The Top 10 Gaps in USP 797 Compliance

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Disclaimer

“Although I am a member of the USP Sterile Compounding Expert Committee, I am speaking today in my individual capacity and not as a member of the Committee or as a USP representative.

The views and opinions presented are entirely my own. They do not necessarily reflect the views of USP, nor should they be construed as an official explanation or interpretation of <797>.”
Hell’s Cleanroom!
Gap Analysis

- What is a gap?
- How do you identify it?
- How do you correct it?
- How do you make sure nothing becomes a gap?
- How often do you perform a gap analysis?
Top 10 Gaps in USP 797 Compliance

- Understanding USP 797 and knowing how to comply
- State Board of Pharmacy position re: USP 797
- Facility meets design requirements
- Caulked Ceiling Tiles
- Dating of MDVs (vaccines)
- Personnel training in hand hygiene, media fill, surface sampling and gloved fingertip sampling
- Personnel equipment training
- Properly documenting temperatures and reporting excursions
- Having a properly tested and certified facility
- Complying with BUDs
Understanding USP<797>

• USP Home Page for Compounding
  • http://www.usp.org/products/797Guidebook/
  • http://www.usp.org/audiences/pharmacist/797FAQs.html
  • http://www.usp.org/audiences/healthcarePro/pharmacists

• ASHP Compounding Resource Center
  • http://www.ashp.org/compounding
    • ASHP Discussion Guide for Compounding Sterile Preparations-2004
    • ASHP Discussion Guide for Compounding Sterile Preparations - Summary of revisions to USP Chapter <797>-2008
Understanding USP<797>

What are we dealing with?
Research standards of care, state and federal laws re: sterile compounding?
• USP Chapter <797> standards
• State Board of Pharmacy Rules and Regulations
• State Department of Health
• Drug Enforcement Agency
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State Board of Pharmacy Position USP <797>
Actual note from State Board of Pharmacy Inspector addressed to the Hospital Pharmacy Director

A note on your pharmacy Inspections last week:

“Your hospital” has not initiated changes in your physical spaces used for Sterile Compounding. The changes in the Administrative Code were added to the Board of Pharmacy regulations in June 2009. The pharmacy inspectors are to note progress on compliance, and initiate deficiencies in January 2010. I have attached a copy of the new administrative code, and a summary of the administrative code that I have simplified.

As you can see, the new administrative code contains a number of issues requiring major changes in the physical space (e.g., ante rooms, buffer space, positive pressure room for intravenous admixtures, and negative pressure for chemotherapy). In addition, the new administrative code has considerable changes in training, testing, and verification of the capabilities of the individuals working in the area. Non-compliance will result in disciplinary action.
What types of CSPs are prepared

- Immediate-Use
- Low-risk level CSPs
- Low-risk level CSPs with 12 hour or less BUD
- Medium-risk level CSPs
- High-risk level CSPs
Top 10 Gaps in USP 797 Compliance

- **High Risk**
  - Use non-sterile components
  - (ex: epidurals, alum)

- **Medium Risk**
  - Uses multiple sterile components
  - (ex: batch compounding, TPNs)

- **Low Risk**
  - Simple, or single, sterile component mixing
  - (ex: one vial into one delivery container)

- **No Risk**
  - (premixed or RTU single doses)
Gap Analysis

Perform a gap analysis

- Available tools:
  - Home grown tool
  - IJPC USP 797 and 795 Gap Analysis
    - http://compoundingtoday.com/USP/USPGap.cfm
  - CriticalPoint, LLC 797 Gap Analysis
    - http://797gaptool.797compoundingiq.com
  - ASHP-no tool
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Facility meets design requirements

Primary Engineering Control

Buffer Area

Ante Area

Stockroom

Direct Compounding Area (DCA)
Facility meets design requirements

<table>
<thead>
<tr>
<th></th>
<th>ISO “Class” Particles/m³</th>
<th>US “Class” Particles/ft³</th>
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<tbody>
<tr>
<td><strong>Stockroom</strong></td>
<td>Uncontrolled</td>
<td>(no particle limits)</td>
</tr>
<tr>
<td><strong>Ante Area</strong></td>
<td>ISO Class 8</td>
<td>Class 100,000</td>
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<tr>
<td></td>
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<td>100,000</td>
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<td><strong>Buffer Area</strong></td>
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<td>Class 100</td>
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<tr>
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Direct Compounding Area (DCA)
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Caulked Ceiling Tiles

- Tiles caulked in place
- Work with facility engineering or cleanroom vendor to resolve matter
  - Caulk can be removed by certifier as needed
- Caulked tiles keep tiles in place when cleaning
- Most important in negative-pressure buffer areas
- Caulk can easily be removed if tile change/repair needed
- An easily identified design feature that State Boards of Pharmacy can cite as a deficiency
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Dating of MDVs (Vaccines)

- Interpreted by TJC and SBOP as a gap or deficiency
- CDC states:
  - The vaccine or diluent may be used up to and including this date unless otherwise stated in the product package insert.
- Consult Product Package Insert
- Refer to USP Chapter <797>
  - Single-dose and Multiple-dose Containers

http://www2a.cdc.gov/vaccines/ed/shtoolkit/pages/inventory_management.htm
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Personnel Training Gaps

- Personnel training-Hand Hygiene
  - Frequency-initially for all personnel
    - Annually for low and medium-risk level operations
    - Semi-annually for high-risk level operation
  - Hand Hygiene
    - Hospital Infection Preventionists
  - CDC Website
    - http://www.cdc.gov/Handhygiene/
  - CDC Interactive Training
    - http://www.cdc.gov/handhygiene/training/interactiveEducation/
  - CriticalPoint, LLC (www.criticalpoint.info)
    - Virtual Compounder™
Personnel Training Gaps

- Personnel Training: Media Fills (Aseptic Technique Assessment)
  - Frequency-initially for all personnel
    - Annually for low and medium-risk level operations
    - Semi-annually for high-risk level operation
  - Media Fill Supplies (S) and Training (T)
    - Valiteq www.valiteq.com (S)(T)
    - QI Medical www.qimedical.com (S)(T)
    - CriticalPoint, LLC www.criticalpoint.info (T)
    - bioMérieux, Inc http://www.pmlmicro.com/our-products/new-products (S)
Top 10 Gaps in USP 797 Compliance

Hmm... this new management fad is crazy enough that it might just work...

Just do your fricking job.
Personnel Training Gaps

- Personnel training-Gloved Fingertip sampling
  - Frequency-initially for all personnel (x 3)
    - Annually for low and medium-risk level operations
    - Semi-annually for high-risk level operation
  - Gloved Fingertip Supplies (S) and Training (T)
    - QI Medical: www.qimedical.com (S)
    - bioMérieux, Inc: www.pmlmicro.com/our-products/new-products (S)
    - CriticalPoint, LLC: www.criticalpoint.info (T)
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Personnel Equipment Training

- Personnel who use equipment:
  - have received training
  - demonstrated the ability to use the equipment properly
  - can troubleshoot the equipment in the event of malfunction.
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Properly Documenting Temperatures

**REFRIGERATOR/FREEZER Temperature Log Sheet**
Temperatures will be recorded with the initials of the person performing the check.
Refrigerator temperature should be between 2 and 8°C (36 and 40°F).
Freezer temperature should be between -20 and -10°C (-4 and 14°F).

Refrigerator #1 (Anteroom)

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<tr>
<td>16</td>
<td>32 F</td>
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Note: Monthly data missing.

2/23 days temperature in range
6/23 days temperature out of range
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Properly Tested and Certified Facility

- USP Chapter <797> has specific requirements
- There is currently no industry based accreditation program for certifiers of sterile compounding facilities.
- NSF International has an accreditation program for certifiers of BSC.
  - For now that program is the best barometer of whether or not an individual has demonstrated an ability to certify this type of equipment.
Properly Tested and Certified Facility
Properly Tested and Certified Facility

- Certification reference material
  - Controlled Environment Testing Association (CETA)
    - [http://www.cetainternational.org](http://www.cetainternational.org)
    - CETA has established an application guides (CAG-003-200X) detailing procedures for certification of sterile compounding facilities
  - Choosing a Certification Professional to Evaluate Your Cleanroom and Engineering Control-James T. Wagner. Published in Pharmacy, Purchasing and Products Magazine (www.pppmag.com)
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- A CSPs beyond-use date identifies the time by which the preparation – once mixed – must be used before it is at risk for chemical degradation, contamination, and permeability of the packaging.
- In other words, the beyond-use date serves to alert pharmacists and caregivers to the time after which a CSP cannot be administered.
- Understanding Beyond-Use Dating for Compounded Sterile Preparations by Patricia Kienle published by Pharmacy, Purchasing and Products Magazine
Putting All Together

**Planning to Change and Changing**
Action planning and implementation against identified gaps bring compliance!

**Identifying What to Change**
Gap analysis is an important activity to identify areas requiring improvement (people, process, facility)

**Ensuring Changes are Permanent**
Control measures ensure changes “stick” and help identify further improvements. “Simplifi 797 Software”
Compliance is an endpoint?

Think about compliance as a 3-step process:
- Identify gaps and action plan
- Achieve compliance
- Maintain compliance: requires constant monitoring and measurement

Consider:
- Linear process of achieving compliance (get to a point in time)
- Cyclical aspect of process improvement: maintain a state of compliance
- “Compliance” isn’t an endpoint or a finish line
Close the Gap

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