Phoenix Controls

SOLUTIONS FOR USP <800>

PHARMACY, HEALTHCARE AND LABORATORY APPLICATIONS

On July 1, 2018, the U.S. Pharmacopeial (USP) <800> code change for hazardous drugs (HDs) storage and compounding takes effect. This code change from USP <797> has very specific requirements, including new sterile storage regulations. It's written to protect all workers, patients and the general public who may be accessing facilities where HDs are prepared. Are you ready?

We can help. For over 30 years, Phoenix Controls has provided fast and consistent air flow controls, keeping occupants safe in pharmacy applications and other healthcare and laboratory conditions. Phoenix Controls can provide solutions to meet the new code requirements.

HOW CAN PHOENIX CONTROLS HELP?

Our primary focus is the controlling of critical environments. We are an engineered system solution provider. And even when a code changes, our highest priority is always safety.

For USP <800>, look to Phoenix Controls to:

- Protect staff and patients by reducing the risk of airborne ventilation contamination and limiting exposure to HDs.
- Maintain proper room pressurization within each room and between spaces
- Ensure correct air changes per hour (ACH) through flexible solutions should room designation change
- Provide cost-effective retrofit or new construction design options
- Deliver multiple control options that include:
  - Integration with BAS integration flexibility
  - Alarm notification should system fail to meet airflow control standards
  - Decontamination modes
  - Flush spaces by increasing ACHs as needed

Plus, the Phoenix Controls global network of partners has the tools and experience to assist with designing for new and existing building codes. We confirm new or retrofit projects are safe, and that they meet or exceed energy targets. We also ensure installed systems are properly maintained to ensure the lowest total cost of ownership.

Contact your local Phoenix Controls representative today to assist with USP <800> and other design needs. Visit www.phoenixcontrols.com/HowToBuy to find your local rep.

MAJOR DIFFERENCES BETWEEN USP <797> & <800>

USP <797> Pharmaceutical Compounding — Sterile Preparations	USP <800> Hazardous Drugs — Handling in Healthcare Settings
Applies to sterile compounding only.	Applies to sterile and non-sterile compounding.
Applies from receipt of inventory up to start of drug administration.	Wider continuum of time; Applies from receipt of inventory through drug administration
All HDs should be stored separately in an area with 12 ACPH and 0.01" w.c. negative to adjacent space.	Antineoplastic HDs must be stored separately from non-HDs in an area with 12 ACPH and 0.01" negative to adjacent space unless coated, final-manufactured dosage forms are clearly labeled as HDs and safety strategies are detailed in SOPs.
Exemption for low-volume compounding.	No low-volume exemption.
CSTD use is a "should."	CSTD use is a "shall" during administration as long as dosage form permits and "should" for compounding.
Defines PECs for HD sterile compounding.	Defines PECs for nonsterile & sterile HD compounding; allows manipulation of HDs that do not produce aerosols (e.g., coated tablets or capsules) outside of C-PEC.
Prohibits SCA for HD compounding; Requires BSC to be housed in ISO class 7 room air that is 0.01" w.c. negative	Permits C-SCA for HDs provided CACI/BSC in area that has 12 ACPH and 0.01" w.c. negative; maximum BUD 12 hours.
Does not require environmental and medical surveillance.	Recommends environmental and medical surveillance.

ACPH = air changes for hour; BSC = biological safety cabinet; BUD = beyond-use date; C-PEC = containment primary engineering control; CACI = compounding aseptic containment isolators; HD = hazardous drug; PECs = primary engineering controls; SCA = segregated compounding area; w.c. = water column.

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