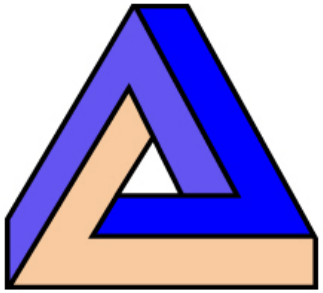


USP-800 Compounding

Understanding the requirements that affect the compliance of your pharmacy

What you need to know

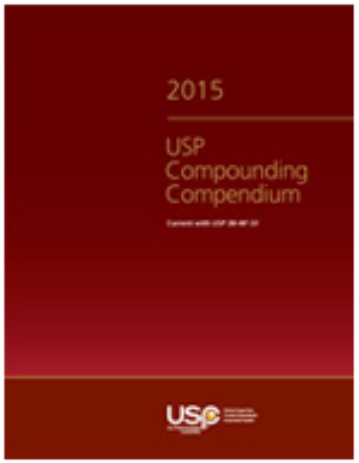
- What changes are pertinent to sterile compounding?
- Designs for safe preparation of medications
- Safe steps for properly preparing chemotherapy
- Devices that should be used when mixing chemo-therapy

Compounding Regualtions

- FDA and state boards of pharmacy responsibility
- Regulations of each and USP definitions in 5 chapters of <795>, <797>, <1160>, <1168>, <800>

USP General Chapter Revisions and Proposals

- General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings New Proposal in PF40(3) May/June 2014



<800> Hazardous Drugs – Handling in Healthcare Settings

- Purpose: To define processes intended to provide containment of hazardous drugs to as low as reasonably achievable

- Note: There is no acceptable level of personnel exposure to Hazardous Drugs!

Testing tells all!

- Smoke testing is often an eye-opener for compounding personnel as any air turbulence around the hands or compounding materials can be clearly observed.
- Incorporating this testing into standard training underscores the importance of maintaining unidirectional airflow.
- CETA requires all USP-797 hoods to be smoked test for validation

Latest USP Compounding Compendium

- The new <800> chapter address the following:

-Standards that apply to all personnel who compound HDs preparations and all places where HDs are prepared, stored, transported, and administered

-Receiving, storing, compounding, dispensing, administering, and disposing of both non sterile and sterile products and preparations

-Altering, counting, crushing, and pouring HDs.

--Standards apply to all personnel and all places where activity may occur

Additional requirements

- Comprehensive approach to prevent worker and environmental exposure
- Specific engineering controls required
- Competent personnel
- Robust work practices
- Availability of personal protective equipment (PPE)
- Medical surveillance program

Compounding Supervisor

- Designated individual
- Develops and implements appropriate policy and procedures
- Oversees compliance with this chapter and all regulatory standards
- Assures environmental control of the compounding area

How is <800> incorporated?

- Chapter builds on the standards existing in compounding chapters
- Adds in the elements of containment of hazardous drugs (HDs).

What is a hazardous drug?

- HD includes any drug identified by at least one of the following six criteria:
- Carcinogenicity
- Teratogenicity or developmental toxicity
- Reproductive toxicity in humans
- Organ toxicity at low doses in humans or animals
- Genotoxicity
- New drugs that mimic existing HDs in structure or toxicity

Facility design requirements

- There must be restricted access all <800> HD areas
- Unpacking procedures must be in place
- Storage of hazardous drugs must be kept separate from non-hazardous drugs
- Covers both sterile and non-sterile compounding of HDs
- All hazardous drugs must be compounded inside a negative pressure room

Engineering Control Concerns

USP-800 areas have special design considerations

- No laminar flow hood (LAFW), or Compounding Aseptic isolators (CAI) allowed for HD compounding

WHY NOT?

- Allows for environmental contamination
- All product must be contained with in Biological Safety Hood

Specific Topics to cover

- Chapter Outline

I.List of Hazardous Drugs
II. Types of Exposure
III. Responsibilities of personnel handling hazardous drugs
IV. Facility design and engineering controls
V. Personal protective equipment
VI. Hazard communication program
VII. Training for compounding personnel
VIII. Receiving
IX. Transporting

Specific Topics (cont)

- X. Dispensing HD dosage forms not requiring alteration
- XI. Compounding HD dosage forms
- XII. Protection when administering HDs
- XIII. Cleaning; deactivation, decontamination, cleaning, and disinfection
- XIV. Spill control
- XV. Disposal
- XVI. Environmental quality and control
- XVII. Documentation
- XVIII. Medical surveillance

Sources of exposure and spread of contamination

- Spatter
- Aerosols
- Touch contamination (sides of vials and packaging)
- Connecting IV administration tubings
- Evaporation or escaping gasses
- Vial breakage
  - -in packaging
  - - during disposal

Personnel Protective Equipment

- Containment primary engineering control (C-PEC) externally vented

- Secondary engineering control
  - Separate room
  - External venting
  - Negative pressure
  - Appropriate air exchanges 30 per hour

Proper garbing & handling

Workers handling hazardous drugs need protection to prevent potentially harmful exposure.

Major difference from <797>

- -Elimination of the exemption for facilities that prepare a low-volume of HDs that permits placement of a BSC or CACI in a non-negative room
- -Allowance of a Containment Segregated Compounding Area (C-SCA), a separate negative pressure room with at least 30 air changes per hour

What next?

- To ensure your pharmacy meets all of the new USP guidelines please contact our specialists for more information.

- Call us at (707) 864-9499 Ext. 101
- Email: Sales@CleanRoomSpecialists.com

Or visit our website at

- www.CleanRoomSpecialists.com