USP <797> Sterile Compounding — Customer Checklist

Disclaimer: These checklists are provided by SOSCleanroom for general educational use and operational planning only. They are recommendations and do not constitute legal, regulatory, clinical, or safety advice, and should not be treated as a statement of fact about your specific facility. SOSCleanroom does not certify compliance through this document. You are responsible for developing, approving, and maintaining your own SOPs, training, documentation, and validation based on the official USP–NF text, your state/federal requirements, and your organization's risk assessment. Always consult qualified professionals and the applicable authorities having jurisdiction (AHJ).

Use this checklist for a rapid internal self-assessment. Align each item to the currently applicable official USP–NF text and your jurisdiction's enforcement posture.

A) Governance and quality system

- [ ] Responsible individual(s) designated; oversight and review cadence defined.
- [ ] SOP set controlled (approvals, versioning, archived copies, change control).
- [ ] Deviation/CAPA process exists; investigations are documented and timely.
- [ ] Audit pack maintained (certifications, EM trends, training/competency, cleaning logs).

B) Personnel, garbing, and aseptic technique

- [ ] Initial training documented before independent sterile compounding.
- [ ] Competency verification program implemented (observation + required assessments).
- [ ] Ongoing requalification schedule tracked; retraining triggers defined for failures/events.
- [ ] Supply staging supports consistency (same products, same locations, minimal improvisation).

C) Facilities and engineering controls

- [ ] Appropriate PEC(s) and room configuration support the CSP activities performed.
- [ ] Certification/maintenance records are current; reviews are documented.
- [ ] Material transfer pathways are controlled (outer packaging and uncontrolled items managed).
- [ ] Clutter control and cleanable surface expectations are enforced.

D) Cleaning, disinfection, sterile alcohol use, sporicidal program

- [ ] Approved chemistries and contact times defined in SOPs; compatibility considerations documented.
- [ ] Wiping/mopping technique standardized (pattern, overlap, face control, change-out rules).
- [ ] Cleaning schedule implemented and logged; missed events are escalated and corrected.
- [ ] Tools are cleanroom-appropriate (low-lint, controlled packaging, consistent formats).

E) Environmental monitoring and trending

- [ ] Viable air and surface monitoring program exists and is executed consistently.
- [ ] Data is trended; adverse trends trigger documented investigation and corrective action.
- [ ] Monitoring locations and timing reflect real operations (not only ideal moments).

F) BUD, labeling, storage, transport, traceability

- [ ] CSP categorization approach defined; BUD logic aligned to conditions and documented.
- [ ] Labels support traceability (ingredients, lots, preparer, timestamps, storage conditions).
- [ ] Storage/transport conditions match BUD assumptions; deviations are documented.

Official USP references (source-of-truth):

- USP <797> portal: https://www.usp.org/compounding/general-chapter-797
- USP–NF notice on <797> publication/official status: https://www.uspnf.com/notices/797-pub-announcement-20221101
- USP–NF DOI pathway: https://doi.usp.org/USPNF/USPNF_M99925_07_01.html
- USP FAQ – Identifying official text: https://www.usp.org/frequently-asked-questions/identifying-official-text