USP 797/800: What You Need to Know
Overview of Standards

- Federal standard issued by US Pharmacopeia
- **USP 797**
  - Focus is protection of product
  - Current version 2008; adopted by CMS
  - Revisions are under review
- **USP 800**
  - Focus is protection of employee
  - In effect December 1, 2019
- State requirements
Layout of Non-HD Buffer Room with Anteroom

STERILE ANTEROOM
ISO CLASS 8
30 air changes per hour

STERILE WORKROOM
BUFFER-ROOM
ISO CLASS 7
30 air changes per hour

LAMINAR FLOW
WORKSTATION
ISO CLASS 5

CART

PASS-THROUGH

BENCH

CART

GARB CART
Layout of Containment Segregated Compounding Area (HD)

- CONTAINMENT SEGREGATED COMPOUNDING AREA
  - Low-risk, 12-H BUD
  - Unclassified area
  - 12 ACH

- HD REFRIGERATOR
- HD STORAGE
- BENCH
- GARB CART

- COMPounding ASEPTIC CONTENTainment ISolator
  - ISO CLASS 5
    - (100% Exhaust)

- CART

- SINK
  - at least 1 meter away from CACI

- -0.01 to -0.03 in WC (Negative Pressure)
Layout of HD and Non-HD Buffer Rooms with Anteroom

- HAZARDOUS DRUG BUFFER ROOM
  - ISO CLASS 7
  - 30 ACH

- ANTEROOM
  - ISO CLASS 7
  - 30 ACH

- SINK
  - at least 1 meter away from door

- HD STORAGE

- ISO CLASS 5
  - PEC (100% Exhausted)

- NON-HAZARDOUS DRUG BUFFER ROOM
  - ISO CLASS 7
  - 30 ACH

- CARB CART

- BENCH

- ISO CLASS 5
  - PEC

Note: The layout diagram includes various safety and operational guidelines, such as the placement of sinks and the specification of air change rates (ACH) for different areas.
Status of USP <797> and <800>

- **Sept 2015**: Draft issuance of USP <797> Sterile Compounding
- **Feb 1, 2016**: USP <800> HD Compounding published
- **July 1, 2016**: TJC/CMS USP <797> inspections start
- **November 30, 2018**: Public comment period ends for USP <797>
- **December 1, 2019**: Anticipated official date of USP <797>
- **December 1, 2019**: Delayed implementation USP <800>
**Self-Reported Compliance with USP <797> Requirements**

- Meets all requirements: 37%
- Meets most requirements: 50%
- Meets some requirements: 8%
- Planning to address: 4%
- No plan for compliance: 1%

▲ Self-reported <797> compliance rates have remained relatively static over the past few years, with just over one-third of facilities stating that they are fully compliant. Notably, the fully compliant facilities are almost exclusively located in states that require compliance with <797>.

**Self-Reported Compliance to USP <800>**

- Meets or exceeds all requirements: 8%
- Meets most <800> requirements: 38%
- Meets some <800> requirements: 32%
- Currently planning to address <800> requirements: 21%
- No plan to address <800>: 1%

▲ Pharmacy is fully aware of their need to change practices (and in some cases upgrade facilities) in order to achieve <800> compliance. Only 8% of facilities are confident that they are currently compliant.
Conversion to USP Chapter <800>

Is More than just a cleanroom

- Receipt
- Storage
- Compounding
- Use and maintenance of proper engineering controls (e.g. C-PECs, C-SECs and C-SCA)
- Hand hygiene and use of PPE
- Hazardous Drug List
- Transport

- Cleaning, and disinfection
- Deactivation and decontamination
- Administration
- Environmental monitoring
- Disposal
- Spill control
- Medical surveillance
How to prepare for USP 797/800 Compliance

- Perform a gap analysis
- Educate staff and leadership and obtain capital funding ($$$$$)
- Perform risk assessment
- Develop Plan - Develop Timeline - Assemble a team
  - Pharmacy
  - Mechanical Engineering
  - Facilities
  - Architect
  - Nursing
  - Quality and Risk
- Create operational plan to operate during construction -
  - Update SOPs
  - Temporary cleanroom (C-SCA - Contained Segregated Compounding Area)
  - Mobile cleanroom
  - Outsourcing
- Evaluate staff understanding of standards
- Maintain strong communications