Welcome

The standard of trust

Open Forum Session

Proposed Revisions to USP General Chapter ⟨797⟩ *Pharmaceutical Compounding – Sterile Preparations*

January 19, 2022
10:00 AM - 12:00 PM EDT

General Chapter ⟨797⟩ Open Forum

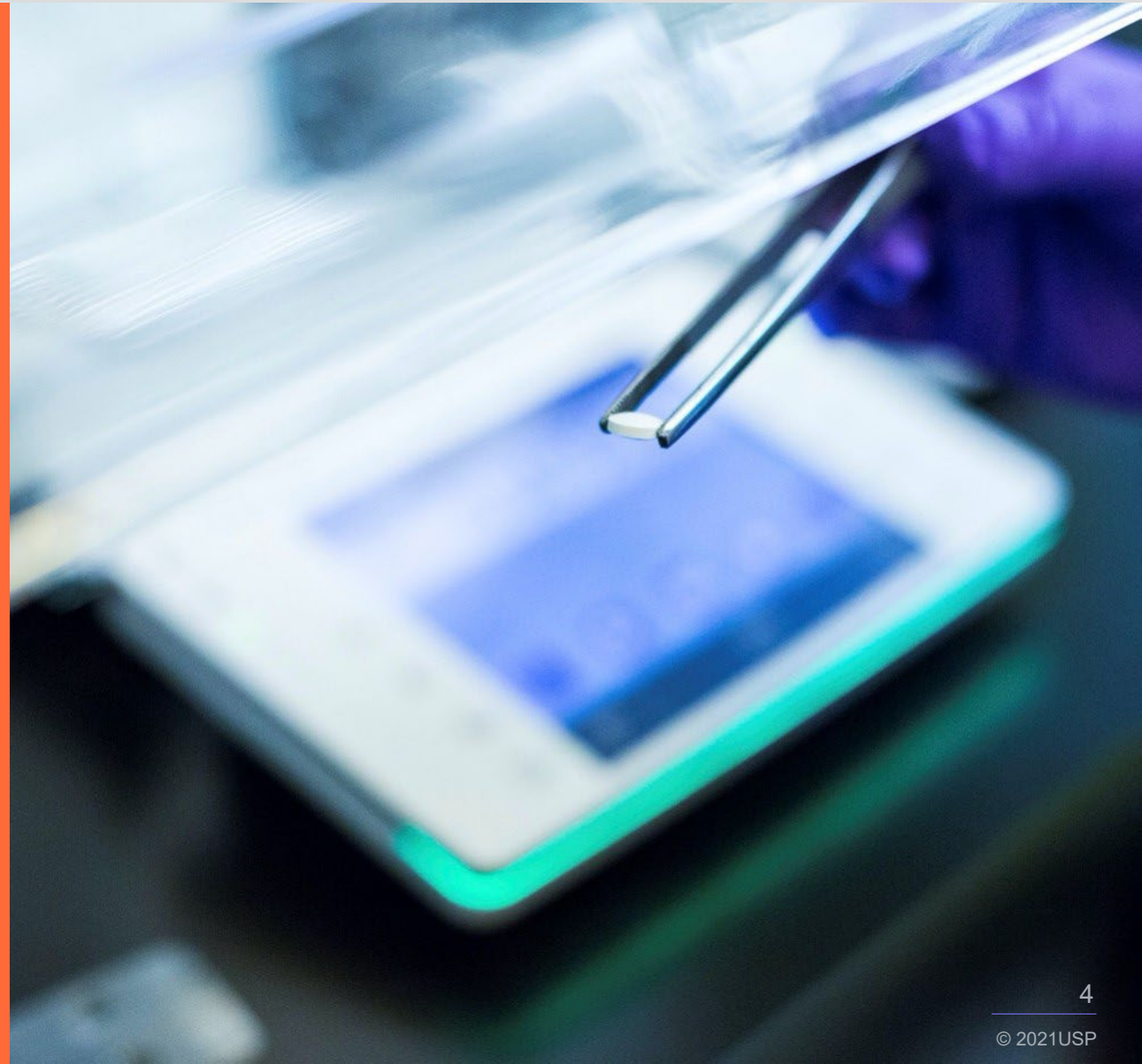
NOTICE TO PARTICIPANTS:

- Please note this session is currently being recorded and will be made available on USP's website at http://www.usp.org/compounding/general-chapter-797
- Disclaimer
  - This open forum is for informational purposes only
  - All comments must be submitted via the public comment form

General Chapter ⟨797⟩ Open Forum

NOTICE TO PARTICIPANTS:

- To minimize background noise, all lines will be muted upon joining the session
- During the meeting, you may ask questions at any time by using the **Q&A** function
  - Select the Q&A icon on the bottom right-hand column of your WebEx view page
  - Use the text box at the bottom to enter your question, and hit send
- Questions will be collated for the Q&A portion of the session



Agenda

Session Overview	Speakers
Welcome	Selma Mitiche, Senior Scientist, Personalized Medicines
• USP Overview • Background • Overview of Revised General Chapter ⟨797⟩ *Pharmaceutical Compounding – Sterile Preparations* • Supplementary Materials	Brenda Jensen, Chair, Compounding Expert Committee Connie Sullivan, Chair, ⟨797⟩ Subcommittee
Submitting Comments Next Steps	Selma Mitiche, Senior Scientist, Personalized Medicines
Question & Answer Session	**Moderator:** Selma Mitiche, Senior Scientist, Personalized Medicines **Panelists:** Compounding Expert Committee

USP Overview

The 2020 – 2025 Council of Experts

Biologics

Biologics Monographs 1–Peptides & Oligonucleotides
Michael De Felippis

Biologics Monographs 2–Proteins
Wendy Saffell-Clemmer

Biologics Monographs 3–Complex Biologics & Vaccines
Earl Zablackis

Biologics Monographs 4–Antibiotics
Matthew Borer

Biologics Monographs 5–Advanced Therapies
Mehrshid Alai

Small Molecules

Small Molecules 1
Mary Seibel

Small Molecules 2
Justin Pennington

Small Molecules 3
Eric Kesslen

Small Molecules 4
Kim Huynh-Ba

Small Molecules 5
Amy Karren

Over-the-Counter (OTC) Methods & Approaches
Raphael Ornaf

Excipients

Simple Excipients
Eric Munson

Complex Excipients
Otilia Koo

Excipients Test Methods
Chris Moreton

General Chapters

General Chapters–Dosage Forms
Martin Coffey

General Chapters–Chemical Analysis
Nancy Lewen

General Chapters–Microbiology
Donald Singer

General Chapters–Packaging & Distribution
Renaud Janssen

General Chapters–Measurement & Data Quality
Jane Weitzel

General Chapters–Statistics
Charles Tan

General Chapters–Physical Analysis
Xiaorong He

Healthcare Quality & Safety

Nomenclature & Labeling
Stephanie Crawford

Healthcare Safety & Quality
Melody Ryan

Compounding
Brenda Jensen

Healthcare Information & Technology
Jeanne Tuttle

Dietary Supplements & Herbal Medicines, Food Ingredients

Botanical Dietary Supplements & Herbal Medicines
Robin Marles

Non-botanical Dietary Supplements
Guido F Pauli

Dietary Supplements Admission Evaluation & Labeling
Tieraona Low Dog

Food Ingredients
Jon DeVries

2020 – 2025 Compounding Expert Committee

Chair: Brenda Jensen, MBA, Owner and Compounding Pharmacy Consultant, Compounding Consultants, LLC
Vice Chair: Robert Shrewsbury, Ph.D., Associate Professor, UNC Eshelman School of Pharmacy

EC Member	Affiliation
Lisa Ashworth, B.S. Pharm.	Compounding Specialist and Clinical Pharmacist, Children's Health System of Texas
Phil Ayers, Pharm.D.	Chief, Clinical Pharmacy Services, Mississippi Baptist Medical Center
Gus Bassani, Pharm.D.	Chief Scientific Officer, PCCA
Suzanne Blevins, B.Sc.	Laboratory Director, Aerobiology Laboratory
Brett Cordes, DVM	Veterinarian, Private Practice
Gigi Davidson, B.S. Pharm.	Veterinary Pharmacy Consultant, VetPharm Consulting, LLC
Edmund Elder, Ph.D., B.S. Pharm.	Director, Zeeh Pharmaceutical Experiment Station, University of Wisconsin-Madison
Kevin Hansen, Pharm.D., MS	Assistant Director of Pharmacy, Cone Health
Patricia Kienle, MPA, B.S. Pharm.	Director, Accreditation and Medication Safety, Cardinal Health
Vanessa Pinheiro, M.S., B.S. Pharm.	Pharmacist and Consultant, Medisca and LP3 Network
Elizabeth Rebello, M.D., B.S. Pharm.	Professor and Anesthesiologist, University of Texas MD Anderson Cancer Center
Rick Rhoads, Pharm.D.	Director of Compounding, University Compounding Pharmacy
Connie Sullivan, B.S. Pharm.	President and CEO, National Home Infusion Association

How we work

Stakeholders

USP actively seeks engagement with stakeholders throughout the standard-setting process through stakeholder meetings, advisory roundtables, and open-microphone webinars.

- Healthcare Practitioners
- Patients
- Academicians
- Healthcare Industry
- Regulatory Authorities
- Manufacturers

USP Process

1. Public Health Need
- Need identified by any stakeholder or USP
- Need evaluated for possible standard development

2. Draft Standard
- Best practices and scientific information collected

3. Public Comment Period
- Draft standard published for stakeholder input

4. Review & Approval
- Comments evaluated and addressed <or> Comments evaluated and further revision and comment needed

Revision Continues

Approved

5. Publication
- Final standard published with official date at least 6 months after publication

USP Expert Committee

USP convenes a committee of independent experts that are knowledgeable on the public health issue to develop the standard.

- Healthcare Practitioners
- Academicians
- Healthcare Industry
- Regulatory Authorities (Non-voting Liaisons)
- Manufacturers

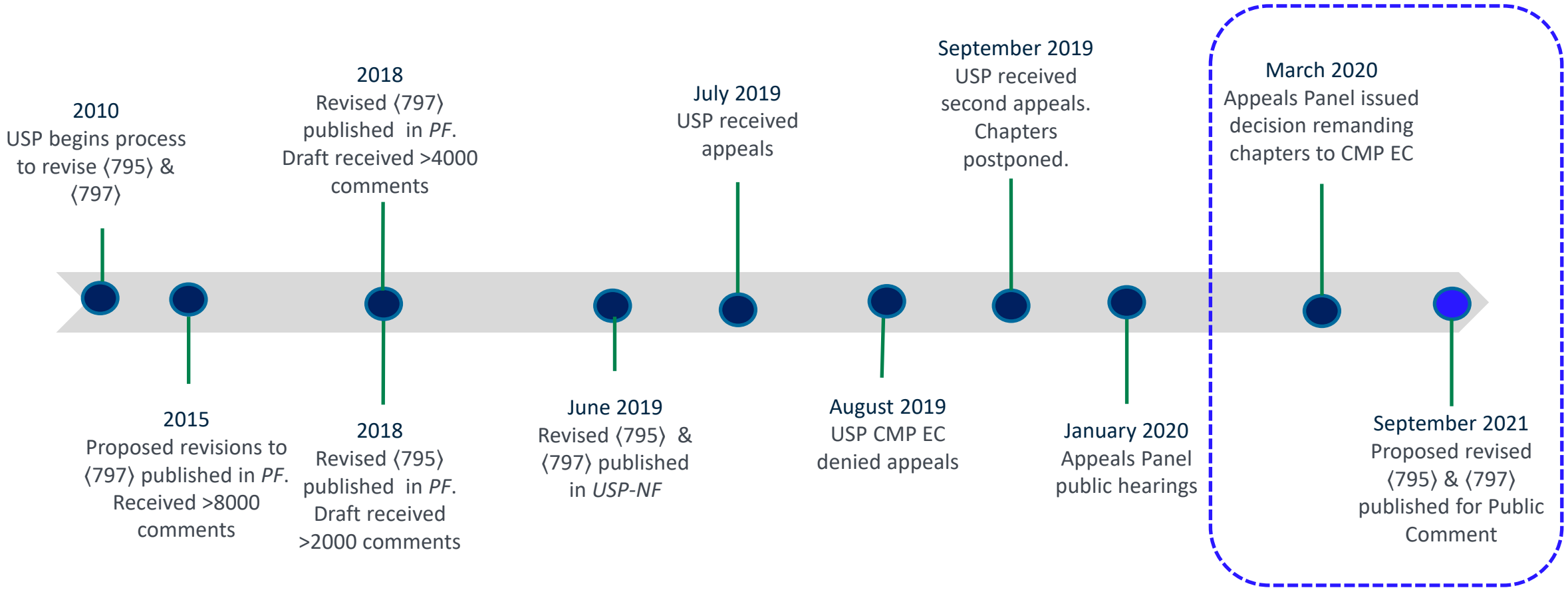
Stakeholder Implementation

Regulatory Authorities, State Practice Boards, Healthcare Industry, Healthcare Practitioners and other stakeholders utilize USP Healthcare Quality & Safety standards within their specific authority to help ensure public health.

History of ⟨797⟩

- **First Sterile Compounding Standard**
  - ⟨1074⟩ *Dispensing Practices for Sterile Drug Products Intended for Home Use* **(1992)**
  - ⟨1206⟩ *Sterile Drug Products for Home Use* **(1995)**
- **General Chapter ⟨797⟩**
  - Published in USP27-NF22 **(2004)**
    - Incorporated ⟨1206⟩
  - Revised in USP USP31-NF26 2S **(2008)**
    - CURRENTLY OFFICIAL

History of Revisions and Appeals



Approach to Revisions after the Appeals

- The Appeals Panel held public hearings in January 2020 regarding the proposed ⟨797⟩ chapter
  - The Appeals Panel remanded the proposed chapter to the Compounding Expert Committee (CMP EC) with a recommendation for further engagement on the issues raised by stakeholders, particularly concerning beyond-use date (BUD) provisions
  - The Appeals Panel did not determine the chapters to require revision, but noted that the issues raised in the appeals warranted additional dialogue and consideration
  - It was left to the purview of the CMP EC to determine the appropriateness of future revisions to the chapter, if any

Approach to Revisions after the Appeals

- Stakeholder Engagement
  - Reviewed feedback, including *PF* public comments and issues raised in the appeals
  - Held stakeholder semi-structured interviews (May 2020)
  - Roundtable session (July 28, 2020)
  - Open forum (September 15, 2020)
- Identified key stakeholder engagement discussion topics as a framework
- Also had general considerations throughout the review process
  - Scientifically robust, risk-based approach to assigning BUDs
  - Physical and chemical stability considerations
  - Sterility assurance
  - Operational implications
  - Balancing the need for patient access to cost-effective CSPs with rigorous quality standards
  - Implications on regulatory oversight and enforcement

Overview of Revised General Chapter ⟨797⟩ *Pharmaceutical Compounding – Sterile Preparations*

Purpose of Current Revision

- To address the information raised in the appeals and from stakeholder engagement sessions
- To address areas requiring further clarification
- To align revisions with:
  - ⟨795⟩ *Pharmaceutical Compounding – Nonsterile Preparations*
  - ⟨800⟩ *Hazardous Drugs – Handling in Healthcare Settings*
- Supplementary materials were also developed to complement navigation of the chapter

⟨797⟩ Proposed Revisions

Proposed Chapter Outline

1. Introduction and Scope
2. Personnel Training and Evaluation
3. Personal Hygiene and Garbing
4. Facilities and Engineering Controls
5. Certification and Recertification
6. Microbiological Air and Surface Monitoring
7. Cleaning, Disinfecting, and Applying Sporicidal Disinfectants in Compounding Areas
8. Introducing Items into the SEC and PEC
9. Equipment, Supplies, and Components
10. Sterilization and Depyrogenation
11. Master Formulation and Compounding Records
12. Release Inspections and Testing
13. Labeling
14. Establishing Beyond-Use Dates
15. Use of Conventionally Manufactured Products as Components
16. Use of CSPs as Components
17. SOPs
18. Quality Assurance and Quality Control
19. CSP Handling, Storage, Packaging, Shipping, and Transport
20. Documentation
21. Compounding Allergenic Extracts

- Glossary

⟨797⟩ Proposed Revisions

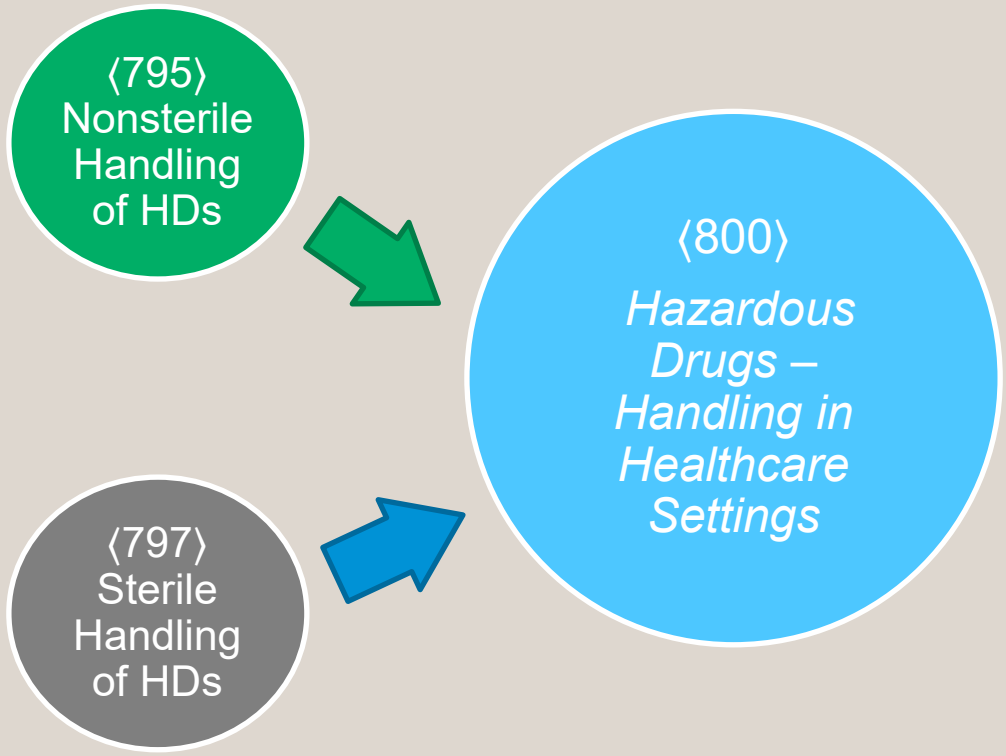
Administration is out of the scope of the chapter

- Sterile compounding is defined as:
  - Combining
  - Admixing
  - Diluting
  - Pooling
  - Reconstituting
  - Repackaging
  - Otherwise altering a drug or bulk drug substance to create a sterile medication

⟨797⟩ Proposed Revisions

Scope

- *Eliminates* provisions for handling of hazardous drugs
  - Compounded sterile hazardous drugs *are subject to* ⟨800⟩



- *Eliminates* provisions for radiopharmaceuticals
  - Compounding radiopharmaceuticals *are subject to* ⟨825⟩ *Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging*

⟨797⟩ Proposed Revisions

Alternative Technologies

- The use of technologies, techniques, materials, and procedures other than those described in this chapter is not prohibited as long as they are noninferior to those described herein
- The alternative technologies, techniques, or materials must not be used to modify requirements outlined in this chapter (e.g., extending beyond-use dates, the amount of time a single-dose or multiple-dose container may be used, compounding in alternative environments)

⟨797⟩ Proposed Revisions

Immediate-Use CSPs

Requirements for Immediate-Use CSPs
Aseptic techniques, processes, and procedures are followed, and written SOPs are in place to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, and mix-ups with other conventionally manufactured products or CSPs.
Personnel are trained and demonstrate competency in aseptic processes as they relate to assigned tasks and the facility's SOPs.
The preparation is performed in accordance with evidence-based information for physical and chemical compatibility of the drugs (e.g., approved labeling, stability and compatibility studies).
The preparation involves not more than 3 different sterile products.
Any unused starting component from a single-dose container must be discarded after preparation for the individual patient is complete. Single-dose containers must not be used for more than one patient.
Administration begins within 4 hours following the start of preparation. If administration has not begun within 4 hours following the start of preparation, it must be promptly, appropriately, and safely discarded.
Unless administered by the person who prepared it or administration is witnessed by the preparer, the CSP must be labeled with the names and amounts of all active ingredients, the name or initials of the person who prepared the preparation, and the exact 4-hour time period within which administration must begin.

⟨797⟩ Proposed Revisions

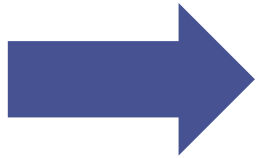
Preparation Per Approved Labeling

- Clarifies that compounding does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling
- Preparing a conventionally manufactured sterile product in accordance with the directions in the manufacturer's approved labeling is out of scope of this chapter only if:
  - The product is prepared as a single dose for an individual patient; and
  - The approved labeling includes information for the diluent, the resultant strength, the container closure system, and storage time
- Proprietary bag and vial systems
  - Docking and activation in accordance with the manufacturer's labeling for *immediate* administration to an individual patient is not considered compounding and may be performed outside of an ISO Class 5 environment
  - Docking for *future activation* and administration is considered compounding and must be performed in accordance with this chapter, with the exception of *14. Establishing Beyond-Use Dates*. BUDs for proprietary bag and vial systems must not be longer than those specified in the manufacturer's labeling

⟨797⟩ Proposed Revisions

Categories of CSPs

- High-Risk
- Medium-Risk
- Low-Risk
- Low-Risk with 12 Hour BUD



Category 1 CSPs

- May be prepared in a PEC located in an unclassified segregated compounding area
- Assigned a BUD of ≤ 12 hours at controlled room temperature or ≤ 24 hours when refrigerated

Category 2 CSPs

- Must be prepared in a cleanroom suite
- May be assigned a BUD of > 12 hours at controlled room temperature or > 24 hours if refrigerated

Category 3 CSPs

- Have additional requirements that must be met at all times
- May be assigned a BUD longer than established for Category 2 CSPs, up to 180 days

⟨797⟩ Proposed Revisions

Personnel Qualifications

	Currently Official Chapter (2008)	2015 Revision Proposal	2018 Revision Proposal	2019 Remanded Chapter	2021 Revision Proposal
Visual observation of hand hygiene and garbing	Annually	Every 3 months	Every 6 months	Every 6 months	**Category 1 & 2:** Every 6 months **Category 3:** Every 3 months for personnel who compound Category 3 CSPs
Gloved fingertip and thumb sampling	**Low/Medium-Risk CSPs:** Annually **High-Risk CSPs:** Semi-annually	Every 3 months	Every 6 months	Every 6 months	**Category 1 & 2:** Every 6 months **Category 3:** Every 3 months for personnel who compound Category 3 CSPs as part of garbing competency and aseptic competency
Media-fill testing	**Low/Medium-Risk CSPs:** Annually **High-Risk CSPs:** Semi-annually	Every 3 months	Every 6 months	Every 6 months	**Category 1 & 2:** Every 6 months **Category 3:** Every 3 months for personnel who compound Category 3 CSPs

⟨797⟩ Proposed Revisions

Minimum Garbing Requirements

Currently Official Chapter (2008)	2015 Revision Proposal	2018 Revision Proposal	2019 Remanded Chapter	2021 Revision Proposal
• Gown • Dedicated shoes or shoe covers • Head and facial hair covers • Face masks • Sterile gloves	Determined based on: • Category • Type of PEC Included: • Gown or coveralls • Disposable covers for shoes • Disposable covers for head and facial hair • Sterile gowns or sleeves • Sterile gloves	• Gown • Disposable covers for shoes • Disposable covers for head and facial hair • Face mask • Sterile gloves If using RABS → disposable gloves inside of gauntlet gloves	• Gown • Disposable covers for shoes • Disposable covers for head and facial hair • Face mask • Sterile gloves If using RABS → disposable gloves inside of gauntlet gloves	• Low-lint garment with sleeves that fit snugly around the wrists and an enclosed neck (e.g., gowns) • Low-lint covers for shoes • Low-lint cover for head that covers the hair and ears, and if applicable, cover for facial hair • Low-lint face mask • Sterile powder-free gloves • If using a RABS, (i.e., a CAI or CACI), disposable gloves should be worn inside the gloves attached to the RABS sleeves. Sterile gloves must be worn over the gloves attached to the RABS sleeve

⟨797⟩ Proposed Revisions

Minimum Garbing Requirements

2021 Revision Proposal – Category 3

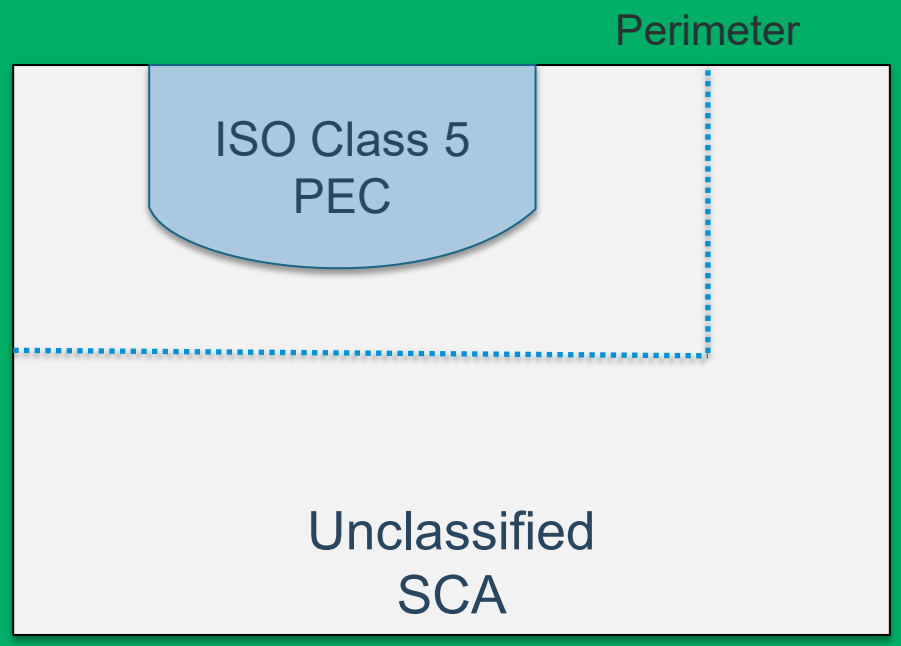
If the facility compounds Category 3 CSPs, additional garbing requirements must be continuously met. The following additional garbing requirements must be followed in the cleanroom suite where Category 3 CSPs are prepared for all personnel regardless of whether Category 3 CSPs are compounded on a given day:

1. Not allow any exposed skin in the buffer room. (i.e., face and neck must be covered)
2. All low-lint garb must be sterile
3. Disposable garbing items must not be reused, and laundered garb must not be reused without being laundered and resterilized with a validated cycle

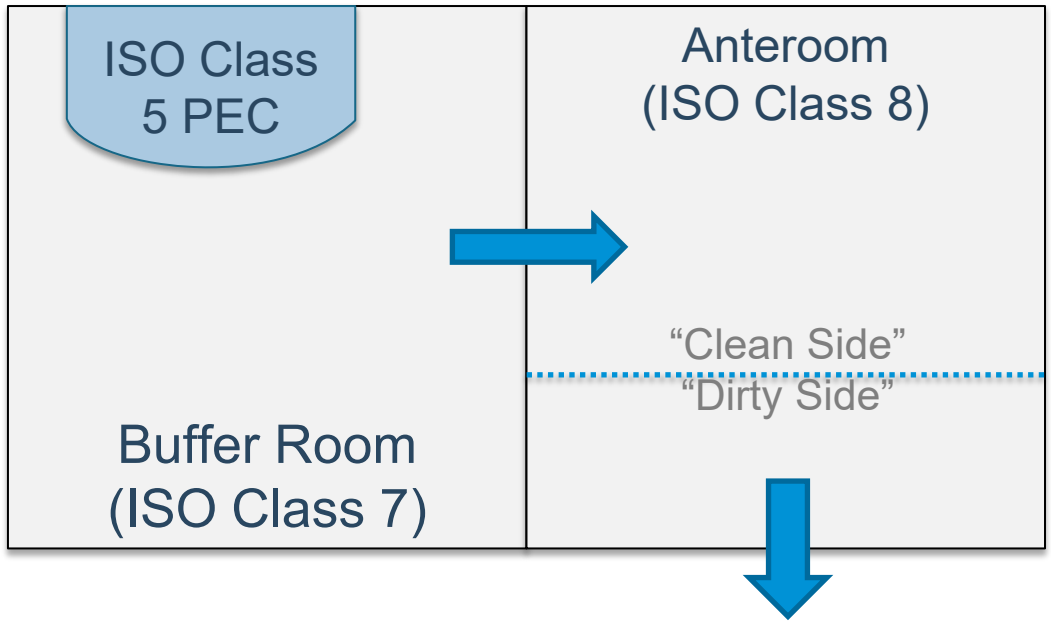
⟨797⟩ Proposed Revisions

Minimum PEC Placement

Category 1 CSPs



Category 2 or 3 CSPs



⟨797⟩ Proposed Revisions

Microbiological Air and Surface Monitoring

	Currently Official Chapter (2008)	2015 Revision Proposal	2018 Revision Proposal	2019 Remanded Chapter	2021 Revision Proposal
Viable air sampling	Every 6 months	Monthly	Every 6 months	Every 6 months	**Category 1 & 2:** Every 6 months **Category 3:** Monthly
Surface sampling	Periodically	Monthly	Monthly	Monthly	**Category 1 & 2:** Monthly **Category 3:** Weekly

⟨797⟩ Proposed Revisions

Cleaning, Disinfecting, and Applying Sporicidal Disinfectants in Compounding Areas

- Frequencies specified for separate activities
  - Cleaning
  - Disinfecting
  - Applying a sporicidal disinfectant
- Cleaning supplies (e.g., wipers, sponges, pads, and mop heads)
  - Must be low-lint
  - Should be disposable
  - Reusable cleaning tools must be dedicated for use

⟨797⟩ Proposed Revisions

Cleaning, Disinfecting, and Applying Sporicidal Disinfectants in Compounding Areas

- Cleaning and disinfecting supplies used in the PEC must be sterile with the exception of tool handles and holders, which must be cleaned and disinfected prior to use in a PEC
  - Sterile cleaning agent
  - Sterile disinfecting agent
  - Sterile sporicidal disinfectant
  - Sterile water
  - Sterile 70% IPA

- Reusable cleaning tools must be made of cleanable materials and must be cleaned and disinfected before and after each use
  - e.g., handles should not be made of wood or any other porous material

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Master Formulation and Compounding Records

Master Formulation Record

- Required for
  - Category 1, Category 2, Category 3, and immediate-use CSPs prepared for more than one patient
  - CSPs prepared from nonsterile ingredient(s)

Compounding Record

- Required for
  - Category 1, Category 2, Category 3, and immediate-use CSPs prepared for more than one patient
  - CSPs prepared from nonsterile ingredient(s)
- May be in the form of prescription or medication order, or label
- May be stored electronically through ACD, workflow management system, or other similar equipment
  - As long as it is retrievable and contains the required information

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Release Inspections and Testing

Visual Inspection

Sterility Testing

- Required for **Category 2** CSPs assigned a BUD that requires sterility testing, and for all **Category 3** CSPs
- **The maximum batch size for all CSPs requiring sterility testing must be limited to 250 final yield units**
- If the number of CSPs to be compounded in a single batch is less than the number of CSPs needed for testing as specified in *USP* ⟨71⟩, *Table 3*, additional units must be compounded to perform sterility testing
  - If between 1 and 39 CSPs, test number of units equal to 10% of CSPs prepared
  - If > 40 CSPs, test based on *USP* ⟨71⟩, *Table 3*
- If an alternative method is used for sterility testing, the method must be validated (see ⟨1223⟩) and demonstrated to be suitable for that CSP formulation

⟨797⟩ Proposed Revisions

Release Inspections and Testing

Bacterial Endotoxins Testing

- Required for
  - **Category 2** injectable CSPs compounded from one or more nonsterile component(s) and assigned a BUD that requires sterility testing
  - **Category 3** injectable CSPs compounded from one or more nonsterile component(s)

- **Category 2** CSPs assigned a BUD that does not require sterility testing, but made from one or more nonsterile component(s) **should** be tested

⟨797⟩ Proposed Revisions

Establishing Beyond-Use Dates

Stability factors

- Chemical and physical stability properties of the drug and/or its formulation
- Compatibility of the container closure system with the finished preparation (e.g., leachables, interactions, adsorption, and storage conditions)

Sterility factors

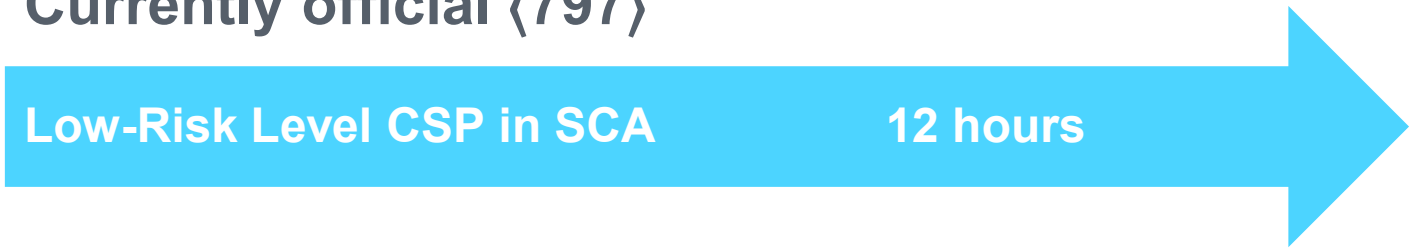
- Conditions of the environment in which the CSP is prepared
  - Cleanroom suite or SCA
- Aseptic processing and sterilization method
- Starting components
  - Sterile or nonsterile starting ingredients
- Whether or not sterility testing is performed
- Storage conditions
  - Packaging and temperature

⟨797⟩ Proposed Revisions

Category 1 CSP BUDs

Storage Conditions	
Controlled Room Temperature (20°–25°)	Refrigerator (2°–8°)
≤ 12 hours	≤ 24 hours

Currently official ⟨797⟩



⟨797⟩ Proposed Revisions

Category 2 CSP BUDs

Preparation Characteristics		Storage Conditions		
Compounding Method	Sterility Testing Performed & Passed	Controlled Room Temperature (20°–25°)	Refrigerator (2°–8°)	Freezer (−25° to −10°)
Aseptically processed CSPs	No	Prepared from one or more nonsterile starting component(s): 1 day	Prepared from one or more nonsterile starting component(s): 4 days	Prepared from one or more nonsterile starting component(s): 45 days

Currently official ⟨797⟩

High-Risk Level CSPs	1 day	3 days	45 days

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Category 2 CSP BUDs

Preparation Characteristics		Storage Conditions		
Compounding Method	Sterility Testing Performed & Passed	Controlled Room Temperature (20°–25°)	Refrigerator (2°–8°)	Freezer (−25° to −10°)
Aseptically processed CSPs	No	Prepared from only sterile starting components: 4 days	Prepared from only sterile starting components: 10 days	Prepared from only sterile starting components: 45 days

Currently official ⟨797⟩

Medium-Risk Level CSPs	**30 hours**	**9 days**	**45 days**
Low-Risk Level CSPs	**48 hours**	**14 days**	**45 days**

⟨797⟩ Proposed Revisions

Category 2 CSP BUDs

Preparation Characteristics		Storage Conditions		
Compounding Method	**Sterility Testing Performed & Passed**	**Controlled Room Temperature (20°–25°)**	**Refrigerator (2°–8°)**	**Freezer (−25° to −10°)**
Aseptically processed CSPs	No	Prepared from one or more nonsterile starting component(s): 1 day	Prepared from one or more nonsterile starting component(s): 4 days	Prepared from one or more nonsterile starting component(s): 45 days
		Prepared from only sterile starting components: 4 days	Prepared from only sterile starting components: 10 days	Prepared from only sterile starting components: 45 days
	Yes	30 days	45 days	60 days
Terminally sterilized CSPs	No	14 days	28 days	45 days
	Yes	45 days	60 days	90 days

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Category 3 CSP BUDs

Preparation Characteristics	Storage Conditions		
Compounding Method	**Controlled Room Temperature (20°–25°)**	**Refrigerator (2°–8°)**	**Freezer (-25°–10°)**
Aseptically processed, sterility tested, and passing all applicable tests for Category 3 CSPs	60 days	90 days	120 days
Terminally sterilized, sterility tested, and passing all applicable tests for Category 3 CSPs	90 days	120 days	180 days

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Additional Requirements for Category 3 CSPs

- Category 3 CSPs undergo sterility testing, supplemented by endotoxin testing when applicable, and have more requirements than Category 2 CSPs for
  - Personnel qualification
  - Use of sterile garb
  - Frequency of applying sporicidal disinfectants
  - Frequency of environmental monitoring
  - Stability determination
- The maximum batch size for all CSPs requiring sterility testing must be limited to 250 final yield units

⟨797⟩ Proposed Revisions

Multiple-Dose CSPs

- A multiple-dose CSP must be prepared as a Category 2 or Category 3 CSP
- For preserved aqueous multiple-dose CSPs, antimicrobial effectiveness testing must be passed in accordance with *USP* ⟨51⟩
- Time within which multiple-dose preserved CSPs must be used:
  - Whichever is shorter:
    - BUD limit assigned based on if CSP is compounded as Category 2 (*Table 11*) or Category 3 (*Table 12*)
    - Up to 28 days after container is initially entered or punctured, if supported by ⟨51⟩ testing
- Time within which multiple-dose nonpreserved aqueous ophthalmic CSPs must be used:
  - BUD limit assigned based on if CSP is compounded as Category 2 (*Table 11*) or Category 3 (*Table 12*), and
  - Discarded 24 hours after first opening if stored at room temperature, or 72 hours if refrigerated

Supplementary Materials

⟨797⟩ Supplementary Materials

DISCLAIMER

- These supplemental documents are **not part of the proposed chapters**, are **not comprehensive overviews** of the proposed chapters, and are **not intended to be used in place** of the proposed chapters

- These documents **do not reflect the CMP EC's opinions on further revisions to the chapters**

- These documents are **not intended to be subject to public comment**
  - Stakeholders are encouraged to submit comments on the proposed chapters for the CMP EC to continue to evaluate revisions to the chapters
  - The CMP EC will consider all comments received on the chapters

- Please note that **neither the proposed chapters nor these documents are official *United States Pharmacopeia – National Formulary* (*USP–NF*) text**, and they are not intended to be enforceable by regulatory authorities
  - Users must refer to the *USP–NF* for official text

⟨797⟩ Supplementary Materials

- BUD Reference for the 2021 Proposed Revisions to ⟨797⟩
  - Resource for assigning the proposed BUDs and comparing the requirements for the different proposed CSP categories
- CMP EC Responses to Stakeholder Engagement Themes for the 2021 Proposed Revisions to ⟨797⟩
  - Responses and proposed chapter revisions made based on stakeholder engagement
- BUD Scientific Rationale for the 2021 Proposed Revisions to ⟨797⟩
  - Evolution of USP's BUD limits at USP
  - Rationale for the proposed BUD limits
- Stability Study Reference Document for the 2021 Proposed Revisions to ⟨795⟩ and ⟨797⟩
  - Explanation of the details and purpose of stability studies
  - Resources for conducting a study
- All supplementary resources are posted online with the proposed chapters
  - https://go.usp.org/Proposed_2021_Revisions_795_797

Submitting Comments

Submitting Comments

- All information related to ⟨797⟩ is on the USP Compounding Page
  - http://www.usp.org/compounding/general-chapter-797
- The proposed chapters and supplementary materials are posted online at
  - https://go.usp.org/Proposed_2021_Revisions_795_797
- The ⟨797⟩ electronic submission form is at
  - https://usp.az1.qualtrics.com/jfe/form/SV_81VZpnzjwcQJlZA

⟨797⟩ Public Comment Form

Link to the public comment form can also be found in the briefing statement of the chapter

BRIEFING

⟨797⟩ Pharmaceutical Compounding—Sterile Preparations. This proposal is based on the version of the chapter official as of May 1, 2020. The Compounding Expert Committee proposes to revise this chapter to improve clarity and to respond to stakeholder input. Major edits to the chapter include:

1. Reorganize the chapter to group similar topics and clarify requirements. Include section and subsection numbers and place procedural information in boxes.
2. Expand guidance for assigning beyond-use dates (BUD) for compounded sterile preparations (CSPs).
3. Rename CSP microbial risk levels and update terminology. Category 1 and 2 CSPs are distinguished primarily by the facility in which they are made and the length of time within which they must be used. Category 1 CSPs have shorter BUDs and may be prepared in an unclassified segregated compounding area; Category 2 CSPs have longer BUDs and must be prepared in a cleanroom suite. Additionally, Category 3 CSPs are those that may be assigned longer BUDs than the limits for Category 1 or Category 2 CSPs, up to 180 days, if additional requirements are met.
4. Add a maximum batch size of 250 final yield units for all CSPs requiring sterility testing.
5. Add guidance on assigning BUDs to compounded multiple-dose containers, including information on assigning BUDs for non-preserved ophthalmic CSPs.
6. Add guidance on the use and storage of entered or punctured conventionally manufactured products.
7. Add information on notification and recall of CSPs with out-of-specification results.
8. Clarify requirements for compounding allergenic extract prescription sets.
9. Add requirements for maintaining master formulation and compounding records.
10. Provide guidance on the use of isolators.
11. Remove specific information related to the handling of hazardous drugs and add cross-references to *Hazardous Drugs—Handling in Healthcare Settings* ⟨800⟩
12. Remove specific information related to radiopharmaceuticals as CSPs and add cross-references to *Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging* ⟨825⟩.

A copy of this proposal and additional supplementary materials are posted online here.
Please submit comments using the electronic submission form here.
Additionally, minor editorial changes have been made to update this chapter to current *USP* style.

⟨797⟩ Public Comment Form

Public Comments requested through the electronic submission form

Welcome to the electronic form for submitting your comments on USP's proposed General Chapter <797> Pharmaceutical Compounding – Sterile Preparations.

USP General Chapter <797> provides standards for compounding quality sterile preparations. The chapter describes requirements for the compounding process, facilities, equipment, components, documentation, quality controls, and training.

The USP Compounding Expert Committee proposes to revise General Chapter <797> to improve clarity and respond to stakeholder input. The revision proposal is available at www.uspnf.com/notices/general-chapter-797-proposed-revisions.

If you have any questions, please email CompoundingSL@usp.org.

Please enter your contact information

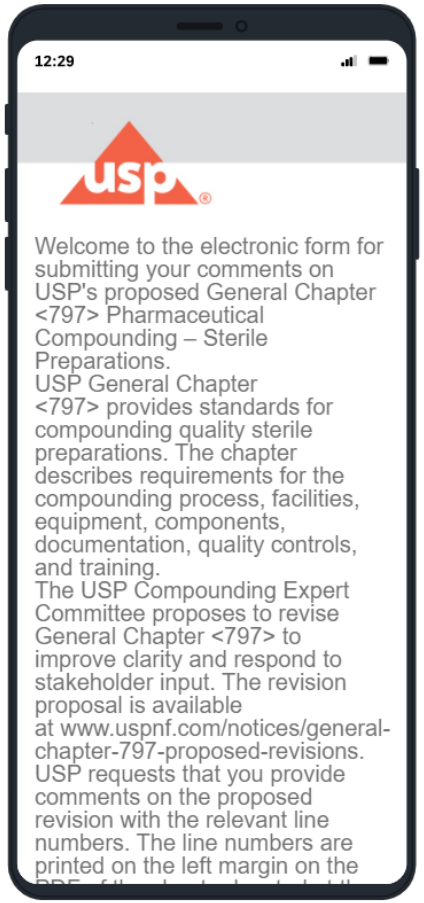
First Name

Last Name

Email

Title

Organization



⟨797⟩ Public Comment Form

Please enter your contact information

First Name

Last Name

Email

Title

Organization

Address

Address 1

Address 2

City

State

Zip

Country

Please select the type of organization that most closely represents where you work

- Government Agency
- Health Plan
- Healthcare Association
- Healthcare Practitioner
- Healthcare Professional Associations
- Patient

→

⟨797⟩ Public Comment Form

I am submitting these comments on behalf of:

Myself

My Organization

Please indicate the type of comments you have for General Chapter <797>.

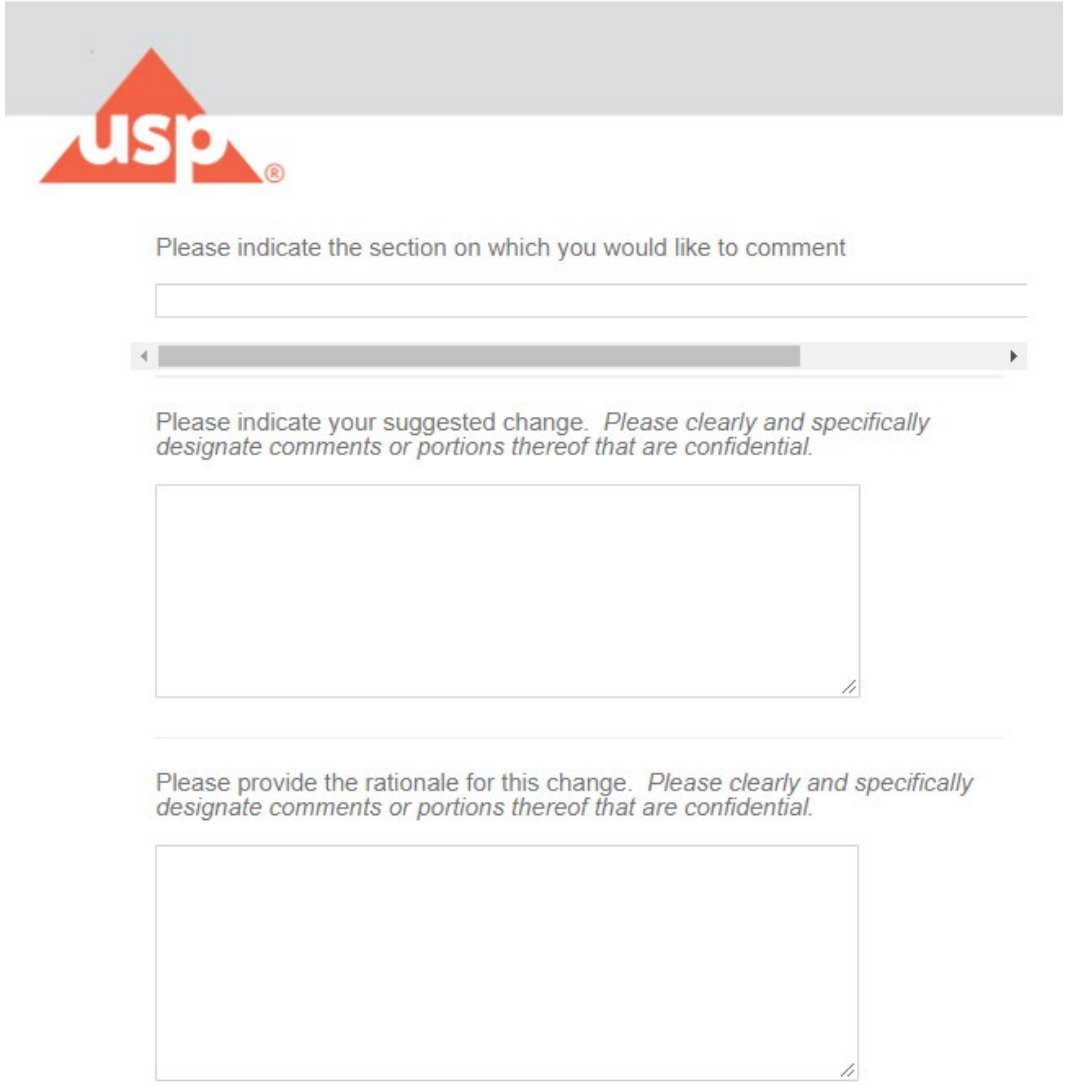
- **Specific Comments** - Please select this option if you have comments about a specific section. You will have the opportunity to submit multiple comments in this form.
- **General Comments** - Please select this option if you have comments that do not correspond to a specific section.

If you have both specific and and general comments, please check both boxes. Please clearly and specifically designate comments or portions thereof that are confidential.

Specific Comments

General Comments

⟨797⟩ Public Comment Form



Please indicate the section on which you would like to comment

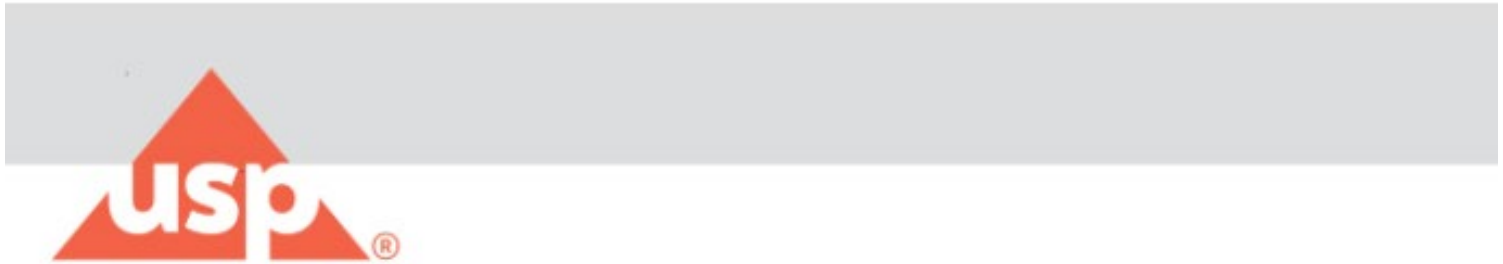
Please indicate your suggested change. *Please clearly and specifically designate comments or portions thereof that are confidential.*

Please provide the rationale for this change. *Please clearly and specifically designate comments or portions thereof that are confidential.*

Please indicate the section on which you would like to comment

1. INTRODUCTION AND SCOPE
1.1. Scope
1.2. Administration
1.3. Immediate Use CSPs
1.4. Preparation Per Approved Labeling
1.5. CSP Categories
2. PERSONNEL TRAINING AND EVALUATION
2.1. Demonstrating Knowledge and Competency of Core Skills
2.2. Demonstrating Competency in Garbing and Hand Hygiene
2.3. Competency Testing in Aseptic Manipulation
3. PERSONAL HYGIENE AND GARBING
3.1. Personnel Preparation
3.2. Hand Hygiene
3.3. Garbing Requirements
4. FACILITIES AND ENGINEERING CONTROLS
4.1. Protection from Airborne Contaminants
4.2. Facility Design and Environmental Controls
4.3. Creating Areas to Achieve Easily Cleanable Conditions
4.4. Water Sources

⟨797⟩ Public Comment Form

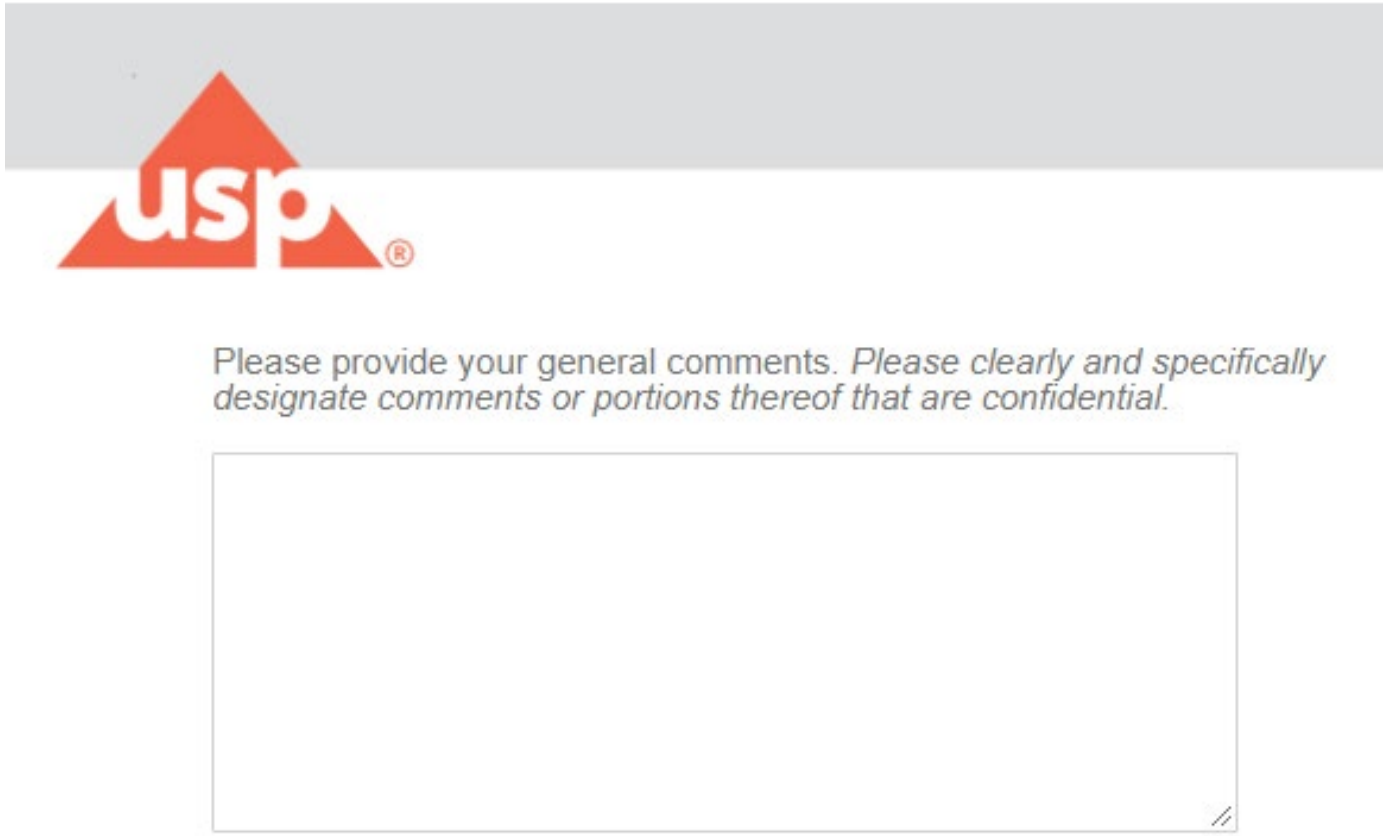


Do you have additional specific comments you would like to share?

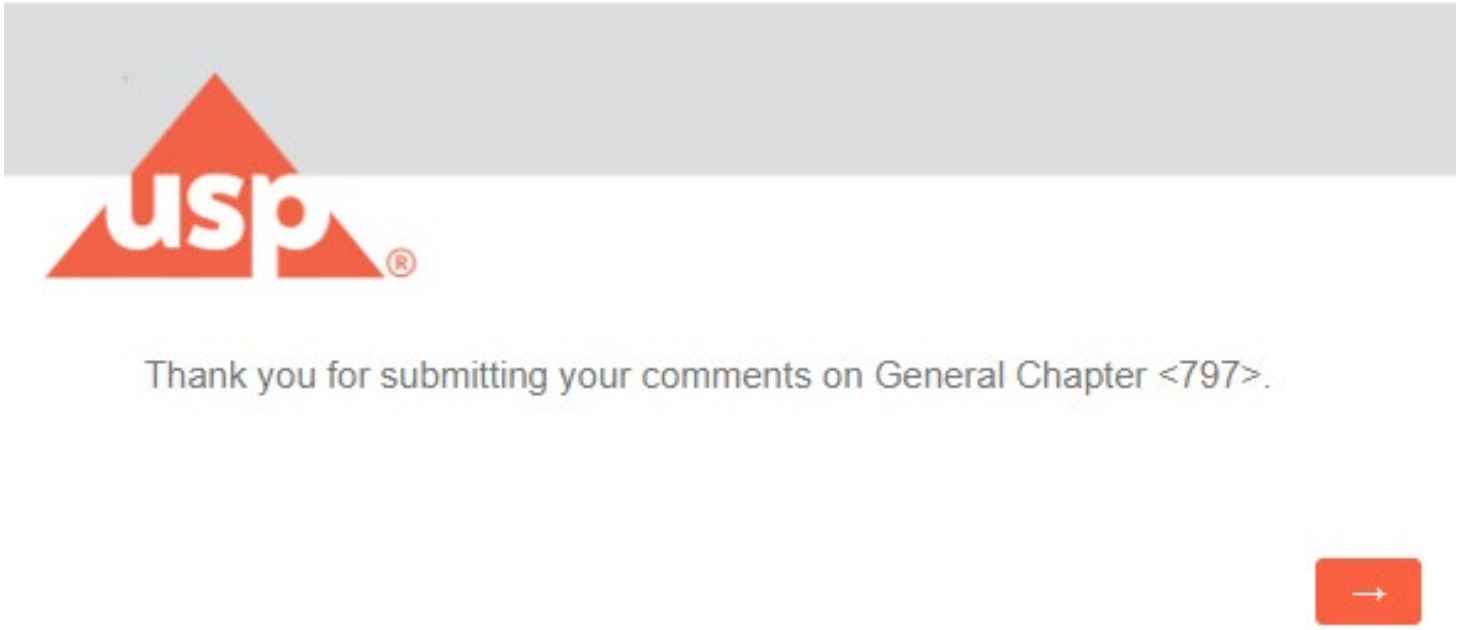
Yes

No

⟨797⟩ Public Comment Form



⟨797⟩ Public Comment Form



Next Steps

⟨797⟩ Revision Proposal

Next Steps

- The CMP EC will review all comments that are submitted before March 17, 2022, as they consider revisions to the chapters
  - Comments will be addressed through commentary posted on the USP website
- Sign up for updates to ⟨795⟩, ⟨797⟩, and other topics related to USP Healthcare Quality and Safety Standards
  - https://www.usp.org/hqs-signup-form
- Attend the Compounding Expert Committee's Official Meetings
  - https://www.usp.org/events-training/search?type%5B0%5D=event_types%3AExpert%20Committee/Panel%20Meeting

Question and Answer Session

2020 – 2025 Compounding Expert Committee

EC Member	Affiliation
Brenda Jensen, MBA	Owner and Compounding Pharmacy Consultant, Compounding Consultants, LLC
Robert Shrewsbury, Ph.D.	Associate Professor, UNC Eshelman School of Pharmacy
Lisa Ashworth, B.S. Pharm.	Compounding Specialist and Clinical Pharmacist, Children's Health System of Texas
Phil Ayers, Pharm.D.	Chief, Clinical Pharmacy Services, Mississippi Baptist Medical Center
Gus Bassani, Pharm.D.	Chief Scientific Officer, PCCA
Suzanne Blevins, B.Sc.	Laboratory Director, Aerobiology Laboratory
Brett Cordes, DVM	Veterinarian, Private Practice
Gigi Davidson, B.S. Pharm.	Veterinary Pharmacy Consultant, VetPharm Consulting, LLC
Edmund Elder, Ph.D., B.S. Pharm.	Director, Zeeh Pharmaceutical Experiment Station, University of Wisconsin-Madison
Kevin Hansen, Pharm.D., MS	Assistant Director of Pharmacy, Cone Health
Patricia Kienle, MPA, B.S. Pharm.	Director, Accreditation and Medication Safety, Cardinal Health
Vanessa Pinheiro, M.S., B.S. Pharm.	Pharmacist and Consultant, Medisca and LP3 Network
Elizabeth Rebello, M.D., B.S. Pharm.	Professor and Anesthesiologist, University of Texas MD Anderson Cancer Center
Rick Rhoads, Pharm.D.	Director of Compounding, University Compounding Pharmacy
Connie Sullivan, B.S. Pharm.	President and CEO, National Home Infusion Association

Alan Parr, Pharm.D., Ph.D. (*advisor*)	Director of Biopharmaceutics, BioCeutics, LLC
Brenda Yuzdepski, B.S. Pharm. (*advisor*)	Owner and CEO, Medical Arts Pharmacy

Thank You

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Email questions to CompoundingSL@USP.org

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