

Cleanroom Compliance Guide



What is a controlled environment?

- » A controlled environment is a space designed to maintain defined environmental conditions to reduce contamination risks.
- » These conditions may include particulate levels, temperature, humidity, pressure differentials, and microbial control
- » Controlled environments are used in spaces where regulated, contamination sensitive activities are performed, including pharmaceutical manufacturing, biotechnology, medical device production, life sciences research, and healthcare



Compliance objective: reduce contamination risks that could impact product quality, patient safety, or process integrity

What is a Cleanroom?

A controlled environment that meets the classification requirements of ISO 14644-1

ISO 14644-1 classifies cleanrooms based on allowable airborne particle concentration per cubic meter

Used in environments where contamination-sensitive manufacturing, compounding, or research activities require controlled airborne particulate levels



Compliance objective: maintain controlled airborne particulate levels within defined ISO 14644-1 classification limits

Defined Boundaries

Controlled environments are separated from surrounding areas by walls, ceilings, floors, doors, and sealed penetrations.

Boundaries distinguish classified from unclassified spaces. Gaps or cracks in flooring can create contamination risks.

Cleanroom flooring should be a continuous surface to support the integrity of the cleanroom envelope.



HEPA filtration and airflow control

- » HEPA filtration removes airborne particles from supply and recirculated air.
- » Airflow is designed to move from cleaner to less clean areas using controlled pressure differentials.
- » Flooring should minimize particle buildup and support contamination control at the room surface level.
- » Smooth, non-shedding surfaces reduce particle generation and help maintain cleanroom standards.



Anteroom / Airlock

A controlled transition space between unclassified zones and cleanroom areas.

PPE Staging:
In cleanrooms, anterooms provide a controlled space for donning and doffing PPE to reduce particle transfer.



Airlocks: Anterooms use interlocking doors to ensure only one door opens at a time, protecting the integrity of the buffer room.

Flooring Requirements:
Floors must handle frequent cleaning, chemicals, and traffic while preserving seam integrity.

Examples of Anteroom/ Airlock Usage



Pharmaceutical

Used for sterile compounding, manufacturing, and hazardous drug handling to control contamination transfer.

Used in isolation areas to support airflow control and limit particle transfer.

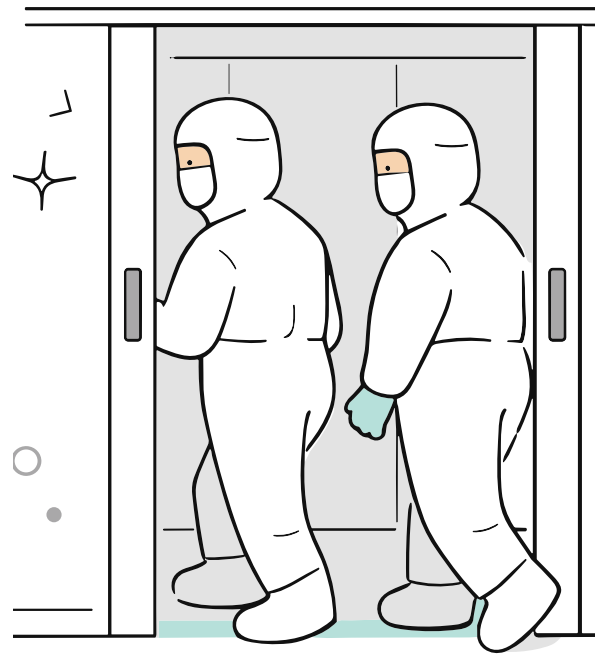


Healthcare/ Isolation



Manufacturing

Used in microelectronics and high-tech manufacturing to limit particle contamination.



Takeaway for flooring: Seamless flooring supports efficient cleaning in transition areas.



Why flooring matters for compliance

Flooring performance supports cleanability, contamination control, chemical resistance, and safety over the lifecycle of the facility. Auditors routinely assess flooring condition during inspections as part of overall cleanroom compliance

Gerflor Solutions

ISO 14644-1

ISO 14644-1 defines classes by allowable airborne particle concentration per cubic meter, with ISO Class 1 being the cleanest and ISO Class 9 the least clean. **Flooring systems may be evaluated for surface integrity and low particle emission as part of contamination-control strategies in classified environments.**

GMP Grades A-D

GMP requirements define environmental controls for pharmaceutical manufacturing; sterile environments may reference Grades A-D (e.g. EU GMP Annex 1). **Flooring should support cleaning and contamination control appropriate to the room's classification and risk. Seam integrity and durability are essential for compliant flooring performance.**

USP 797 / 800

US Pharmacopeia standards guide pharmaceutical compounding. USP <797> applies to sterile compounding, and USP <800> applies to hazardous drug handling. **Flooring should be compatible with disinfectants and cleaning agents used in the space. Seamless, non-porous surfaces support effective cleaning and contamination control.**

FDA / Cleanability expectations- General Guidelines

Cracks, gaps, and surface damage are commonly identified as contamination risks during inspections. **Flooring selection should support overall contamination-control strategies.**

Gerflor Technical Floor & Wall Covering Solutions

Heat-Welded Seams

Heat-welded seams form sealed, impermeable flooring that prevent particle or moisture traps and improve cleanability.



Low-Shedding Surfaces

Dense, smooth floors and walls limit particle release and wear. Surface integrity supports ISO and GMP contamination control.



Chemical Resistance

Floors must tolerate disinfectants and routine cleaning chemicals. Durability supports USP and GMP cleaning protocols and extends floor life. Compatibility varies by concentration, dwell time, and cleaning method.



ESD Performance

Manages electrostatic discharge in sensitive areas. Controlled resistance protects equipment and products. Performance must be monitored over the floor's lifecycle and align with facility risk requirements.



Clean Corners

Gerflor floor-to-ceiling smooth transition. GMP-compliant. Easy coving and resilient corner profiles. Fast cleaning and strong contamination control. Watertightness system included.

