CHAMPIONING MEDICALLY INTEGRATED ONCOLOGY:

Celebrating a Decade of Impact

2025 NCODA INTERNATIONAL FALL SUMMIT

Beyond Clean:
Strategies for Safe Compounding and Contamination Prevention

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OBJECTIVES

1. Describe healthcare teams' responsibilities in preventing contamination according to USP <797> and USP <800> standards.
2. Identify the types of cleaning agents used in sterile compounding, including appropriate selection, frequency of use, and required dwell times.
3. Explain the role of documented cleaning schedules in maintaining compliance with regulatory and institutional protocols.
4. Recognize potential sources of contamination resulting from improper cleaning techniques or product misuse.
5. Review a real-world contamination case example to enhance cleanroom practices and ensure the safety of patients and staff.

DISCLOSURES

There are no relevant conflicts of interest to disclose for this presentation for the following faculty and planners of this activity:

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Sterile Compounding Key Terms

Acronym	Term
CSP	Compounded Sterile Preparation
SOP	Standard Operating Procedures (or Protocols)
LAFW	Laminar Air Flow Workbench
BSC	Biological Safety Cabinet
PEC	Primary Engineering Control(s)
SEC	Secondary Engineering Control(s)
IPA/sIPA	Isopropyl Alcohol (or Sterile Isopropyl Alcohol)
HD	Hazardous Drug

Pharmacy Team Responsibilities in Preventing Contamination

An overview of Responsibilities under USP<797> and USP<800> Standards

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Review of USP Standards

USP<797> focuses on protecting patients from microbial contamination in sterile compounding

USP<800> focuses on protecting healthcare workers, patients, and the environment from hazardous drug contamination

United States Pharmacopeial Convention. *General Chapter <800> Hazardous Drugs—Handling in Healthcare Settings*. In: *United States Pharmacopeia–National Formulary (USP–NF)*. Rockville, MD: United States Pharmacopeial Convention; 2023. Accessed October 7, 2025.

Personal Protective Equipment (PPE) and the Garbing Process

- Gloves (ASTM D6978) – Two sets
  - o Sterile, Powder-free
  - o Changed every 30 minutes (or earlier, if torn)
- Gowns – Two sets
  - o Disposable, Close in the back, long sleeve, closed cuffs that are elastic or knit
  - o Changed every 2-3 hours
- Head, Hair, Shoe (2 pairs), and Sleeve Covers (if needed)
- Eye and Face Protection
- Respiratory Protection

United States Pharmacopeial Convention. *General Chapter <797> Pharmaceutical Compounding—Sterile Preparations*. In: *United States Pharmacopeia–National Formulary (USP–NF)*. Rockville, MD: United States Pharmacopeial Convention; 2023. Accessed October 7, 2025.

Preventing Contamination

Environmental Controls

- Maintain controlled cleanroom environments w/ appropriate ISO classifications
- Perform routine cleaning of primary and secondary engineering controls
- Conduct viable and nonviable air and surface sampling

Aseptic Technique & Hand Hygiene

- Perform proper hand hygiene and garbing
- Follow aseptic technique during compounding to prevent microbial contamination

United States Pharmacopeial Convention. *General Chapter <797> Pharmaceutical Compounding—Sterile Preparations*. In: *USP–NF*. Rockville, MD: United States Pharmacopeial Convention; 2023.

Preventing Contamination (cont.)

Personnel Training and Competency

- Initial and ongoing training on aseptic techniques, garbing, and hand hygiene
- Media fill and gloved fingertip testing

Product Integrity

- Use appropriate beyond use dating based on stability and sterility
- Inspect all CSP's for particulate matter, leaks, or other defects

Quality Assurance and Documentation

- Documenting cleaning, training, and testing
- Investigate and remediate any contamination events

United States Pharmacopeial Convention. *General Chapter <797> Pharmaceutical Compounding—Sterile Preparations*. In: *USP–NF*. Rockville, MD: United States Pharmacopeial Convention; 2023.

Introducing items into the Secondary Engineering Control (SEC)

Before items are introduced to the clean side of the ante room, placed into a pass-through, or brought into a segregated compounding area (SCA):

- Wipe with a sporicidal agent, EPA-registered disinfectant, or Sterile 70% IPA by personnel wearing gloves.
- If sporicidal agent or disinfectant is used, agent must be allowed to dwell for minimum contact time
- If Sterile 70% IPA is used, allow items to dry
- Wiping procedures should not compromise package integrity

United States Pharmacopeial Convention. General Chapter <797> Pharmaceutical Compounding—Sterile Preparations. In: United States Pharmacopeia–National Formulary (USP–NF). Rockville, MD: United States Pharmacopeial Convention; 2023. Accessed October 7, 2025.

Introducing items into the Primary Engineering Control (PEC)

Just before items are introduced into the PEC:

- Wipe with Sterile 70% IPA and allow to dry before use
- Sterile items in sealed containers may be removed from covering as supplies are introduced into the ISO-5 PEC without the need to wipe individual sterile supply items with sterile 70% IPA
- Wiping procedures should not compromise package integrity

United States Pharmacopeial Convention. General Chapter <797> Pharmaceutical Compounding—Sterile Preparations. In: United States Pharmacopeia–National Formulary (USP–NF). Rockville, MD: United States Pharmacopeial Convention; 2023. Accessed October 7, 2025.

QUESTION 1

All the following are methods of preventing contamination, except:

a. Perform routine cleaning of Primary and Secondary Engineering Controls
b. Frequent conversations with colleagues during compounding to maintain team communication
c. Follow aseptic technique when compounding CSP's
d. Inspect CSP's for particulate matter, leaks, or other defects

Cleaning Agents & Contamination Control in Sterile Compounding

USP <797> & USP <800> Overview

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Types of Cleaning Agents

Detergents

- Removes
  - o Dirt
  - o Residues
  - o Debris

Disinfectants

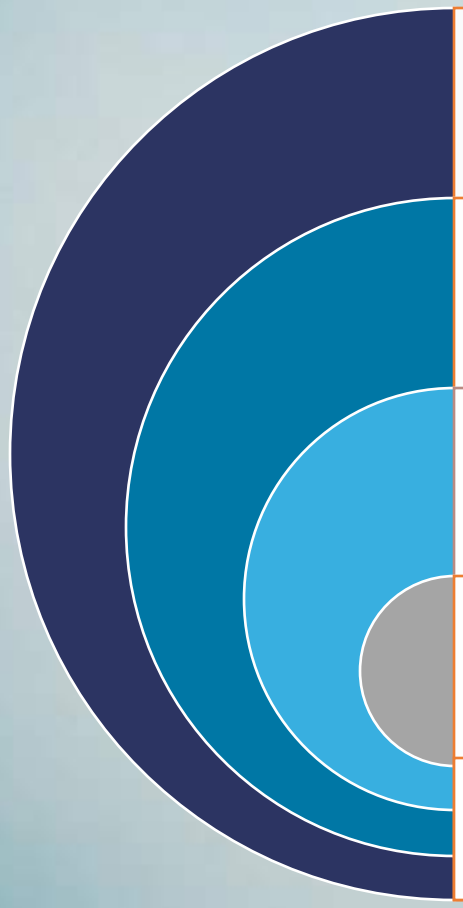
- Kills Microorganisms
  - o 70% sterile IPA
  - o Quats
  - o Phenolics
  - o Peroxides

Sporicidal Agents

- Destroy resistant spores
  - o Bleach
  - o Peroxide Blends

United States Pharmacopeial Convention. *General Chapter <797> Pharmaceutical Compounding—Sterile Preparations*. In: *USP–NF*. Rockville, MD: United States Pharmacopeial Convention; 2023. Section 7: Cleaning, Disinfecting, and Applying Sporicidal Disinfectants and Sterile 70% IPA.

Appropriate Selection



Routine Cleaning	• Detergent • Disinfectant
Daily Disinfecting	• Sterile 70% in ISO 5 areas
Monthly	• Sporicidal agent on all compounding surfaces
Hazardous Drug Areas	• Agents that deactivate and decontaminate o Bleach, Peroxide

United States Pharmacopeial Convention. *General Chapter <797> Pharmaceutical Compounding—Sterile Preparations.* In: *USP–NF*. Rockville, MD: United States Pharmacopeial Convention; 2023. Table 10: Minimum Cleaning Frequencies.

Frequency of Use

Regularly

When

- Start of shift
- Before batches
- Every 30 mins
- After Spills

PECs

- Hoods
- Isolators

Daily

- Counters
- Work Surfaces
- Floors

Monthly

- Walls
- Ceilings
- Shelving

At Least Monthly

- Sporicidal Agent

United States Pharmacopeial Convention. *General Chapter <797> Pharmaceutical Compounding—Sterile Preparations.* In: *USP–NF*. Rockville, MD: United States Pharmacopeial Convention; 2023. Table 10: Minimum Cleaning Frequencies.

Dwell Times

Agents must stay wet for manufacturer-specified time

Air Dry

Do NOT Wipe

Often require several minutes before wiping/rinsing

United States Pharmacopeial Convention. *General Chapter <797> Pharmaceutical Compounding—Sterile Preparations.* In: *USP–NF*. Rockville, MD: United States Pharmacopeial Convention; 2023. Table 10: Minimum Cleaning Frequencies.

Sterility Requirements

Sterile 70% IPA

- Required in ISO 5 areas

Other Agents

- Detergents, Sporicidal
- Not required to be sterile unless used in critical areas

United States Pharmacopeial Convention. *General Chapter <797> Pharmaceutical Compounding—Sterile Preparations.* In: *USP–NF*. Rockville, MD: United States Pharmacopeial Convention; 2023. Table 10: Minimum Cleaning Frequencies.

QUESTION 2

Which of the following practices violates USP <797> standards for introducing items into the cleanroom?

a. Wiping outer containers with a sporicidal agent before placing them in the pass-through
b. Allowing Sterile 70% IPA to fully dry before placing items in the PEC
c. Wiping supply packaging with a dry cloth before entry into the SEC
d. Using EPA-registered disinfectants with proper contact time prior to cleanroom entry

Cleaning Schedules and Documentation in Practice

Ensuring compliance with Regulatory and Institutional Standards

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Minimum Cleaning Frequencies

Site	Cleaning	Disinfecting	Applying sporicidal disinfectant
PEC(s) and equipment inside the PEC(s)	▪ Equipment and all interior surfaces of the PEC daily on days when compounding occurs and when surface contamination is known or suspected	• Equipment and all interior surfaces daily on days when compounding occurs and when surface contamination is known or suspected	▪ Monthly for entities compounding Category 1 and/or Category 2 CSPs ▪ Weekly for entities compounding Category 3 CSPs
Removable work tray of the PEC, when applicable	▪ Work surface of the tray daily on days when compounding occurs ▪ All surfaces and the area underneath the work tray monthly	▪ Work surface of the tray on days when compounding occurs ▪ All surfaces and the area underneath the work tray monthly	▪ Work surfaces of the tray monthly ▪ All surfaces and the area underneath the work tray monthly
Pass-through chambers	▪ Daily on days when compounding occurs	▪ Daily on days when compounding occurs	▪ Monthly for entities compounding Category 1 and/or Category 2 CSPs ▪ Weekly for entities compounding Category 3 CSPs
Work surface(s) outside the PEC	▪ Daily on days when compounding occurs	▪ Daily on days when compounding occurs	
Floor(s)	▪ Daily on days when compounding occurs	▪ Daily on days when compounding occurs	
Wall(s), Door(s), and door frame(s)	▪ Monthly	▪ Monthly	▪ Monthly
Ceiling(s)			
Storage shelving and bin(s)			
Equipment outside the PEC(s)			

USP <797> Pharmaceutical Compounding—Sterile Preparations. Section 7: Cleaning, Disinfecting, and Applying Sporicidal Disinfectants and Sterile 70% IPA [Table 10]. USP–NF. Rockville, MD: United States Pharmacopeial Convention; 2023

Documentation Requirements

- Facility Standard Operating Procedures (SOP's)
  - o Frequency, methods, and locations of cleaning areas
  - o Contact/dwell times for cleaning agents
- Personnel training, competency assessments, and qualification records including corrective actions for failures
- Certification Reports
- Equipment records (e.g., calibration)
- Results of investigations and corrective actions

United States Pharmacopeial Convention. *General Chapter <797> Pharmaceutical Compounding—Sterile Preparations*. In: *USP–NF*. Rockville, MD: United States Pharmacopeial Convention; 2023. Table 10: Minimum Cleaning Frequencies.

QUESTION 3

Which of the following areas should be cleaned at least daily (when compounding has occurred)?

a. Wall(s) and Ceiling(s)
b. The PEC (and equipment inside the PEC)
c. Floors
d. Storage Shelves and bins
e. Both B and C

Potential Contamination

Technique Errors

- Not cleaning clean > dirty, top > bottom
- Reusing wipes or mops spreads contamination
- Wiping dry before dwell time ends
- Touching cleaned surfaces with hands/gloves

United States Pharmacopeial Convention. *General Chapter <797> Pharmaceutical Compounding—Sterile Preparations*. In: *USP–NF*. Rockville, MD: United States Pharmacopeial Convention; 2023. Section 4: Responsibilities of Compounding Personnel and Section 7: Cleaning and Disinfection..

Product Misuse

Frequency & Environment

Key Takeaways

Cleaning Agents

- Proper Agent Selection
- Correct Frequency
- Sterile IPA use are critical

Potential Contamination

- Improper Cleaning
- Misuse Introduces Contaminants

Patient Safety

- USP <797> & <800> requirements protect patient safety

QUESTION 4

Which of the following is most likely to contribute to contamination in a cleanroom environment?

a. Using sterile 70% IPA with proper dwell time
b. Performing cleaning tasks outside of designated frequency schedules
c. Reviewing SOPs before each shift
d. Documenting cleaning procedures immediately after completion

Real World Case Example

New England Compounding Center (NECC)

- September 2012 – Health authorities including CDC and FDA began investigating multi-state outbreak of fungal meningitis
- CDC traced the outbreak to 3 lots of contaminated methylprednisolone (used for epidural steroid injection) compounded by NECC
- Doses from these 3 lots were distributed to 75 medical facilities in 23 states
- At least 64 confirmed deaths and over 700 injured by contaminated product
- One of the deadliest pharmaceutical contamination event in U.S. history

Dearen J. *Kill Shot: A Shadow Industry, a Deadly Disease*. New York, NY: Penguin Random House; 2021.

What went wrong?

Sterility and Manufacturing Practices

- Improper sterile technique: compounding processes did not meet safe standards
- Cleaning/disinfection of compounding equipment was inconsistent
- Lots were shipped before sterility test results were completed

Inadequate Environmental Cleaning

- Visible dirt, debris, and mold in cleanrooms where sterile drugs were made
- Poor cleaning frequency; Required cleaning schedules were not followed as USP<797> required

Documentation Failures

- Cleaning logs incomplete, backdated, or falsified
- Environmental monitoring results showed repeated positive results for fungi and bacteria
- No corrective action taken; sterile compounding continued

Dearen J. *Kill Shot: A Shadow Industry, a Deadly Disease*. New York, NY: Penguin Random House; 2021.

Mold Culture Sample

An aspergillus fumigatus mold culture grown from a patient's spinal fluid

Dearen J. *Kill Shot: A Shadow Industry, a Deadly Disease*. New York, NY: Penguin Random House; 2021.

Outcomes of NECC tragedy

- **NECC license was revoked and operations ceased**
- Criminal Indictments for multiple executives/employees
  - Owner sentenced to 14 ½ years in prison
  - Supervisory pharmacist sentenced to 10 ½ years in prison
- Regulatory Reforms:
  - Drug Quality and Security Act (DQSA) of 2013
  - Defined outsourcing facilities (503B)

Dearen J. *Kill Shot: A Shadow Industry, a Deadly Disease*. New York, NY: Penguin Random House; 2021.

SUMMARY

- Cleaning protocols in sterile compounding must align with USP <797> and <800>
- Proper selection and rotation of cleaning agents are critical (detergents, disinfectants, sporicidal)
- Documentation and competency assessments support accountability and compliance
- Real-world events like NECC illustrate the risks of non-compliance
- All members of the healthcare team play a vital role in contamination prevention

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