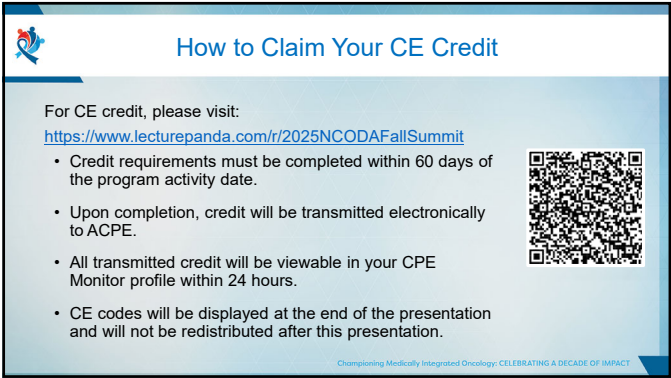




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OBJECTIVES

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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.

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DISCLOSURES

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

• David Johnson, CPhT-Adv, CSPT

• Edil Sanchez, CPhT, CSPT, BCSCPT

• Tahsin Imam, PharmD

• Taryn Newsome, CPhT

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Sterile Compounding Key Terms

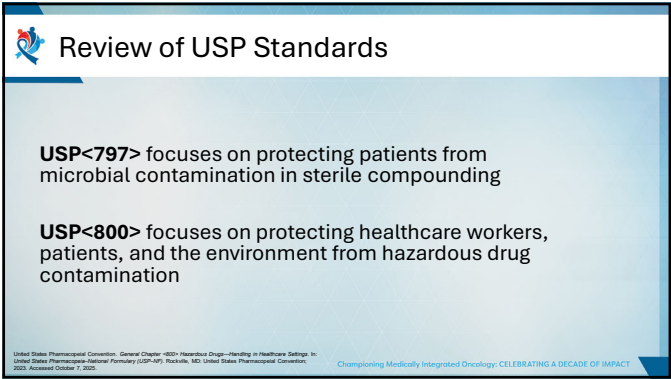
Acronym	Term
CSP	Compounded Sterile Preparation
SOP	Standard Operating Procedures (or Protocols)
LAFW	Laminar Air Flow Workbench
BSC	Biological Safety Cabinet
PEC	Primary Engineering Control(s)
SEC	Secondary Engineering Control(s)
IPA/sIPA	Isopropyl Alcohol (or Sterile Isopropyl Alcohol)
HD	Hazardous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

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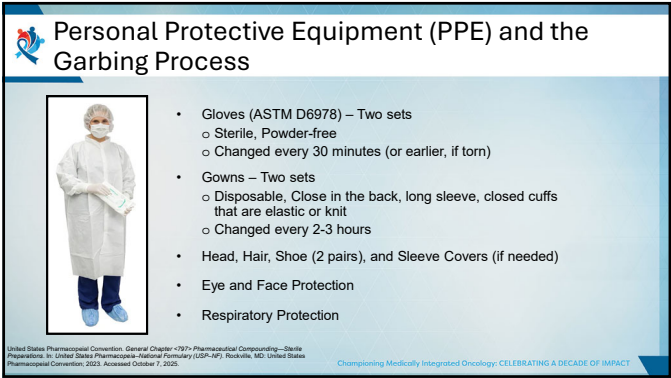
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 Preventing Contamination

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, 11, USP-NF, Rockville, MD, United States Pharmacopeial Convention, 2023. Championing Medically Integrated Oncology: CELEBRATING A DECADE OF IMPACT

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 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

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 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, 11, USP-NF, Rockville, MD, United States Pharmacopeial Convention, 2023. Championing Medically Integrated Oncology: CELEBRATING A DECADE OF IMPACT

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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.

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QUESTION 1

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All the following are methods of preventing contamination, except:

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

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Cleaning Agents & Contamination Control in Sterile Compounding

USP <797> & USP <800> Overview

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Types of Cleaning Agents

Detergents	Disinfectants	Sporicidal Agents
- Removes - Dirt - Residues - Debris	- Kills Microorganisms 70% sterile IPA - Quats - Phenolics - Peroxides	- Destroy resistant spores - Bleach - Peroxide Blends

United States Pharmacopeial Convention, General Chapter <107> Pharmaceutical Compounding—Sterile Preparations in USP[®]
NF Monographs, MD: United States Pharmacopeial Convention, 2023, Section 7: Cleaning, Disinfecting, and Applying Sporocidal
Disinfectants and Sterile ISO 5s

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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 - Bleach, Peroxide

United States Pharmacopeial Convention, General Chapter <107> Pharmaceutical Compounding—Sterile Preparations in USP[®]
NF Monographs, MD: United States Pharmacopeial Convention, 2023, Table 10: Minimum Cleaning Frequencies

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Frequency of Use

Regularly	Daily	Monthly	At Least Monthly
When - Start of shift - Before batches - Every 30 mins - After Spills PECs - Rooms - Isolators	Counters Work Surfaces Floors	Walls Ceilings Shelving	Sporicidal Agent

United States Pharmacopeial Convention, General Chapter <107> Pharmaceutical Compounding—Sterile Preparations in USP[®]
NF Monographs, MD: United States Pharmacopeial Convention, 2023, Table 10: Minimum Cleaning Frequencies

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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 10 USP
USP Pharmacopeia, MD, United States Pharmacopeial Convention, 2023 Table 10 Minimum Dwell Time

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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 10 USP
USP Pharmacopeia, MD, United States Pharmacopeial Convention, 2023 Table 10 Minimum Dwell Time

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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

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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)			
Ceiling(s)	• Monthly	• Monthly	• Monthly
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 Pharmacopoeial Convention; 2023

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Documentation Requirements

- Facility Standard Operating Procedures (SOP's)
 - Frequency, methods, and locations of cleaning areas
 - 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 Pharmacopoeial Convention. General Chapter <797> Pharmaceutical Compounding—Sterile Preparations. In: USP-NF. Rockville, MD: United States Pharmacopoeial Convention; 2020. Table 10: Minimum Cleaning Frequencies

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QUESTION 3

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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

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Potential Contamination

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Technique Errors

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Not cleaning clean > dirty, top > bottom

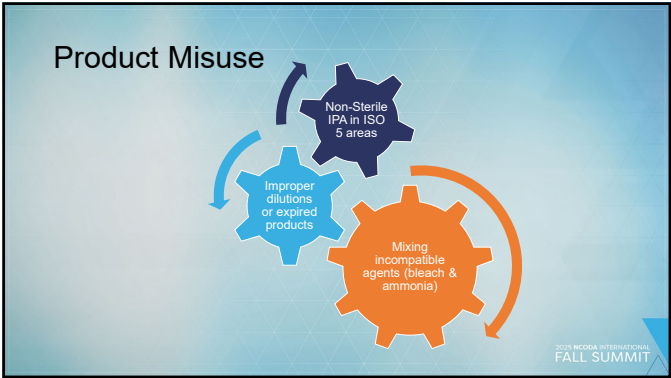
Reusing wipes or mops spreads contamination

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
20</br>24</br> <797> Testing, 401 United States Pharmacopeial Convention, 2020 Section 4: Responsibilities of Compounding Personnel and
Section 7: Cleaning and Disinfection.

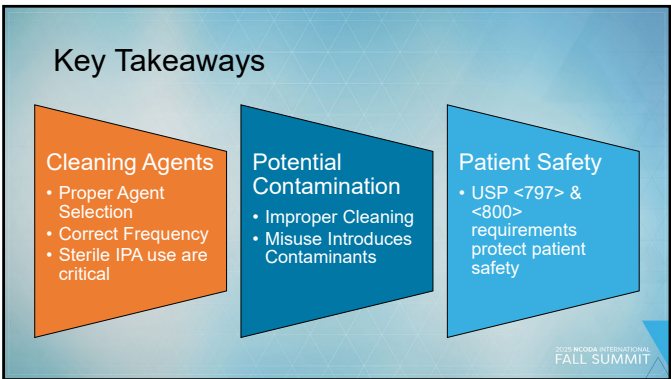
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QUESTION 4

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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

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Real World Case Example

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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

Source: J. Hill Donat. A Shadow Industry: a Deadly Disease. New York, NY: Penguin Random House; 2021.

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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

Sources: J. All Star! A Shadow Industry, a Deadly Disease, New York, NY: Penguin Random House, 2021. Championing Medically Integrated Oncology: CELEBRATING A DECADE OF IMPACT

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Mold Culture Sample



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

Sources: J. All Star! A Shadow Industry, a Deadly Disease, New York, NY: Penguin Random House, 2021. Championing Medically Integrated Oncology: CELEBRATING A DECADE OF IMPACT

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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)

Sources: J. All Star! A Shadow Industry, a Deadly Disease, New York, NY: Penguin Random House, 2021. Championing Medically Integrated Oncology: CELEBRATING A DECADE OF IMPACT

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SUMMARY

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- 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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QUESTION & ANSWER

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**Beyond Clean:
Strategies for Safe Compounding and
Contamination Prevention**

Edil Sanchez, CPhT, CSPT, BCSCPT
Yale New Haven

David Johnson, CPhT-Adv, CSPT
VA Medical Center

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CE CODE

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**Beyond Clean:
Strategies for Safe Compounding
and Contamination Prevention**

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