ISO vs GMP CLEANROOMS



WHAT'S THE DIFFERENCE?

Cleanrooms keep products safe by controlling particles. Two major systems are used to classify them:

ISO (ISO 14644 STANDARDS)	GMP (EU GMP ANNEX 1)
classifies cleanrooms based on airborne particles only	classifies cleanrooms on particles and microbes (nonviable and viable particles)

Most pharmaceutical cleanrooms have both ISO and GMP classifications.
Many industrial/electronic cleanrooms use ISO only, because microbes are not a concern.

WHAT ARE ISO CLEANROOMS?

- Particle focused
- Standard used: ISO 14644 series
- Classification is based only on particle counts in the air
- Classes run from ISO 9 (least clean) to ISO 1 (cleanest)
- Does not include microbial limits
- Common in industries where particles, not microbes, matter e.g. Semiconductors, Electronics assembly, Optics & Lasers, Aerospace, Precision manufacturing
- Consumables focus on low lint, low particles e.g. non-sterile wipes, garments, gloves
- Sterile disinfectants are not required

WHAT ARE GMP CLEANROOMS?

- Microbe focused
- Standard used: EU GMP Annex 1 / FDA cGMP
- Classification is based on particle counts and microbe counts
- Grades run from Grade A (most clean) to Grade D (least D)
- Common in industries where microbes matter e.g. Pharmaceutical manufacturing, Injectables & biologics, Sterile medical devices, Vaccines, High-risk food & Nutraceuticals
- GMP focuses on; Airborne particles, Microbial contamination, Personnel behaviour, Process controls & documentation
- Consumables must meet strict microbiological bioburden limits and many must be sterile (especially Grade A/B)

WHICH ISO IS EQUAL TO WHICH GMP? (Airborne particles ≥0.5 µm)

GMP Grade	ISO Class (At Rest)	Particles at Rest	Particles in Operation
A	ISO 5	3,520	3,520
B	ISO 5	3,520	352,000
C	ISO 7	352,000	3,520,000
D	ISO 8	3,520,000	Not defined

KEY DIFFERENCES AT A GLANCE

Aspect	ISO Cleanrooms	GMP Cleanrooms
Focus	Airborne particles only	Particles and microbes
Standard	ISO 14644	EU GMP Annex 1
Cleanliness Scale	ISO 1–9	Grades A–D
Industries	Semiconductor, optics, aerospace, electronics	Pharmaceuticals, biologics, sterile devices
Consumables	Low-lint, non-sterile	Sterile consumables, high-level disinfectants
Purpose	Control particles	Protect sterile products & patient safety

IN SUMMARY

- ISO = particle control - ideal for industrial cleanrooms
- GMP = particle and microbial control - required for pharmaceuticals and steriles
- The two systems overlap, but they are not interchangeable
- GMP has tighter rules, more documentation, and requires sterile consumables and validated cleaning/disinfection routines



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