USP <797> Facility Compliance Checklist

Use this checklist as a practical guide to help evaluate your facility's alignment with USP <797> minimum facility and engineering standards. This checklist is intended to support internal reviews and identify areas that may require further attention. It is not an exhaustive compliance assessment.

How to Use This Checklist

1. Review each standard listed below.
2. Mark whether your facility is currently compliant.
3. Note any gaps, concerns, or planned corrective actions in the "Corrective Action Plan" section.
4. When complete, submit your checklist to receive a complimentary review from a QleanAir cleanroom compliance expert.

What Happens Next

A QleanAir expert will review your checklist results and guide you through a Compliance Risk Index Assessment to help you:

- Identify your highest compliance risks
- Understand potential regulatory exposure
- Compare the cost of non-compliance versus implementation solutions
- Evaluate whether a QleanAir modular cleanroom solution may be a practical fit for your facility

Important Note

USP <797> compliance requirements can vary based on your compounding category, facility design, workflow, and operational risk level. Final compliance determinations should always include a comprehensive facility-specific assessment.

Prepared by Restore Health Consulting LLC

USP <797> Minimum Facility and Engineering Standards	Compliant?	Corrective Action Plan
The anteroom, buffer room, and SCA must be separated from areas not directly related to compounding.		
The design of the facility should take into account: number of personnel; their movements; number and placement and type(s) of equipment, supplies, and components; number and complexity of operations performed.		
Air quality (total particle count per cubic meter of air) meets ISO standards: ISO 5: 3,520, ISO 7: 352,000, ISO 8: 3,520,000		
Anteroom to positive pressure buffer must meet ISO 8 classification.		
Anteroom to negative pressure buffer must meet ISO 7 classification.		
Buffer room must meet ISO 7 classification.		
Category 1, 2, and 3 CSPs must be compounded in ISO 5 or better PEC.		
Facility must be well-lit.		
Cleanroom suite (anteroom + buffer room) should be maintained at a temperature of 20°C or cooler and relative humidity of 60% or below.		
Temperature and humidity of cleanroom suite must be monitored each day compounding is performed (either manually or by continuous recording). Results must be documented at least once daily or stored in readily retrievable continuous recording device.		
Free-standing air conditioners, humidifiers, and dehumidifiers must not be used within the classified area or SCA.		

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Temperature and humidity monitoring devices must be calibrated annually or as required by manufacturer.		
PEC must be located in the buffer room or SCA in a manner that minimizes contamination (e.g., away from doors, personnel traffic, etc.).		
Classified rooms must be equipped with a pressure differential monitoring system.		
Air must be introduced through HEPA filters in the ceiling.		
Air returns must be low on the wall (unless smoke study demonstrates absence of stagnant airflow).		
Anteroom must have a line of demarcation separating the clean side and dirty side. Alternatively, the facility may be designed with two separate anterooms (a dirty and a clean).		
Airlocks and interlocking doors may be used to facilitate better control of air balance between different ISO areas.		
If pass-through chambers are used, both doors must never be opened at the same time; doors should be interlocking.		
Seals and sweeps should not be installed at doors between buffer rooms and anterooms.		
Access doors should be hands-free.		
Tacky mats must be placed outside ISO areas.		
For compounding both nonsterile and sterile preparations: PECs must be placed in separate rooms unless PECs can maintain ISO 7 continuously. If PECs are placed in the same room, they must be placed 1 meter apart.		
A PEC may be located within an unclassified segregated compounding area (SCA); but only Category 1 CSPs may be produced.		
The SCA must be located away from unsealed windows, doors that connect to outdoors, traffic flow, and areas with environmental challenges (e.g., restrooms, warehouses, food prep, etc.). Sterile compounding must be dedicated to the area within 1 meter of the PEC.		
PECs must meet ISO 5 classification and maintain unidirectional airflow.		
Types of acceptable PECs for sterile compounding: LAFW, Integrated Vertical Laminar Flow Zone (IVLFZ), Class II BSC, RABS, CAI, CACI, and Pharmaceutical Isolator.		
PECs placed in ISO 7 buffer room with ISO 8 anteroom may compound Category 2 and 3 CSPs. Exception: Pharmaceutical Isolators placed in ISO 8 rooms can also compound Category 2 and 3 CSPs.		
ACPH Requirements (Under Dynamic Conditions): Unclassified SCA: No requirement ISO 7: ≥30 ACPH ISO 8: ≥20 ACPH		
Pressure Differential Requirements: Cleanroom Suite: at least 0.020”WC between buffer room and anteroom and between anteroom and unclassified area. SCA: No requirement.		
Pressure differential monitoring device must be used to continuously monitor the pressure differentials. Results must be reviewed and documented at least daily when compounding occurs.		
When preparing Category 2 or 3 CSPs from nonsterile starting components, weighing and mixing must be performed in ISO 8 conditions or better within single-use containment glove bags, CVEs, BSCs, or CACIs that are certified every 6 months.		
Surfaces of ceilings, walls, floors, doors, door frames, fixtures, shelving, work surfaces, counters, and cabinets should be smooth, impervious, free from cracks and crevices, non-shedding and resistant to damage.		
Junctures between the ceiling and the walls and between the walls and the floor must be sealed.		
Ceilings with inlaid panels must be caulked.		
Walls must be durable and the integrity of the surface maintained.		
Panels must be joined together and sealed.		

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Floors must include coving to the sidewall or be caulked.		
Classified areas should minimize dust-collecting overhangs (e.g., exposed utility pipes), ledges (e.g., windowsills). If present, they must be easily cleanable.		
Exterior light fixture surface must be smooth, mounted flush, and sealed.		
Sinks should be hands-free and must be cleaned and disinfected each day of use.		
The buffer room must not contain plumbed water sources. The anteroom must not contain floor drain(s). Sprinklers (if installed) should be recessed and covered.		
Cleanroom Suites: Sinks for hand hygiene may be placed either inside or outside the anteroom. If located outside, it must be located in a clean space.		
SCAs: Sinks for hand hygiene must be placed not closer than 1 meter to the PEC, and may be located either inside the SCA or in close proximity to the SCA.		
Only necessary furniture, equipment and materials are permitted in a classified area or SCA. They should be low-shedding and easily cleaned.		
No cardboard is allowed in the classified area or SCA.		
Only necessary equipment (including robotics) is permitted in the PEC. Its placement must be verified initially by dynamic airflow smoke pattern test.		
Cleanroom Suites, SCAs, and PECs must be independently certified before the area is used for compounding and repeated every 6 months thereafter and when changes occur (e.g., redesign, construction, PEC relocation/replacement, alteration of configuration, etc.).		
Certification includes: Airflow testing – velocity, ACPH, pressure differentials HEPA filter integrity testing Total particle count testing Dynamic airflow smoke pattern test Microbiological air and surface test		
If total particle count or microbiological test results exceed limits, the cause must be investigated and corrective actions must be taken including process or facility improvements or HEPA filter replacement or repair.		

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What Happens Next

Submit your completed checklist to connect with a QleanAir USP <797> compliance specialist. We'll help you evaluate your current state, prioritize risks, and determine the most efficient path toward compliance.

Contact a QleanAir Expert