

## USP <800> Hazardous Drugs Handling — 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 HD inventory control

- |                          |   |
|--------------------------|---|
| <input type="checkbox"/> | HD list approach documented (NIOSH-referenced logic) and reviewed on a defined cadence. |
| <input type="checkbox"/> | Task-based PPE/work practice rules defined; staff can explain them.                     |
| <input type="checkbox"/> | Deviation/CAPA process exists for exposure events, spills, and contamination concerns.  |

### B) Receipt and unpacking controls

- |                          |  |
|--------------------------|--|
| <input type="checkbox"/> | Receiving/unpacking area defined; outer packaging does not enter clean/critical areas. |
| <input type="checkbox"/> | Damage/spill response pathway documented and staff trained to execute it.              |

### C) Storage and segregation

- |                          |   |
|--------------------------|---|
| <input type="checkbox"/> | Storage zones labeled; segregation rules prevent cross-contamination. |
| <input type="checkbox"/> | Storage area decontamination/cleaning schedule defined and logged.    |

### D) Compounding/manipulation controls (where applicable)

- |                          |   |
|--------------------------|---|
| <input type="checkbox"/> | Containment engineering controls used as defined by policy; maintenance/certification evidence current. |
| <input type="checkbox"/> | Surface decontamination steps standardized (tools, method, contact time) and logged.                    |

### E) Administration and transport controls (where applicable)

☐ Handling steps minimize risk; work surfaces are decontaminated/cleaned on a defined cadence.

☐ PPE doffing rules reduce self-contamination; training supports consistent behavior.

### F) Spill response and hazardous waste

☐ Spill response supplies are accessible; staff can demonstrate response steps.

☐ Waste streams are controlled and labeled; disposal practices are documented.

### G) Training, competency, and documentation

☐ Initial and ongoing HD-handling training is documented; competency checks have a defined cadence.

☐ Logs are complete and reviewed routinely (cleaning, incidents, maintenance, training).

#### Official USP references (source-of-truth):

- USP <800> portal: <https://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare>
- USP–NF DOI pathway: [https://doi.usp.org/USPNF/USPNF\\_M7808\\_07\\_01.html](https://doi.usp.org/USPNF/USPNF_M7808_07_01.html)
- USP FAQ – Identifying official text: <https://www.usp.org/frequently-asked-questions/identifying-official-text>