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USP Compliance Checklist

A technical, audit-ready assessment tool

1. Facility Design & Engineering Controls

- ☐ ISO-classified rooms meet required classifications (ISO 5 PECs, ISO 7 buffer, ISO 8 ante)
- ☐ Pressure differentials meet USP requirements and are continuously monitored
- ☐ Air change rates (ACPH) meet minimum thresholds for each room classification
- ☐ HEPA-filtered unidirectional airflow is validated in all PECs
- ☐ Surfaces are seamless, cleanable, and non-porous with coved transitions
- ☐ Material and personnel flows minimize contamination risk
- ☐ Hazardous drug areas meet negative-pressure and containment requirements (if applicable)

2. Airflow & Environmental Performance

- ☐ HEPA/ULPA filter integrity testing performed at required intervals
- ☐ Airflow visualization (smoke studies) completed for PECs and room-to-room transitions
- ☐ Differential pressure, temperature, and humidity are continuously monitored
- ☐ Recovery time testing performed and documented
- ☐ Non-viable particle counts meet ISO 14644-1 limits (as-built, at-rest, operational)

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3. Environmental Monitoring Program

- ☐ Viable air sampling performed at required frequencies and locations
- ☐ Surface sampling performed using contact plates or swabs
- ☐ Action and alert limits established and justified
- ☐ Trending program in place with documented investigations for excursions
- ☐ Monitoring equipment calibrated and qualified
- ☐ Sampling performed during dynamic (operational) conditions

4. Certification & Qualification

- ☐ ISO 14644-1 classification testing current and documented
- ☐ ISO 14644-2 compliance verification performed
- ☐ PECs certified to ISO 5 with documented airflow velocity and pattern testing
- ☐ Temperature, humidity, and pressure mapping completed
- ☐ IQ/OQ/PQ documentation available for cleanroom systems and PECs
- ☐ Annual recertification performed by a qualified provider

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5. Operational Controls & SOP Compliance

- ☐ Gowning procedures align with risk category (Category 1 or Category 2)
- ☐ Cleaning and disinfection SOPs validated and followed
- ☐ Approved disinfectants used with proper contact times
- ☐ Personnel competency assessments performed and documented
- ☐ Material transfer procedures minimize contamination
- ☐ BUDs assigned according to USP risk categories
- ☐ Documentation practices meet ALCOA+ principles

6. Compounding Personnel & Training

- ☐ Initial and annual media-fill testing completed
- ☐ Gloved fingertip sampling meets USP acceptance criteria
- ☐ Training documented for aseptic technique, cleaning, and gowning
- ☐ Personnel demonstrate proper hand hygiene and garbing sequence
- ☐ Corrective actions documented for any failed competency assessments

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7. 21 CFR Part 11 & Monitoring System Compliance

- ☐ Environmental monitoring system supports secure audit trails
- ☐ Electronic signatures and role-based access controls implemented
- ☐ Data retention meets regulatory expectations
- ☐ Alarm management procedures defined and validated
- ☐ 24/7 monitoring of temperature, humidity, pressure, and particle counts
- ☐ System validated (IQ/OQ/PQ) with documented change control

8. Documentation & Quality System Integration

- ☐ SOPs current, controlled, and aligned with USP
- ☐ Deviation, CAPA, and change-control systems in place
- ☐ Cleaning logs, monitoring logs, and certification reports maintained
- ☐ Risk assessments performed for critical processes
- ☐ Quality oversight documented for all compounding activities