

GMP Cleanroom Self-Audit Checklist

32 CHECKPOINTS · ZONING / AIR / PERSONNEL / SURFACES / DOCS · FREE ENGINEERING REVIEW

A. ZONING & LAYOUT

- ☐ Personnel and material flows are one-way and never cross
- ☐ Cleanliness classes mapped room-by-room (100K/10K) and posted
- ☐ Airlocks or pass boxes at every clean/non-clean boundary
- ☐ Pressure cascade ≥ 10 Pa steps, gauges installed at boundaries
- ☐ Buffer rooms sized for gowning without congestion
- ☐ Waste route separated from product route

B. AIR SYSTEM

- ☐ Air changes meet class (ISO 8: 20-30/h, ISO 7: 30-60/h)
- ☐ HEPA terminals H13 minimum, DOP/PAO tested after install
- ☐ Pre-filters replaced on schedule and logged
- ☐ Temperature 20-26 C, RH 45-65% recorded continuously
- ☐ Return air grilles low-level, unobstructed
- ☐ AHU maintenance log up to date

C. PERSONNEL HYGIENE

- ☐ Entry line complete: lockers -> wash -> disinfect -> boot wash -> air shower
- ☐ Air shower cycle time set and interlocks functioning
- ☐ Sensor (no-touch) hand wash stations at every entry
- ☐ Gowning SOP posted with photos at gowning point
- ☐ Street shoes never cross the barrier line
- ☐ Visitor procedure defined and logged

D. SURFACES & CLEANING

- ☐ Wall/ceiling panels intact, joints sealed, corners coved
- ☐ Floor epoxy unbroken, no dust-trapping cracks
- ☐ Cleaning agents rotated and logged
- ☐ Cleaning tools dedicated per zone, color-coded
- ☐ No wood, cardboard or rust inside clean zones
- ☐ Pest control devices at entries, mapped

E. MONITORING & DOCUMENTATION

- ☐ Particle counts done at defined points and frequency
- ☐ Settle plates / microbial monitoring per schedule
- ☐ Third-party certification report current (≤ 12 months)
- ☐ Deviations logged with corrective actions
- ☐ Filter replacement history retained
- ☐ As-built drawings available and current
- ☐ Training records for all cleanroom staff
- ☐ Change control procedure for any modification

SCORE & NEXT STEP

- 28-32 checked: audit-ready. 20-27: fix gaps before your next audit. <20: talk to an engineer.
- Free option: send this checklist with your marks + a floor-plan photo to info@bescolin.com - our chief engineer returns a gap review within 48 hours.

Get factory pricing in 24h | WhatsApp +86 138 0000 0000 | info@bescolin.com

THIRD-PARTY INSPECTION (SGS / BV / TUV) WELCOME AT YOUR APPOINTED AGENCY