Open Microphone Session on USP General Chapter <797> Pharmaceutical Compounding – Sterile Preparations

September 5, 2018
1:00 – 3:00 pm ET
NOTICE TO PARTICIPANTS:

- To minimize background noise, all lines will be muted upon joining the session.

- During the meeting, you may ask questions or make comments at any time by using the Chat function
  - Select the Chat icon from the task menu on the bottom of your WebEx view page
  - Use the text box to enter your question
  - In the “Send” dropdown, select “Host”

- Questions will be collated for the Q&A portion of the WebEx.
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](http://www.usp.org/compounding/general-chapter-797)

**General Chapter <797> Pharmaceutical Compounding – Sterile Preparations**

Millions of medications are compounded each year in the US to meet the unique needs of patients. Compounding provides access to medication for patients who may not be able to use commercially available formulations due to dosing requirements, allergies or rare diseases. Medications that are required to be sterile include those administered through injection, intravenous infusion (IV), intraocular (injection in the eye) or intrathecal (injection in the spine).

**Important Updates**

- July 27, 2018 - The proposed <797> revision will be Pre-Posted on this page for Public Comment**

[Download the Proposed Revision to GC <797>]

[Submit Comments to the Proposed Revision to GC <797>]

- Instructions on how to submit comments to the Proposed Revision GC <797>
# Agenda

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<td>Overview of Revised General Chapter &lt;797&gt;</td>
<td>Gigi Davidson, Chair Compounding Expert Committee</td>
</tr>
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<td>• Background</td>
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<td>• Overview of Revised Content</td>
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<td>Submitting Comments</td>
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<tr>
<td>Timeline and Next Steps</td>
<td>Jeanne Sun, Manager, Compounding</td>
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<tr>
<td>Question &amp; Answer Session</td>
<td><strong>Moderator:</strong> Jeanne Sun, Manager, Compounding</td>
</tr>
<tr>
<td></td>
<td><strong>Panelists (Expert Committee Members):</strong></td>
</tr>
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<td></td>
<td>• Gigi Davidson</td>
</tr>
<tr>
<td></td>
<td>• Patti Kienle</td>
</tr>
<tr>
<td></td>
<td>• Abby Roth</td>
</tr>
<tr>
<td></td>
<td>• Connie Sullivan</td>
</tr>
<tr>
<td></td>
<td>• Jim Wagner</td>
</tr>
</tbody>
</table>
USP Overview

Tiffany Chan
Who we are

Empowering a healthy tomorrow

A healthier world needs a strong foundation—one that establishes quality, sets the bar for scientific rigor and technological progress, and epitomizes collaboration between industry, nonprofits, government and academia.

From the standards we create to the partnerships and conversations we foster, our scientists, advocates and network of experts are critical to constructing and reinforcing this foundation to ensure people stay healthy.
200 years building quality foundations for a healthier world
Mission
To improve global health through public standards and related programs that help ensure the quality, safety and benefit of medicines and foods
Advocating for quality

USP is an organization of organizations, with 450+ members representing academia, health practitioners, manufacturers, governmental bodies and consumer organizations.
800+ external experts from industry, governments, nonprofits and academia
The experts behind our standards

2015–2020 Council of Experts

Healthcare Quality Standards Collaborative Group

- Nomenclature & Labeling
- Compounding
- Healthcare Quality

Chemical Medicines Monographs Collaborative Group

- Chemical Medicines Monographs 1
- Chemical Medicines Monographs 2
- Chemical Medicines Monographs 3
- Chemical Medicines Monographs 4
- Chemical Medicines Monographs 5
- Chemical Medicines Monographs 6

Biologics Collaborative Group

- B101 Peptides
- B102 Proteins
- B103 Complex Biologicals
- BIO4 Antibiotics
- GC Biological Analysis

Excipient Monographs Collaborative Group

- Excipient Monographs 1
- Excipient Monographs 2

Dietary Supplements/Herbal Medicines/Foods Collaborative Group

- Non-Botanical Dietary Supplements
- Botanical Dietary Supplements & Herbal Medicines
- Food Ingredients

General Chapters Collaborative Group

- Chemical Analysis
- Physical Analysis
- Statistics
- Microbiology
- Dosage Forms
- Packaging & Distribution
# 2015 – 2020 Compounding Expert Committee

**Chair:** Gigi Davidson, B.S. Pharm, DICVP, NC State College of Veterinary Medicine  
**Vice Chair:** Connie Sullivan, B.S. Pharm, National Home Infusion Association

<table>
<thead>
<tr>
<th>Member</th>
<th>Affiliation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lisa Ashworth, B.S. Pharm</td>
<td>Children's Health System of Texas</td>
</tr>
<tr>
<td>Gus Bassani, Pharm.D.</td>
<td>PCCA</td>
</tr>
<tr>
<td>Edmund Elder, Ph.D., B.S. Pharm</td>
<td>University of Wisconsin-Madison</td>
</tr>
<tr>
<td>Ryan Forrey, Pharm.D., M.S.</td>
<td>Becton Dickinson</td>
</tr>
<tr>
<td>Deborah Houston, Pharm.D.</td>
<td>Novant Health - Kernersville Medical Center</td>
</tr>
<tr>
<td>Brenda Jensen, M.A.</td>
<td>Compounding Consultants, LLC</td>
</tr>
<tr>
<td>Patricia Kienle, MPA, B.S. Pharm</td>
<td>Cardinal Health</td>
</tr>
</tbody>
</table>
# 2015 – 2020 Compounding Expert Committee

**Chair:** Gigi Davidson, B.S. Pharm, DICVP, NC State College of Veterinary Medicine  
**Vice Chair:** Connie Sullivan, B.S. Pharm, National Home Infusion Association

<table>
<thead>
<tr>
<th>Member</th>
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</tr>
</thead>
<tbody>
<tr>
<td>William Mixon, B.S. Pharm</td>
<td>The Compounding Pharmacy</td>
</tr>
<tr>
<td>John Musil, Pharm.D.</td>
<td>Avella, Inc</td>
</tr>
<tr>
<td>David Newton, Ph.D.</td>
<td>Shenandoah University (retired)</td>
</tr>
<tr>
<td>Alan Parr, Pharm.D., Ph.D.</td>
<td>BioCeutics, LLC</td>
</tr>
<tr>
<td>Abby Roth, B.Sc.</td>
<td>Clinical IQ</td>
</tr>
<tr>
<td>Robert Shrewsbury, Ph.D.</td>
<td>UNC Eshelman School of Pharmacy</td>
</tr>
<tr>
<td>James Wagner</td>
<td>Controlled Environment Consulting</td>
</tr>
<tr>
<td>Brenda Yuzdepski, B.S. Pharm</td>
<td>Saskatoon Medical Arts Pharmacy</td>
</tr>
</tbody>
</table>
## 2015 – 2020 Compounding Expert Committee

### Expert Consultants

<table>
<thead>
<tr>
<th>Expert Consultants</th>
<th>Affiliation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jane Axelrad</td>
<td>Axelrad Solutions, LLC</td>
</tr>
<tr>
<td>Dennis E. Doherty, MD, FCCP</td>
<td>University of Kentucky College of Medicine</td>
</tr>
<tr>
<td>Andrew Murphy, MD</td>
<td>Asthma Allergy and Sinus Center</td>
</tr>
<tr>
<td>Elizabeth Rebello, MD, FASA</td>
<td>The University of Texas MD Anderson Cancer Center</td>
</tr>
<tr>
<td>Allison T. Vidimos, R.Ph., M.D.</td>
<td>Cleveland Clinic</td>
</tr>
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</table>
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

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

USP Timeline for General Chapter Revisions

February 2016
Publication USP-NF

July 27, 2018
Web pre-posting
*9/4 publication in
Pharmaceutical Forum

Sept 5, 2018
Open Microphone
Session

Nov 30, 2018
Close of public
comment

June 1, 2019
Intended Publication
USP-NF

Dec 1, 2019
Intended Official Date

Note: The current version of General Chapters <795> and <797> published in USP-NF are official.
Overview of Revised General Chapter <797> Pharmaceutical Compounding – Sterile Preparations
Background

1996
First Chapter published for sterile compounding in <1206> Sterile Drug Products for Home Use

June 2008
First major revision to <797> became official

Sept 25, 2015
Proposed major revision to <797> garnered >8000 comments

July 27, 2018
Based on the public comments, <797> revised and republished for public comment

Dec 2019
Revised <797> anticipated to be official 6 months after publication in the USP-NF

2004
Revised and renumbered chapter to <797>

July 2010
Newly formed EC began revisions to <797>

Jun 2019
Revised <797> anticipated to be published in the USP-NF

• Roundtables
• Discussion Forums
• Expert Consultants
To address public comments received in the first revision proposal in September 2015

- Incorporate feedback and discussion from:
  - Roundtables
  - Discussion Forums
  - Expert Consultants

To clarify topics that are frequently queried and misconstrued

To align revisions to:
  - <795> Pharmaceutical Compounding – Nonsterile Preparations
  - <800> Hazardous Drugs – Handling in Healthcare Settings
## Overview

### Proposed Chapter Outline

<table>
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<tr>
<th>Chapter</th>
<th>Title</th>
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<td>1.</td>
<td>Introduction and Scope</td>
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<tr>
<td>3.</td>
<td>Personal Hygiene and Garbing</td>
</tr>
<tr>
<td>4.</td>
<td>Facilities and Engineering Controls</td>
</tr>
<tr>
<td>5.</td>
<td>Microbiological Air and Surface Monitoring</td>
</tr>
<tr>
<td>6.</td>
<td>Cleaning and Disinfecting Compounding Areas</td>
</tr>
<tr>
<td>7.</td>
<td>Equipment, Supplies, and Components</td>
</tr>
<tr>
<td>8.</td>
<td>Sterilization and Depyrogenation</td>
</tr>
<tr>
<td>9.</td>
<td>SOPs and Master Formulation and Compounding Records</td>
</tr>
<tr>
<td>10.</td>
<td>Release Testing</td>
</tr>
<tr>
<td>11.</td>
<td>Labeling</td>
</tr>
<tr>
<td>12.</td>
<td>Establishing Beyond-Use Dates</td>
</tr>
<tr>
<td>13.</td>
<td>Use of Conventionally Manufactured Products</td>
</tr>
<tr>
<td>14.</td>
<td>Use of CSPs As Components</td>
</tr>
<tr>
<td>15.</td>
<td>Quality Assurance and Quality Control</td>
</tr>
<tr>
<td>16.</td>
<td>CSP Storage, Handling, Packaging, Shipping, And Transport</td>
</tr>
<tr>
<td>17.</td>
<td>Documentation</td>
</tr>
<tr>
<td>18.</td>
<td>Compounding Allergenic Extracts</td>
</tr>
<tr>
<td></td>
<td>▶ Glossary</td>
</tr>
<tr>
<td></td>
<td>▶ Appendices</td>
</tr>
</tbody>
</table>
Administration is out of the scope of the chapter

- Direct and immediate application of a conventionally manufactured product or CSP
- Withdrawal of doses
- Preparation of non-hazardous CSPs for a single patient using only sterile starting ingredients when administration will begin within 1 hour of beginning the preparation
Proposal

Scope

- **Eliminates** provisions for handling of hazardous drugs
  - Compounding sterile hazardous drugs **must additionally** comply with <800>

- **Eliminates** provisions for radiopharmaceuticals
  - Compounding radiopharmaceuticals are **subject** to <825> *Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging*
Categories of CSPs

CSP Microbial Contamination Risk Levels

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

**Category 1 CSPs**
- May be prepared in a PEC located in a unclassified segregated compounding area
- Assigned a BUD of \( \leq 12 \) hours at controlled room temperature or \( \leq 24 \) hours when refrigerated

**Category 2 CSPs**
- Must be prepared in a cleanroom suite
- Assigned a BUD of \( > 12 \) hours at controlled room temperature or \( > 24 \) hours if refrigerated

<797> Proposal
## Personnel Qualifications

<table>
<thead>
<tr>
<th>Activity</th>
<th>Currently Official Chapter (since 2008)</th>
<th>2015 Revision Proposal</th>
<th>2018 Revision Proposal</th>
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</thead>
<tbody>
<tr>
<td>Visual observation of hand hygiene and garbing</td>
<td>Annually</td>
<td>Every 3 months</td>
<td>Every 6 months</td>
</tr>
<tr>
<td>Gloved fingertip and thumb sampling</td>
<td>• Annually – Low/Medium-Risk CSPs</td>
<td>Every 3 months</td>
<td>Every 6 months</td>
</tr>
<tr>
<td></td>
<td>• Semi-annually → High-Risk CSPs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Media fill testing</td>
<td>• Annually – Low/Medium-Risk CSPs</td>
<td>Every 3 months</td>
<td>Every 6 months</td>
</tr>
<tr>
<td></td>
<td>• Semi-annually → High-Risk CSPs</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
# Garbing Requirements

<table>
<thead>
<tr>
<th>Currently Official Chapter (since 2008)</th>
<th>2015 Revision Proposal</th>
<th>2018 Revision Proposal</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Gown</td>
<td>Determined based on:</td>
<td>• Gown</td>
</tr>
<tr>
<td>- Dedicated shoes or shoe covers</td>
<td>• Category</td>
<td>• Disposable covers for shoes</td>
</tr>
<tr>
<td>- Head and facial hair covers</td>
<td>• Type of PEC</td>
<td>• Disposable covers for head and facial hair</td>
</tr>
<tr>
<td>- Face masks</td>
<td>Included:</td>
<td>• Face mask</td>
</tr>
<tr>
<td>- Sterile gloves</td>
<td>- Gown or coveralls</td>
<td>• Sterile gloves</td>
</tr>
<tr>
<td></td>
<td>- Disposable covers for shoes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Disposable covers for head and facial hair</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Sterile gowns or sleeves</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Sterile gloves</td>
<td>If using RABS → disposable gloves inside of gauntlet gloves</td>
</tr>
</tbody>
</table>
Facility Design

Category 1 CSPs

- ISO Class 5 PEC
- Unclassified SCA

Category 1 or 2 CSPs

- Ante-Room (ISO Class 8)
- Buffer Room (ISO Class 7)

- "clean side"
- "dirty side"

ISO Class 5 PEC

perimeter
### Facility Requirements

- **For Category 1 CSPs**
  - All PECs may be placed in an unclassified SCA

- **For Category 2 CSPs**
  - LAFS and RABS must be placed in an ISO Class 7 positive pressure buffer room with an ISO Class 8 positive pressure ante-room

| Laminar airflow system (LAFS) | Laminar Airflow Workbench (LAFW)  
|                              | Integrated Vertical Laminar Flow Zone (IVLFZ)  
|                              | Class II Biological Safety Cabinet (BSC)  
| Restricted-access barrier system (RABS) | Compounding Aseptic Isolator (CAI)  
|                                 | Compounding Aseptic Containment Isolator (CACI)  

- Isolators must be placed in an ISO Class 8 or better positive pressure room
Facility Requirements

- Added clarifications on **Air Exchange Requirements**
  - HEPA filters must be located in the ceiling
  - Returns must be low on the wall

<table>
<thead>
<tr>
<th>Compounding Area</th>
<th>ACPH Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unclassified SCA</td>
<td>No requirement</td>
</tr>
<tr>
<td>ISO Class 7 room(s)</td>
<td>≥ 30 APCH</td>
</tr>
<tr>
<td>ISO Class 8 room(s)</td>
<td>≥ 20 APCH</td>
</tr>
</tbody>
</table>

- **Water Sources**
  - Sink may be placed inside or outside of ante-room
  - Buffer room must not contain water sources
Proposal

Certification

- During dynamic operating conditions
- Required every 6 months
- Includes:
  - Airflow testing
  - HEPA filter integrity testing
  - Total particle count testing
  - Smoke visualization studies
### Microbiological Air and Surface Monitoring

- Viable Air Sampling
- Surface Sampling
  - Flat Surface Sampling
  - Irregular Surface Sampling

#### Procedures including incubation times described in Boxes

<table>
<thead>
<tr>
<th></th>
<th>Currently Official Chapter (since 2008)</th>
<th>2015 Revision Proposal</th>
<th>2018 Revision Proposal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viable air sampling</td>
<td>Every 6 months</td>
<td>Monthly</td>
<td>Every 6 months</td>
</tr>
<tr>
<td>Surface sampling</td>
<td>Periodically</td>
<td>Monthly</td>
<td>Monthly</td>
</tr>
</tbody>
</table>
Cleaning and Disinfecting Compounding Areas

- Frequencies specified for separate activities
  - Cleaning
  - Disinfecting
  - Applying a sporicidal

- Cleaning supplies (e.g., wipers, sponges, mop heads)
  - Must be low-linting
  - Should be disposable
  - Must be dedicated for use
<797> Proposal

Component Selection
- API must be obtained from an FDA-registered facility
  • Must comply with USP-NF monograph if one exists

Sterilization Methods
- Aseptic Preparation
  • Compounding with only sterile ingredients
  • Sterilization by filtration
- Terminal Sterilization is preferred
  • Dry heat
  • Steam
  • Irradiation

Sterility Assurance Level of $10^{-6}$
<797> Proposal

Documentation and Records

Master Formulation Record

- Required if
  - CSP prepared in a batch for > 1 patient
  - CSPs prepared from nonsterile ingredient(s)

Compounding Record

- Required for all CSPs
  - May be in the form of prescription or medication order, compounding log, or label
  - May be stored electronically through ACD, repeater pump, workflow management system
Release Testing

- **Visual Inspection**

- **Sterility Testing**
  - If between 1 and 39 CSPs, sterility test number of units equal to 10% of CSPs prepared
  - If > 40 CSPs, sterility test based on <71>, Table 3

- **Bacterial Endotoxin Testing**
  - Excludes inhalations and topical ophthalmics
  - Required for Category 2 CSPs
    - Made from one or more nonsterile ingredient(s) or component(s) AND
    - Assigned a BUD that requires sterility testing
Establishing Beyond-Use Dates

Stability factors
- Chemical and physical properties
- Compatibility of the container-closure system

Sterility factors
- Environment in which the CSP is prepared
  - Cleanroom suite or SCA
- Aseptic preparation and sterilization method
- Components
  - Sterile or nonsterile starting ingredients
- Sterility Testing
- Storage conditions (e.g., packaging and temperature)
# <797> Proposal

## Category 1 CSP BUDs

<table>
<thead>
<tr>
<th>Storage Conditions</th>
<th>Controlled Room Temperature (20°–25°)</th>
<th>Refrigerator (2°–8°)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BUD</td>
<td>≤ 12 hours</td>
<td>≤ 24 hours</td>
</tr>
</tbody>
</table>

Currently official <797>

- Low-Risk Level CSP in SCA: 12 hours
## Category 2 CSP BUDs

<table>
<thead>
<tr>
<th>Preparation Characteristics</th>
<th>Storage Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterilization Method</td>
<td>Controlled Room Temperature (20°–25°)</td>
</tr>
<tr>
<td>Aseptically prepared CSPs</td>
<td>Prepared from one or more nonsterile starting component(s): 1 day</td>
</tr>
<tr>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

**Currently official <797>**

<table>
<thead>
<tr>
<th>High-Risk Level CSPs</th>
<th>1 day</th>
<th>3 days</th>
<th>45 days</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>&lt;797&gt; Proposal</th>
</tr>
</thead>
</table>

© 2017 USP
## Category 2 CSP BUDs

<table>
<thead>
<tr>
<th>Preparation Characteristics</th>
<th>Storage Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterilization Method</td>
<td>Sterility Testing Performed &amp; Passed</td>
</tr>
<tr>
<td>Aseptically prepared CSPs</td>
<td>No</td>
</tr>
</tbody>
</table>

### Currently official <797>:

- **Medium-Risk Level CSPs**
  - Prepared: 30 hours
  - Refrigerator: 9 days
  - Freezer: 45 days

- **Low-Risk Level CSPs**
  - Prepared: 48 hours
  - Refrigerator: 14 days
  - Freezer: 45 days
## Category 2 CSP BUDs

<table>
<thead>
<tr>
<th>Sterilization Method</th>
<th>Sterility Testing Performed &amp; Passed</th>
<th>Controlled Room Temperature (20°–25°)</th>
<th>Refrigerator (2°–8°)</th>
<th>Freezer (−25° to −10°)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aseptically prepared CSPs</td>
<td>No</td>
<td>Prepared from one or more nonsterile starting component(s): 1 day</td>
<td>Prepared from one or more nonsterile starting component(s): 4 days</td>
<td>Prepared from one or more nonsterile starting component(s): 45 days</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>Prepared from only sterile starting components: 4 days</td>
<td>Prepared from only sterile starting components: 9 days</td>
<td>Prepared from only sterile starting components: 45 days</td>
</tr>
<tr>
<td></td>
<td>30 days</td>
<td>45 days</td>
<td>60 days</td>
<td></td>
</tr>
<tr>
<td>Terminally sterilized CSPs</td>
<td>No</td>
<td>14 days</td>
<td>28 days</td>
<td>45 days</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>45 days</td>
<td>60 days</td>
<td>90 days</td>
</tr>
</tbody>
</table>
Proposal

Use of Conventionally Manufactured Products and CSPs

- Eliminates the previously proposed “in-use time” concept
- Address the time within which an entered or punctured Conventionally Manufactured Product must be used

<table>
<thead>
<tr>
<th>Type of Container</th>
<th>Time within which product must be used</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single-dose container</td>
<td>ISO Class 5 → 6 hours</td>
</tr>
<tr>
<td></td>
<td>Unclassified Air → 1 hour</td>
</tr>
<tr>
<td>Multiple-dose Container</td>
<td>28 days</td>
</tr>
<tr>
<td>Pharmacy Bulk Package</td>
<td>As specified by the manufacturer</td>
</tr>
</tbody>
</table>

- Added guidance for Compounded Stock Solutions
  - Must be entered or punctured in an ISO Class 5 or cleaner air
  - May be used for up to 6 hours after initial entry or puncture
<797> Proposal

Notification and Recall

- If dispensing before testing results are known, the facility must have procedures to:
  - Immediately notify the prescriber
  - Determine whether a recall is necessary

- The **SOP for recall** must contain procedures:
  - To determine the severity and the urgency
  - To determine the distribution of any affected CSP
  - To identify patients who have received the CSP
  - For disposition and reconciliation of the recalled CSP
Section applicable only when:
- The compounding process involves simple transfer of conventionally manufactured products (allergenic products and added substances) AND
- Manipulations are limited to penetrating disinfected stoppers and transferring to sterile vials

Licensed allergenic extracts:

Provisions include:
- Personnel Qualifications
  - Gloved fingertip and thumb sampling every 12 months
  - Media-fill testing every 12 months
- Facilities
  - ISO Class 5 PEC
  - Dedicated Allergenic Extracts Compounding Area (AECA)
- Establishing BUDs
  - No later than the earliest expiration date of any component
  - Must not exceed 1 year
- Documentation
  - Compounding records
Submitting Comments
General Chapter <797> Pharmaceutical Compounding – Sterile Preparations

Millions of medications are compounded each year in the US to meet the unique needs of patients. Compounding provides access to medication for patients who may not be able to use commercially available formulations due to dosing requirements, allergies or rare diseases. Medications that are required to be sterile include those administered through injection, intravenous infusion (IV), intraocular (injection in the eye) or intrathecal (injection in the spine).

Important Updates

- July 27, 2018 - The proposed <797> revision will be Pre-Posted on this page for Public Comment**

Download the Proposed Revision to GC <797>  Submit Comments to the Proposed Revision to GC <797>

Instructions on how to submit comments to the Proposed Revision GC <797>
Welcome to the electronic form for submitting comments on USP’s proposed revisions to General Chapter <797> Pharmaceutical Compounding – Sterile Preparations. USP General Chapter <797> provides standards for compounding quality sterile preparations.

Please use this electronic form to submit your comments to the proposed revisions to <797> (available at http://www.uspntf.com/notices/general-chapter-797-proposed-revisions).

Instructions
• Submit your specific comments with the relevant line numbers provided in the proposed chapter (preferred).
  • [NOTE – line numbers are located on the left side of the proposed chapter revision]
• If you have general comments not associated with a line number, enter them in the text box when prompted in the form.
• Email CompoundingFL@usp.org if you have any questions or additional information.

General Chapter Overview
The Compounding Expert Committee seeks your feedback on the proposed revisions to the chapter, including the following proposed changes:
1. Reorganized the chapter to include section and subsection numbers. Placed procedural information into boxes.
2. Definition of the scope of the chapter to include sterile compounding activities and exclude administration of medication (e.g. withdrawing doses for administration).
3. Simplified compounded sterile preparation (CSP) microbial risk levels from three (low, medium, and high) to two—Category 1 CSPs and Category 2 CSPs. Category 1 and 2 CSPs are distinguished primarily by the facility in which they are made and the time period within which they must be used, i.e., the beyond-use date (BUD).
• Outer CSPs have a shorter BUD and are prepared in an aseptic environment.
Public Comment Form

Please enter your contact information.

First Name
Last Name
Degree
Email
Phone Number
Title
Organization
Please select the type of comments you would like to submit on General Chapter <797> Pharmaceutical Compounding – Sterile Preparations.

- Select Specific Comments if you have specific line numbers corresponding to your comments.
- Select General Comments if you have a general comment that does not have a corresponding line number.

If you have both general and specific comments, please select both options. You will be prompted to enter your general comments first, followed by your specific comments.

Specific Comments - Preferred

General Comments

NEXT
General Comment Entry
This entry format is for comments that do not have corresponding line numbers.

Please enter the comment or specific change requested.

Please enter the rationale for your comment or change requested.
Specific Comment Entry
Please submit one comment at a time.

Please enter the **line number(s)** corresponding to your comment.
(The line number can be found on the left margin of the proposed general chapter.)

Please enter the **specific change** requested.

Please enter the **rationale** for the specific change requested above.
Thank you for submitting comments for <797> Pharmaceutical Compounding – Sterile Preparations. You will receive an email from USP within 5-7 business days confirming receipt of your comments. If you have any questions, please email CompoundingSL@usp.org.

Sign-up to receive the latest news on USP activities by signing up for email updates or visit the USP Compounding Website for more information.
Timeline and Next Steps
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

General Chapter <797> Pharmaceutical Compounding – Sterile Preparations

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USP Timeline for General Chapter Revisions

February 2016
Publication USP-NF

March 30, 2018
Web pre-posting
*5/1 publication in Pharmacopeial Forum

April 20, 2018
Open Microphone Session

July 31, 2018
Close of public comment

July 27, 2018
Web pre-posting
4/9 publication in Pharmacopeial Forum

Sept 5, 2018
Open Microphone Session

Nov 30, 2018
Close of public comment

June 1, 2019
Intended Publication USP-NF

Dec 1, 2019
Intended Official Date

Note: The current version of General Chapters <795> and <797> published in USP-NF are official.
Next Steps

- Stakeholders submit comments using the electronic form
  - Compounding Expert Committee will review all comments
  - Comments will be addressed through commentary posted on the USP website

- Sign up for to received updates on USP Healthcare Quality and Safety Standards
  - https://www.usp.org/hqs-signup-form
Question & Answer Session

Moderator: Jeanne Sun
Panelists (Expert Committee Members):
  • Gigi Davidson
  • Patti Kienle
  • Abby Roth
  • Connie Sullivan
  • Jim Wagner
GENERAL CHAPTER <797> OPEN MICROPHONE

NOTICE TO PARTICIPANTS:

- To minimize background noise, all lines will be muted upon joining the session.

- During the meeting, you may ask questions or make comments at any time by using the Chat function
  - Select the Chat icon from the task menu on the bottom of your WebEx view page
  - Use the text box to enter your question
  - In the “Send” dropdown, select “Host”

- Questions will be collated for the Q&A portion of the WebEx.

Your meeting controls will appear on the bottom of the screen. Select the chat feature

To submit a question, send a message to Jeanne Sun (the Host) in the chat feature
Thank You

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Stay Connected

CompoundingSL@usp.org

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