Research (CDER), 2004.