



Purair Ductless Technology and USP 800 Compliance¹

Creating a better C-PEC

Chambre, Andre: CEO, Air Science LLC

July 2016



Abstract

Provisions outlined in the United States Pharmacopeia (USP) Chapter 800 (USP 800) outline best practices to maintain the highest quality standards for the handling of hazardous drugs. These practices promote patient safety, worker safety and environmental protection at all phases of drug handling.

This paper discusses the design and construction features of a set of engineering controls, collectively known as containment primary engineering controls (C-PECs), for hazardous drugs in healthcare settings. Biological safety cabinets and fume hoods in particular will be examined to identify the features that most effectively prevent exposure and meet USP 800 requirements.

USP 800 details processes intended to minimize exposure to hazardous drugs. The provisions in this chapter apply to all healthcare personnel who handle drug preparations, including pharmacists, pharmacy technicians, nurses and physicians. In addition, all healthcare facilities that store, prepare, transport or administer hazardous drugs are also covered by USP 800.

Most pharmaceuticals in the clinical environment can be hazardous or even deadly if not handled properly by healthcare personnel. If drugs are not properly handled, contamination and impurities can pose a danger to patients.



Quantifying Hazardous

The National Institute for Occupational Safety and Health (NIOSH) classifies drugs as hazardous or potentially hazardous when one or more of the following six criteria is identified:

- Carcinogenicity
- Teratogenicity (Developmental Toxicity)
- Reproductive Toxicity in Humans
- Organ Toxicity at Low Doses in Humans or Animals
- Genotoxicity
- New drug that mimics existing hazardous drugs in structure or toxicity

NIOSH maintains an ongoing list of hazardous drugs that meet the above criteria in a healthcare setting.

The Problem

Maintaining personnel safety while handling and preparing hazardous drugs can be difficult without proper provisions and equipment. Per USP 800, facilities that handle hazardous drugs must be equipped with a health and safety plan that includes engineering controls, personnel training, safe work practices, proper use of appropriate Personal Protective Equipment (PPE), and written policies for hazardous drug waste segregation and disposal at a minimum.

In many instances, potential exposure to hazardous drugs can be controlled through proper procedural development, rather than relying on the last line of defense for personnel (engineering controls and PPE). In cases where engineering controls are the only barrier remaining between safety and exposure, it is important that these controls be held to a high quality and safety standard in order to be effective.

C-PECs

According to the USP 800, C-PECs are ventilated devices specially designed to minimize worker and environmental exposure when directly handling hazardous pharmaceuticals. C-PECs are stored in containment secondary engineering control (C-SEC) rooms.

According to the United States Pharmacopeia Chapter 800, "there is no acceptable level of personnel exposure" to hazardous drugs, and containment of hazardous drugs must be "to as low a limit as reasonably achievable." Hazardous drug compounding must be conducted in separate designated areas, with specified ISO classifications.

USP 800 claims that "final antineoplastic dosage forms that do not require any further manipulation other than counting final dosage forms may be dispensed without any further requirements for containment unless required by the manufacturer. For dosage forms of other HDs on the NIOSH list, the entity may perform an assessment of risk to determine alternative containment strategies and/work practices."

Certain dosage forms of drugs that are defined as hazardous may not pose a significant risk of direct exposure because they are in pill or capsule form. However, dust from tablets and capsules may present a risk of exposure by skin contact and/or inhalation. Containment solutions need to be able to effectively manage the particulates that may arise from hazardous drugs. Containment equipment that meets these requirements include:

- Class I Biological Safety Cabinets (BSC)
- Class II Biological Safety Cabinets (BSC)
- Class III Biological Safety Cabinets (BSC)
- Compounding Aseptic Containment Isolators (CACI)
- Containment Ventilated Enclosures / Powder Hoods

Differences: Ductless vs. Ducted

There are two main types of C-PECs: externally vented and redundant HEPA-filtered ductless hoods.

Redundant HEPA Filtered Ductless C-PECs

Ductless recirculating hoods can only be used for non-sterile HD compounding. Ductless C-PEC solutions use redundant HEPA filtration to clean contaminated air, then circulate the filtered air back into the room. Ductless C-PECs do not require any additional HVAC accommodations, are typically highly mobile, and do not put additional load on the laboratory HVAC system. Ductless C-PECs provide a high level of protection for non-sterile compounding procedures. They also incorporate industry leading internal airflow, a variety of construction features to aid in operator safety, and effective HEPA filtration.

Ductless C-PECs are not limited by existing utility and HVAC drop locations within the laboratory. The self-contained units incorporate internal brushless fan motors to draw air through the cabinet. The cabinet internals are designed to provide unobstructed airflow and easy cleaning for operators. The internal HEPA filters provide a range of high performance protection, capturing particles larger than 0.3 microns (HEPA) with >99.999% typical efficiency.

Externally Vented C-PECs

Externally vented C-PECs are the most common and often required in certain facilities, depending on applications and pharmaceuticals handled, particularly when the manipulation of sterile hazardous drugs is necessary. Externally vented C-PECs tie into an existing facility ductwork system to evacuate contaminated air from the C-PEC to the outside. The air will normally pass through an individual unit filter and/or a facility filter in the ductwork before being released into the atmosphere.

Advantages

Externally vented C-PECs do have some advantages. Systems are fairly simple in construction and therefore often cheaper to purchase. If existing ductwork is available, externally vented C-PECs can be quick to install. However, in cases with no existing facility ductwork tie-ins, additional laboratory planning and construction may be required.

Disadvantages

Externally vented C-PECs are stationary in design and often involve more laboratory planning and setup as well as additional expense for ductwork and utility planning. On top of the additional expense for laboratory planning, externally vented C-PECs involve higher lifetime expense due to the additional utility load required to heat and cool air that is lost to outside venting. This also puts an additional load on the facility HVAC system, which may in turn require updating if it was not initially designed to handle the additional load from the new hood.

Common, well-documented disadvantages with ducted C-PECs include:

- **FILTER CHANGES**
Often include filter change out procedures which have antiquated and somewhat ineffective isolation procedures to contain filter contamination. This can result in technician exposure and a loss in production time.
- **FILTER ALARMS**
Without proper filter alarms on the unit-level, technicians may be unaware of the level of filter contamination which could lead to unintentional exposure.
- **AIRFLOW ISSUES**
If existing facility HVAC ductwork was not designed to properly vent the number of C-PECs used in the facility, airflow in individual units can suffer in terms of air speed, containment, and filtration efficiency."

Air Science Designs that Meet USP 800

Air Science® manufactures a complete series of high efficiency ductless fume hoods, ductless workstations, laboratory filtration products, and custom enclosures designed to protect the user, the process and the environment from hazardous vapors, fumes, and particulates. Air Science produces several products that meet or exceed certain USP 800 standards for non-sterile and sterile compounding of hazardous drugs, including:

- The Purair® RX
- The Purair Basic
- The Purair BIO

Purair RX

The Purair RX Hood is a Class I enclosure that meets USP 800 requirements for non-sterile compounding procedures. The Purair RX is designed to protect the user and the environment from hazardous powders and particulates generated on the work surface. At the heart of the Purair product line is innovative ductless technology that creates a safe work environment in a wide variety of applications throughout the industry.



The Purair RX also incorporates a variety of features and benefits that help the unit comply with USP 800 requirements for non-sterile compounding:

- The filter identification window helps ensure the proper HEPA filtration is installed and also assists technicians in monitoring the change dates for the installed filter.
- Side Waste Chutes allow safe transfer of waste from the work surface to the proper disposal receptacle, without exposing the technician to dangerous particles.
- Rear internal baffle systems ensure a smooth, horizontal airflow pattern and safe capture of any particulates on the work surface.
- Horizontal airflow causes less fluctuation to readings on balances and scales than vertical airflow, allowing for more accurate measurements.
- The flexibility to use as a recirculating hood when fitted with redundant HEPA filtration or connected to externally vented ductwork using the exhaust port on top.
- PTEG panels provide superior alcohol resistance compared to polycarbonate and acrylic.
- Electronic controls, alarms and displays include switches for the blower and low airflow alarm.

Purair Basic Fume Hoods

Purair Basic ductless fume hoods are designed to provide the user and the environment high level protection from hazardous vapors generated on the work surface. At the heart of the Purair fume hood product line is the innovative Air Science Multiplex™ Filtration Technology that creates a safe work environment over the widest range of applications in the industry. The Purair Basic fume hood can meet non-sterile compounding requirements as outlined by USP 800 if equipped with redundant HEPA filtration. Additional features that help the Purair Basic comply with USP 800 include:



- A high capacity air handling system that delivers a face velocity of 100 fpm, coupled with a low airflow alarm for insufficient face velocity.
- A unique filter clamping design eliminates bypass leakage outside the cabinet and an optional filter saturation alarm assists in ensuring the technician knows when to change the HEPA filter.
- The Purair Basic incorporates an analog air velometer to monitor face velocity and electronic controls and displays equipped with switches for the blower and low airflow alarm.
- An electrostatic pre-filter provides 99.5% effectiveness and is accessible from within the chamber to control the release of any particulates that it may trap. The pre-filter can be changed while the unit is operating to prevent operator exposure to chemical vapors and particulates.
- A continuous air velocity monitoring system with an integrated airflow alarm warns of face velocity that is too low to protect the operator from contamination.

Purair BIO Biological Safety Cabinet

The Purair® BIO BSC is designed to protect individuals, the environment and products from a variety of biological particulates, serving as the primary barrier in life science research and experimentation. In certain situations, the Purair BIO can meet USP 800 requirements for sterile compounding procedures.

HEPA filtration scours 70% of the incoming room air to protect the products, while the remaining 30% of exhausted air is filtered by a second HEPA filter. The Purair BIO uses AstroCel® HEPA filters to provide a range of high performance protection. These self-contained filters are designed to physically capture particles larger than 0.3 microns with >99.995% typical efficiency.

Additional Purair BIO features that assist in meeting USP 800 requirements include:

- HEPA AstroCel II Fluid Seal Filters feature an integral groove filled with gel at the air inlet side, ensuring a perfect seal to the housing system. A patented HEPA filtration lock maintains filter efficiency, minimizes the chance of leakage and prolongs filter life.
- High quality control system with rocker switches and easy-to-read gauges for safety and durability.
- Double-wall design creates a unique plenum which surrounds contaminated areas with negative pressure and prevents the possibility of contamination from leaks in filter seal, gasket or cabinet structure.
- International standard compliance, as the Purair BIO undergoes 10 internal quality tests prior to leaving the factory, including pressure decay testing, downflow velocity testing and HEPA filter leak testing.
- USP800 requires C-PECs used for sterile HD compounding to be exhausted to the outside of the building. An optional exhaust collar (8 inch OD) allows the Purair BIO to connect to in-house ductwork.
- All Stainless steel interior with a removable worktop allows for easy cleaning. A germinal UV light can be used to provide secondary decontamination.



Conclusions

Air Science has created several ductless solutions to meet USP 800 requirements in the Purair line of products. The Purair RX and Purair Basic can be configured to meet USP 800 for non-sterile compounding procedures for hazardous drugs, while the Purair BIO can be configured to meet sterile compounding procedures for hazardous drugs in select cases.

Significant design features have been considered to ensure Air Science products meet USP 800 requirements. Through sound design principles, innovative product features and continued rigorous product testing, Air Science products continually perform best-in-class at an affordable price.

About the Author: Andre Chambre

Andy Chambre is the founder and CEO of Air Science, LLC and has been associated with the ductless fume hood industry for more than 25 years. He was formerly the US Vice President for Captair Labx and President of Astec Microflow US. He was named President of Filtco Corporation in 2003 and also currently serves as a Director of Air Science Technologies Ltd. in the UK. Mr. Chambre has written numerous articles on fume hood safety and assisted in the development of safety standards by serving on various committees, such as the Canadian Standards Association subcommittee on fume hoods and the SEFA 9 Ductless Enclosures Committee.

Sources

- Proposed <800> Hazardous Drugs—Handling in Healthcare Settings, PF 41(2), U.S. Pharmacopeial Convention.

¹ *Notice to California Residents: The State of California has adopted an independent series of regulations associated with containment products intended for use in hazardous drug processes generally included in criteria set forth in USP800. For information on applications in California, and state and local regulations, refer to the California Code of Regulations §1735, Article 4.5 of Division 17 of Title 16.*



120 6th Street • Fort Myers, FL 33907
T/239.489.0024 • Toll Free/800.306.0656 • F/800.306.0677
www.airscience.com

Air Science, Multiplex and Purair are registered trademarks of Air Science Corporation.

