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USP 800 Compliance

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USP 800 is a new enforceable USP standard that is currently official and takes effect in July 2018. However, some states, such as California, have implemented USP 800 requirements already. Since compliance may require construction and/or significant changes to the pharmacy workflow, it is important that pharmacists start determining what is required for them to comply. USP 800 is a safety standard that resembles OSHA requirements more than the typical USP compounding standards. Therefore, it can be intimidating for a pharmacist to work through hazardous drug language that they are not typically accustomed to. This course provides an overview of USP 800 requirements and discusses how they impact pharmacy practice in various settings.

Learning Objectives

Pharmacist

1. Determine if drugs are considered hazardous and what USP 800 requirement level they fall under.
2. Describe which drugs must adhere to USP 800 requirements and which are subject to a risk assessment.
3. Design an appropriate floor plan that would meet the requirements for hazardous drug compounding.
4. Explain the requirements for a hazard communication program and personnel training.
5. List the SOPs that are required for a pharmacy compounding hazardous drugs

Pharmacy Technician

1. List potential opportunities for exposure to hazardous drugs.
2. Explain the requirements for personal protective equipment and the reasons why these safeguards are necessary.
3. Describe requirements for deactivating, decontaminating, cleaning and disinfecting.
4. Describe which drugs must adhere to USP 800 requirements and which are subject to a risk assessment.

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Target Audience

Pharmacists, Pharmacy Technicians

Universal Activity Number

Pharmacist
0798-0000-18-259-H07-P

Pharmacy Technician
0798-0000-18-259-H07-T

Credit Hours

2.0 Hours

Activity Type

Knowledge-Based

CE Broker Tracking Number

20-642959

Activity Release Date

January 3, 2019

Activity Offline Date

December 3, 2021

ACPE Expiration Date

December 3, 2021

Educational Support Provided By

PharmCon, Inc.

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Each year new drugs are developed to manage organ transplantation, autoimmune diseases, cancer and infections. However, these are not innocuous agents and healthcare providers, patients and family members may be exposed to these hazardous drugs. Compromised reproductive health and fertility, including an increased risk for spontaneous abortion has been identified as a risk to health care workers exposed to antineoplastic agents. One study found that nurses who were regularly exposed to antineoplastic agents were two times more likely to experience a spontaneous abortion.1 Another study looking at nursing and pharmacy staff also found an increased risk of spontaneous abortion when exposed to antineoplastic agents.2 A cross-sectional study found measurable chemotherapy concentrations in the urine of one pharmacy technician and two pharmacists after preparing antineoplastics for administration.3 There is also some evidence that occupational exposure to hazardous drugs increases the risk of certain cancers. However, this data is primarily limited to epidemiological studies and case reports. Non-antineoplastic hazardous drugs such as hormonal agents, anti-viral agents, and bioengineered drugs, have been linked to skin rashes, reproductive effects, and cancer.4 Exposure to hazardous drugs can occur from a variety of activities including manipulating parenteral formulations, disposing of drug vials and contaminated materials, counting tablets and capsules, administrating medications, transporting medications, and compounding.

The United States Pharmacopeial Convention (USP) is a nonprofit organization that develops standards in the pursuit of its mission "To improve global health through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods." (USP-NF). The USP has no enforcement capability, but the standards are enforceable by the Food and Drug Administration (FDA), and they are adopted by many state boards of pharmacy and The Joint Commission. On August 1, 2016, USP released the final version of USP General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings". USP chapters numbered less than 1000 are enforceable while chapters greater than 1000 are informational-only. Therefore, USP <800> will be enforceable when it becomes official on July 1, 2018.

USP <800> describes standards for handling hazardous drugs that are designed to promote safety of patients, workers and the environment. This chapter is unique compared to other USP chapters in that it focuses largely on the safety of the healthcare worker versus the product quality focus of other chapters. USP <800> encompasses all aspects of hazardous drug handling including receipt, storage, dispensing, compounding, administration and disposal of sterile and nonsterile products. This chapter applies to all healthcare workers that come into contact with hazardous drugs regardless of practice setting. Therefore, this chapter applies to pharmacies, outpatient treatment clinics and veterinary hospitals in addition to traditional human hospital systems.

The National Institute for Occupational Safety and Health (NIOSH) Alert: Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Healthcare Settings was originally published in September 2004. Updated lists were published in 2010, 2012, 2014 and 2016. The NIOSH defines hazardous drugs as "those that exhibit one or more of the following six characteristics in humans or animals: carcinogenicity, teratogenicity or other developmental toxicity, reproductive toxicity, organ toxicity at low doses, genotoxicity, and structure and toxicity profiles of new drugs that mimic existing drugs determined hazardous by the above criteria." The NIOSH list consists of approved drug products, and divides hazardous drugs into three groups. Group 1 consists of antineoplastic agents such as bleomycin, cyclophosphamide, lomustine, and methotrexate. Group 2 consists of non-antineoplastic agents that meet one or more of the NIOSH criteria for a hazardous drug such as azathioprine, cyclosporine, methimazole, and spironolactone. Group 3 consists of non-antineoplastic drugs that primarily have adverse reproductive effects such as colchicine, fluconazole, paroxetine, and warfarin. Note that Group 1 and Group 2 drugs may also pose a reproductive risk. The NIOSH list is updated periodically and it's important that each institution reviews the current list. However, veterinary drugs, drugs that are approved between updates and investigational drugs will not be included on the NIOSH list. Consequently, these medications must be evaluated based on their structure, toxicity profiles, and manufacturer handling precautions and considered hazardous if they are similar to drugs included on the list. If there is not enough information available to determine if a drug is hazardous, it should be considered hazardous until sufficient information is available.

As an initial step towards complying with USP <800>, each facility should develop a list of hazardous drugs that are handled within that facility. This list can be developed by reviewing the current revision of the NIOSH list for any drugs carried in that facility. Additionally, a pharmacist should review drugs that are carried that have been introduced to the market since the last update, have a veterinary label and/or are investigational to determine if they should be included in the facility's hazardous drug list. A facility's hazardous drug list must be reviewed at least every 12 months, and whenever a new drug is stocked it should be considered for inclusion on the facility's list. Furthermore, the facility's list should be broken down into two sections 1.) drugs that must follow all of the engineering and handling standards established in USP <800> and 2.) drugs that are eligible for risk assessment and may be used according to an institutional SOP instead of full compliance with the engineering controls in USP <800>. Drugs that must follow USP <800> are all antineoplastic agents requiring manipulation such as injectable chemotherapy agents and all hazardous drug active pharmaceutical ingredients (APIs) such as hormone powders. Other drugs on the NIOSH list are eligible for a risk assessment. This would include final dosage forms of compounded preparations and manufactured products including antineoplastics that don't require additional manipulation other than counting or repackaging such as chlorambucil tablets. These drugs may be exempt from USP <800>

requirements if an assessment of risk is performed. An assessment of risk is considered acceptable for these drugs because their dosage forms (i.e. tablets or capsules) are solid and intact, resulting in less risk compared to dosage forms requiring manipulation. However, it should be noted that dust from these tablets or capsules still poses a risk through skin contact and inhalation. Therefore, an assessment of risk is necessary to determine sufficient containment strategies. At a minimum, the assessment of risk must consider if the drug is a Group 1, 2 or 3 agent, the dosage form, the risk of exposure, product packaging and required manipulations. The assessment of risk must include documentation of alternative containment strategies and work practices used to minimize exposure. This document must be reviewed (with the review documented) at least every 12 months. If an assessment of risk is not performed or appropriately documented then these drugs are subject to all requirements within USP <800>. For example, an assessment of risk for chlorambucil tablets would determine that this is a class 1 agent (antineoplastic), coated tablets, low risk of exposure when dispensing whole tablets, product needs to be counted and packed in a prescription vial. Therefore, the risk of exposure is low. Alternative containment strategies could include counting the tablets on a counting tray designated for hazardous drugs and wearing gloves while handling this medication. This assessment would need to be documented and reviewed each year with that review documented. If it is determined that there is a need to split these tablets, an assessment of risk is no longer appropriate for chlorambucil because it's an antineoplastic agent. The assessment of risk should be done and reviewed by a person qualified to use their professional judgement with regards to risk of exposure.

When preparing an assessment of risk, the pharmacist is required to determine the risk of exposure. All possible avenues of exposure should be considered. USP <800> provides information on potential exposure opportunities based on activity. These include, but are not limited to the following.

- Hazardous drug residue present on drug containers (including outer containers) that are handled during receipt
- Dust resulting from counting and repackaging tablets and capsules
- Manipulating drugs through slitting tablets, diluting injectable medications and any other form of compounding.
- Priming an IV administration set and other administration steps
- Handling contaminated body fluids or materials and disposal of these
- Management of spills
- Moving hazardous drugs throughout the health care setting

USP <800> requires that each facility designate a person to be responsible for developing, implementing and maintaining the requirements of this chapter and other hazardous drug laws and regulations as well as ensuring competency of everyone handling hazardous drugs. The chapter states that this person should be qualified and trained so that they understand the reason for the policies, the risks from handling hazardous drugs, the risks of non-compliance and the responsibility to report situations that may be hazardous to management. This person must also be responsible for overseeing facility monitoring and maintaining the required reports. This person does not have to be a pharmacist, but it may be a pharmacist. While only the designated person is required to oversee compliance with USP <800>, everyone handling hazardous drugs has a responsibility to understand the practices and precautions necessary for safe handling and inspection of final products to minimize contact and prevent patient harm.

Facilities and Engineering Controls

In an effort to increase patient and worker safety and protect the environment, it is critical that hazardous drugs be handled in designated areas. These areas must be clearly marked as hazardous drug areas with a sign prominently displayed by the entrance, and the areas must be restricted to access only by authorized personnel. This protects people that are not involved with handling hazardous drugs. Areas designated for hazardous drug handling must be located in areas that are away from breakrooms and other areas with food and drinks to decrease the risk of exposure through ingestion. There must be designated areas for receipt and unpacking, storage, non-sterile compounding (if performed) and sterile compounding (if performed) of hazardous drugs. Each of these areas has different requirements based on the risk of exposure from the task being completed in that area.

Unpacking hazardous drug from their external shipping containers must be done in an area that is neutral or negative pressure to the surrounding areas, and this area must not be a sterile compounding area. Once the drugs are unpacked, they must be stored in such a way to prevent spilling and breakage, and these drugs must not be stored on the floor. In areas that are prone to certain natural disasters, such as earthquakes, the storage system must meet certain safety requirements such as raised front lip shelves to prevent drugs from sliding off the shelves during an earthquake. Antineoplastic drugs that require any manipulation other than counting/repackaging a final dosage form must be stored in a separate location from non-hazardous drugs. This is to prevent accidental exposure when someone is obtaining a non-hazardous medication. For example, if an antineoplastic bulk powder for compounding is stored next to a non-hazardous bulk powder, some of the hazardous bulk powder may come into contact with the non-hazardous container. If a pregnant technician needs the non-hazardous drug she may unknowing come into contact

with a hazardous drug. Therefore, separate storage is necessary. Antineoplastic hazardous drugs must be stored in an externally vented, negative pressure room that has a minimum of 12 air changes per hour (ACPH). Non-antineoplastic hazardous drugs, and final dosage forms may be stored with non-hazardous drugs if allowed by facility policy after assessment of risk. Refrigerated antineoplastic medications must have a designated refrigerator in a negative pressure area that has at least 12 ACPH.

When compounding hazardous drugs, the risk of exposure is increased compared to handling final dosage forms. Therefore, additional engineering controls are required. There are three categories of engineering controls: primary, secondary and supplementary. A containment primary engineering control (C-PEC) in a device that decreases hazardous drug exposure for the compounder and the environment. This would be something like a glove box or hood. The containment secondary engineering control (C-SEC) is the room where the C-PEC is placed. Supplementary controls are additional devices that offer increased protection, both within the C-PEC/C-SEC and during administration. A closed-system transfer device (CSTD) used when preparing and administering chemotherapy is an example of a supplementary control.

For both sterile and non-sterile hazardous drug compounding, the C-PEC must be located in a C-SEC that is externally vented through high-efficiency particulate air (HEPA) filtration, physically separated, appropriate ACPH, negative pressure between 0.01 and 0.03 inches of water column compared to all adjacent areas. There must also be a sink, and an eye wash station and/or other safety precautions necessary to comply with relevant laws and regulations. However, water sources and drains must be located at least 1 meter away from the C-PEC and in such a way as to not interfere with ISO classifications that are required for sterile compounding. If both sterile and non-sterile compounding is performed, they must be done in separate C-PECs that are in separate rooms. The exception to this is if the C-PEC for non-sterile compounding allows the room to maintain an ISO 7 classification throughout all non-sterile compounding, then both sterile and non-sterile C-PECs may be located in the same C-SEC; however, they must be at least 1 meter apart.

For non-sterile compounding, C-PECs must be either externally vented or have redundant HEPA filters in series. The C-PEC must provide personnel and environmental protection. If

a facility only occasionally compounds non-sterile hazardous drugs, a C-PEC designated for sterile compounding can be used, but it must be sufficiently decontaminated, cleaned and disinfected prior to using it for sterile compounding. The C-PEC must be placed in a C-SEC that is externally vented with at least 12 ACPH, and negative pressure; however, this does not have to be an ISO environment if sterile compounding is not performed in it. All surfaces in the non-sterile compounding area must be smooth, impervious, non-shedding and free from cracks. Surfaces that do not meet these requirements are difficult to remove hazardous drug contamination from.

Sterile hazardous drug compounding requires a C-PEC that is externally vented, negative pressure, and has at least 12 ACPH; however, unlike for non-sterile compounding, a sterile C-PEC must also have an ISO Class 5 or better air quality. A laminar airflow workbench or compounding aseptic isolator are not appropriate for compounding antineoplastic hazardous drugs. The C-PEC used for preparing hazardous drugs should not be used to prepare non-hazardous drugs. However, if it is used, the non-hazardous drug must be treated as a hazardous drug and placed into a protective outer wrapper before being removed from the C-PEC and labeled to require personal protective equipment (PPE) handling precautions. The C-SEC for sterile compounding must be an ISO Class 7 environment with an ante-room or an unclassified containment segregated compounding area (C-SCA). If the C-SEC is a C-SCA, then only low and medium risk sterile preparations may be prepared, and the beyond use date of the product must be limited according to USP <797>. Note well that the risk categories for USP <797> are proposed for change as of January 2016.

Supplemental engineering controls, such as CSTDs provide additional protection when compounding and administering hazardous drugs. However, there is no universal standard for evaluating CSTDs. Therefore, users should carefully evaluate CSTDs, including performance claims, and independent, peer-reviewed studies to make an educated decision about which to use. Regardless of CSTD selected, it cannot be a substitute for a C-PEC when compounding, but should be used in addition if the dosage form allows.

The environment should be evaluated on a routine basis (initially and at least every 6 months, thereafter) using wipe sampling for hazardous drug residues. Areas sampled should include, the interior of the C-PEC and equipment within the C-PEC, pass-through chambers, surfaces located near the C-PEC including staging and work areas, areas adjacent to the C-PEC such as the floor underneath it, areas immediately outside the hazardous drug C-SEC or C-SCA, and drug administration areas. There is no ideal number of samples to obtain or the size of those samples and no acceptable limits for surface contamination. If contamination is discovered, the designated person must determine the cause, document

the finding and contain it. Work practices and training may need to be revamped to prevent future contamination.

Summary of Facility Requirements for Hazardous Drugs

Non-Sterile Hazardous Drugs

- C-PEC
    - Redundant HEPA filtered in series acceptable
        - External ventilation preferred
- C-SEC
    - Externally vented
    - 12 ACPH
    - Negative pressure between 0.01 and 0.03 inches of water column compared to adjacent areas

Sterile Hazardous Drugs

- ISO Class 7 buffer room (C-SEC) with ISO Class 7 ante-room
    - C-PEC
        - Externally vented
    - C-SEC
        - Externally vented
        - 30 ACPH
        - Negative pressure between 0.01 and 0.03 inches of water column compared to adjacent areas
- Unclassified C-SCA (ISO environment not required, but limited BUD)
    - C-PEC
        - Externally vented
    - C-SEC
        - Externally vented
        - 12 ACPH
        - Negative pressure between 0.01 and 0.03 inches of water column compared to adjacent areas

Worker Protection

PPE is essential to provide protection to people handling hazardous drugs. Certain situations may require additional PPE, such as spill cleanup. The NIOSH list provides information about PPE that is necessary for various scenarios. At a minimum, gowns, head, hair and shoe covers and two pairs of chemotherapy gloves must be worn when compounding hazardous drugs, regardless of whether the final product is sterile or non-sterile. Traditional gloves may not adequately prevent contact with the hazardous drug; therefore, gloves designed for chemotherapy must be used whenever handling a hazardous drug – including non-antineoplastic hazardous drugs. These gloves must meet the requirements of the American Society for Testing and Materials (ASTM) standard, and the gloves must be powder-free. If the gloves are not powder-free, the powder could absorb hazardous substances. However, since the FDA banned powdered gloves, this should no longer be a problem.6 Gloves should always be visually inspected to verify that there are no defects that would allow hazardous drug contact. Even pinholes can be problematic. PPE that is appropriate for the situation must be worn whenever in contact with hazardous drugs. This includes unpacking and putting away hazardous drugs, transport, compounding, administration, spill control, cleaning hazardous drug areas, and disposing of contaminated/potentially contaminated waste.

Whenever gowns are required to be worn, they must be disposable and shown to resist hazardous drugs. It's important to select gowns that are appropriate for the hazardous drugs being handled because not all gowns are created equally. For example, some gowns are coated and offer better protection than uncoated gowns. Regardless of gown chosen, they must close in the back, have long sleeves and have cuffs that are either knit or elastic. Lab coats, scrubs, and isolation gowns are not appropriate. These materials are permeable to hazardous drugs and hold spilled drugs against the skin. If clothing becomes contaminated, it must not be taken home for any reason. Head, hair and shoe covers are also necessary. Shoe covers are appropriate for all sterile compounding, but when compounding hazardous drugs, a second pair should be put on immediately before entering the C-SEC and removed when exiting. Shoe covers worn in areas where hazardous drugs are compounded should not be worn in any other area. Eye, face and respiratory protection may be required in certain instances, such as when cleaning up spills. Eye glasses and safety glasses do not adequately protect the eyes, and surgical masks do not provide adequate respiratory protection. Googles and N95 respirators are needed if eye and respiratory protection are required. Googles should be used when there is a risk of splashing and an N95 respirator should be used when there is known or suspected airborne exposure to hazardous powders or vapors. All PPE that is worn when handling hazardous drugs should be treated as if it is at least minimally contaminated. Therefore, it should be placed in appropriate disposal containers based on applicable regulations.

To maximum worker safety, it's important for facilities to clearly communicate potential hazardous to people that may encounter them. There must be standard operating procedures (SOPs) in place to ensure appropriate labeling, storage, transport and disposal of all hazardous drugs and use of Safety Data Sheets (SDS). USP <800> refers to these requirements collectively as a Hazard Communication Program. At a minimum a facility's hazard communication program must include a written plan describing how USP <800> requirements will be implemented, labeling on all containers that identify the contents and applicable hazard warnings, SDS for every hazardous chemical used which must be readily accessible to everyone handling the substance, information and training regarding potential hazardous the person may be exposed to prior to exposure, and personnel that are of reproductive capability must confirm in writing that they understand the risks of handling hazardous drugs. The written plan for USP <800> implementation makes it clear to everyone in the facility and inspectors what precautions are being addressed to ensure worker safety. It is also important that all containers are appropriately labeled because this allows personnel to identify which agents are hazardous and access appropriate SDS. Having a computer connected to the internet that allows ready online access to SDS is considered "readily accessible"; however, personnel must be trained in how to find these sheets quickly online if that route is chosen over paper copies. Personnel must be made aware of hazardous substances and the potential risks of handling them prior to being asked to handle them. Personnel that may become pregnant should be advised of additional risks to the fetus. Written documentation is required for something things by USP <800>, but it is advisable to always document appropriate training and acknowledgement of risks regardless of whether specifically required.

All personnel involved with hazardous drug handling must be trained on appropriate precautions to take with their job duties. The training must occur prior to the employee handling hazardous drugs independently and must be reassessed at least every 12 months. Additional training is required whenever there is a new SOP, new hazardous drug, new piece of equipment or a significant change to any of the above. At a minimum, the training must include an overview of the hazardous drugs handled in the facility and the risks of exposure, review of the facility's SOPs, proper use of PPE and equipment and devices, appropriate response to hazardous drug exposure, spill management and proper disposal of contaminated items. All training must be documented.

SOPs must be in place for receiving hazardous drugs. These should include information about how to handle damaged shipping containers containing hazardous drugs. When receiving hazardous drugs, appropriate PPE should be worn which includes chemotherapy gloves, and a spill kit must be accessible in the area where the drugs are being unpacked. Once the drugs are unpacked, they should immediately be transferred to the hazardous

drug storage area. The facility must also have in place SOPs for labeling, packaging, transporting and disposing of hazardous drugs. These must address steps that must be taken to prevent spills and accidental exposures as well as making sure that hazardous drugs are always able to be identified through appropriate labeling. If shipping hazardous drugs, there must be a SOP regarding appropriate shipping containers and mode of transport to prevent accidental exposure. This includes using containers that decrease the risk of the drug vial breaking or the drug leaking. If hazardous drugs are being shipped outside of the facility, the Transport Information section on the SDS should be consulted and the labeling should be in accordance with the carrier's policies. Additionally, everyone removing waste from hazardous drug areas must be trained on appropriate disposal of hazardous waste to comply with all applicable laws.

Deactivation, decontamination and cleaning are required for all areas where hazardous drugs are handled and all reusable equipment. Disinfecting is also required for sterile compounding areas. Deactivation makes a compounding inactive and decontamination removed the material from the surface. Cleaning removes contaminants such as microbial contaminants and hazardous drug residue and disinfection inhibits or destroys microorganisms. Disinfection is not effective until the area is cleaned. The facility must develop SOPs for decontamination, deactivation, cleaning and disinfection. These should include procedures, agents used and applicable dilutions, frequency and documentation for each step. It is important to note that agents used should be applied to wipes and not applied by a spray bottle. Using a spray bottle increases the likelihood of spreading hazardous drug residue. USP <800> requires that the work area in the C-PEC must be decontaminated when switching between different hazardous drugs, any time a spill occurs and at least daily.

Spill kits must be available in all areas where hazardous drugs are handled, and personnel handling the drugs must be trained in how to appropriately use them. There must be SOPs in place to prevent spills and describe cleanup procedures if spills occur. The SOPs must address the size of the spill, who is responsible for spill management, PPE required, and location and capacity of the spill kit.

Workers handling hazardous drugs as part of their job on a regular basis should be enrolled in a medical surveillance program. This program involves the assessing and documenting symptom complaints, physical findings and laboratory values to determine if they are within normal limits. If findings are outside of the expected normal, the medical surveillance program provided a means for early detection of possible problems. This type of program also allows for evaluating trends in a certain population such as pharmacists to identify

hazardous drug handling procedures that require modification. If health changes related to exposure are identified, immediate re-evaluation of preventative measures should occur.

Dispensing and Administration

Hazardous drugs that are already in their final dosage form (i.e. tablets, capsules) can be dispensed like other tablets and capsules unless the manufacturer instructs otherwise. However, automated counting and packaging machines must not be used for antineoplastic agents because these machines may generate powder contaminants. When administering hazardous drugs, protective devices such as CSTDs must be used, and protective techniques should be employed. USP <800> requires the use of CSTDs for administering antineoplastic agents if the dosage form allows. Protective techniques include priming IV tubing using a non-hazardous solution in the C-PEC and crushing tablets inside a plastic pouch. However, manipulating the final dosage form should be avoided if at all possible because manipulation increases the risk of exposure. Additionally, appropriate PPE must be worn when administering hazardous drugs. After administration, PPE and equipment such as tubing and needles must be disposed of as contaminated.

USP <800> is designed to provide protection to healthcare workers handling hazardous drugs. This is different than other USP compounding chapters that are written to improve the quality of the final product. However, it is not a stand-alone guidance. Applicable local, state and federal laws and regulations with regards to hazardous drug handling, shipping and disposal all still apply. USP <800> simply provides relevant standards in a convenient location that provide exact details on how to comply. USP <800> also does not supersede USP <795> and USP <797>. USP <795> requirements all still apply for non-sterile hazardous drug compounds and USP <797> requirements all still apply for sterile hazardous drug compounds. For example, compounding lomustine capsules would fall under the requirements of USP chapters <795> because it's a non-sterile compounding and <800> because lomustine is an antineoplastic agent. However, compounding piroxicam capsules would fall under only USP <795> because piroxicam is not considered a hazardous drug. Sterile compounds fall under USP <797> and <800> in a similar manner.

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USP 800 Compliance • January 2019 • Volume 41, #1

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Release Date: January 2, 2019

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Universal Activity Number for this activity:
Pharmacists: 0798-0000-18-259-H07-P **Pharmacy Technicians:** 0798-0000-18-259-H07-T
CE Provider Registered # with CE Broker is 50-3515.

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LESSON EVALUATION

Please fill out this section as a means of evaluating this lesson. The information will aid us in improving future efforts. Either circle the appropriate evaluation answer, or rate the item from 1 to 7 (1 is the lowest rating; 7 is the highest).

1a. **PHARMACISTS ONLY:** Does this lesson meet the learning objectives? (Circle choice).

Determine if drugs are considered hazardous and what USP 800 requirement level they fall under.	YES	NO
Describe which drugs must adhere to USP 800 requirements and which are subject to a risk assessment.	YES	NO
Design an appropriate floor plan that would meet the requirements for hazardous drug compounding.	YES	NO
Explain the requirements for a hazard communication program and personnel training.	YES	NO
List the SOPs that are required for a pharmacy compounding hazardous drugs.	YES	NO

1b. **TECHNICIANS ONLY:** Does this lesson meet the learning objectives? (Circle choice).

List potential opportunities for exposure to hazardous drugs.	YES	NO
Explain the requirements for personal protective equipment and the reasons why these safeguards are necessary.	YES	NO
Describe requirements for deactivating, decontaminating, cleaning and disinfecting.	YES	NO
Describe which drugs must adhere to USP 800 requirements and which are subject to a risk assessment.	YES	NO

2. Was the program independent & non-commercial? YES NO

	Low Relevance						Very Relevant
3. Relevance of topic	1	2	3	4	5	6	7

4. What did you like **MOST** about this lesson? _____

_____

5. What did you like **LEAST** about this lesson? _____

_____

6. How would you improve this lesson? _____

_____

PLEASE MARK THE CORRECT ANSWER(S)

1. How are USP standards enforced?
   a. By USP's enforcement committee
   b. By the FDA, Joint Commission and State Boards of Pharmacy
   c. By the USDA
   d. USP standards are not enforceable

2. Which USP chapter describes the standards for handling hazardous drugs?
   a. USP <795>
   b. USP <797>
   c. USP <800>
   d. All of the above

3. Which organization publishes a list of all approved hazardous drugs used in human healthcare?
   a. ASHP
   b. FDA
   c. NIOSH
   d. USP

4. Which groups on the hazardous drug list may pose a reproductive hazard?
   a. Group 1
   b. Group 2
   c. Group 3
   d. Groups 1, 2, and 3

5. Which drugs are required to adhere to USP <800> standards?
   a. All active pharmaceutical ingredients (APIs) on the hazardous drug list
   b. All antineoplastic agents regardless of dosage form
   c. All agents which have been subjected to an assessment of risk
   d. All of the above

6. When must a facility's hazardous drug list be reviewed?
   a. Every 6 months and consider all new drugs added to inventory for inclusion
   b. Every 12 months and consider all new drugs added to inventory for inclusion
   c. Every 24 months and consider all new drugs added to inventory for inclusion
   d. Once it is created, it does not need to be reviewed

7. Which of the following represents an opportunity for hazardous drug exposure?
   a. Residue present on outer containers
   b. Dust from counting tablets
   c. Priming an IV administration set
   d. All of the above

8. Per USP, who is responsible for developing, implementing, and maintaining the requirements for hazardous drug laws and regulations?
   a. Everyone in the facility
   b. The designated person
   c. The facility owner
   d. The pharmacist in charge

9. When compounding transdermal methimazole using the API, which of the following environmental controls must be observed?
   a. A C-SEC that is negative pressure and externally vented with 12 ACPH
   b. A C-PEC that is externally vented with 12 ACPH
   c. An ISO Class 7 buffer area with an ISO Class 7 ante-room
   d. There are no environmental controls for this compound

10. Which of the following is an example of a supplementary engineering control?
    a. A negative pressure glove box
    b. An ante room
    c. A closed system transfer device
    d. All of the above

11. What standard should be used to evaluate CSTDs?
    a. FDA standards
    b. NIOSH standards
    c. USP standards
    d. There is no universal standard

12. What is the minimum PPE required when compounding hazardous drugs?
    a. Gowns, head, hair and shoe covers and two pairs of chemotherapy gloves
    b. Gowns and two pairs of chemotherapy gloves
    c. Gowns, head, hair and shoe covers, two pairs of chemotherapy gloves and respiratory protection
    d. Gowns, shoe covers, two pairs of traditional nitrile gloves and respiratory protection

13. What does USP <800> state regarding personnel of reproductive capacity handling hazardous drugs?
    a. They must not handle drugs classified by NIOSH as reproductive hazards
    b. They must not handle any drugs on the NIOSH list
    c. They must confirm in writing that they understand the risks associated with handling hazardous drugs
    d. USP <800> does not address this population

14. When must personnel be made aware of risks associated with handling hazardous substances?
    a. When handling hazardous substances regularly
    b. Before handling any hazardous substances
    c. During their first day on the job
    d. During their one year performance review

15. Which of the following are required for all hazardous drug compounding areas?
    a. Deactivation, decontamination and disinfecting
    b. Deactivation, cleaning and disinfecting
    c. Decontamination, cleaning and disinfecting
    d. Deactivation, decontamination and cleaning

16. When does the work area in the C-PEC have to be decontaminated?
    a. When switching between difference hazardous drugs
    b. Any time a spill occurs
    c. At least once a day
    d. All of the above

17. Which of the following is true when unpacking hazardous drugs?
    a. The area must be neutral or negative pressure compared to the surrounding areas
    b. This area must be a sterile compounding area that is neutral or negative pressure compared to surrounding areas
    c. This area must be negative pressure compared to the surrounding areas
    d. There are no specific requirements regarding where these drugs are unpacked

18. If the hazardous drug C-PEC is used to prepare a non-hazardous drug, what precautions should be taken?
    a. There are no additional precautions necessary
    b. Decontaminate the final product package prior to removing from the C-PEC
    c. Place the final product into a protective outer wrapper prior to removing from the C-PEC, label as hazardous and administer with hazardous drug precautions
    d. Non-hazardous drugs must never be prepared in a hazardous drug C-PEC

19. If non-sterile and sterile C-PECs meet the requirements to be located in the C-SEC, how far apart must they be?
    a. 2 feet
    b. 1 meter
    c. 2 meters
    d. There is no scenario where these could be in the same C-SEC

20. What is the purpose of PPE?
    a. To improve the quality of the final compound
    b. To protect the patient from contamination that may occur during compounding
    c. To protect the people handling the hazardous drugs
    d. All of the above