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Implementing USP 800

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Disclosure

- I have no conflicts of interest to disclose

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Objectives

1. Understand the purpose of USP 80
2. Describe how to engage key stakeholders and implement the required elements of USP 800
3. Explain what resources are available to implement USP 800 standards

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Overview

- Background
- Basic definitions
- Gap analysis
- Assessment of risk
- Non-Sterile Compounding

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Background

- Awareness of risk
  - Per the CDC, 8 million healthcare workers are potentially exposed[1]
  - Presence of chemotherapy in urine of healthcare workers[2]
  - Long-term repercussions of hazardous drug exposure
- Guidance documents previously released:
  - Oncology Nursing Society (ONS) in 1984
  - Occupational Safety and Health Administration (OSHA) in 1986
  - American Society of Health-System Pharmacists (ASHP) in 1990

1. "Hazardous Drug Exposures in Health Care." *Centers for Disease Control and Prevention*. 15 Sept 2016. Web. 20 Feb 2017.
2. Sorsa M, Anderson D. "Monitoring of occupational exposure to cytostatic anticancer agents." *Mutation Research* 355 (1996): 253-61.

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Background

- Release of the USP 800 chapter is a call to action
- Enforceable standard
  - State BOP and other regulatory bodies can require compliance

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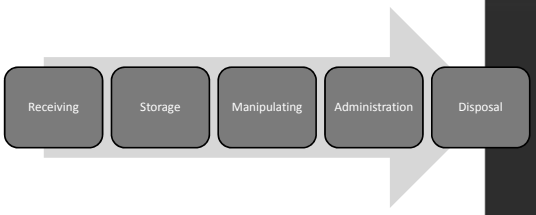
Background: Scope of USP 800



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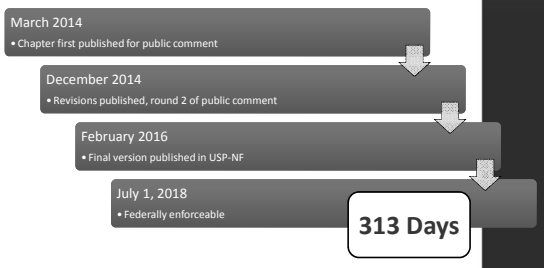
Background- USP 800 Timeline



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USP 800 Chapter Overview

- List of Hazardous Medications
- Personal Protective Equipment (PPE)
- Facilities Design
- Handling Hazardous Medications
- Cleaning
- Medical Surveillance

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Basic Definitions

Acronym in USP 800	Definition	What it really means
CPEC	Containment Primary Engineering Control	The hood
CSEC	Containment Secondary Engineering Control	The room the hood is in
CSCA	Containment Segregated Compounding Area	Segregated area, no requirement for ISO classification

"Should" → Recommendation

"Shall" or "Must" → Requirement

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CPEC: Types of hoods

Laminar Airflow Workbench (LAFW)	Biological Safety Cabinet (BSC)	"Glove boxes"
• Horizontal Airflow • Most common hood found in IV rooms • Can **NOT** be used for HD compounding	• Vertical Airflow • Often referred to as a "Chemo hood" • Classes and Types with % air recirculation	• Compounding Aseptic Isolator (CAI)- **POSITIVE** pressure • Compounding Aseptic Containment Isolator (CACI)- **NEGATIVE** pressure

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CPEC: Sterile Compounding of HDs

- Must be performed in a CPEC within a separate room with ISO Class 5 air
- Laminar airflow workbench (LAFW) or Compounding Aseptic Isolator (CAI) can **NOT** be used for compounding HDs

http://www.nuaire.com/products/pharmacy-isolators
https://www.terrauniversal.com/laminar-flow-hoods/horizontal-laminar-flow-hoods.php

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Changes from <797>

- Elimination of low-volume exemption currently in <797>
  - All HDs must be compounded in BSC or CACI in a negative pressure room
- Allowance for CSCA
- Storage under negative pressure

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Gap Analysis

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Conducting a Gap Analysis

- Compare the best practices with the processes currently in place in your organization
- Determine the "gaps" between your organization's practices and the identified best practices
- Select the best practices you will implement in your organization
- Get organized!

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http://www.buzzanalysis.com/2016/07/31/gap-analysis-what-and-how-all-you-need-to-know/

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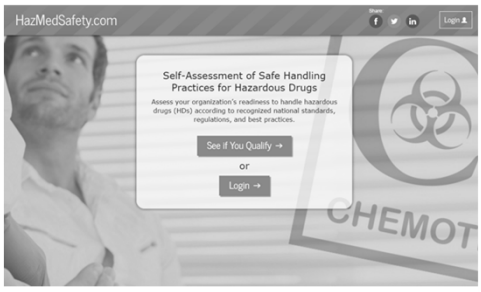
Gap Analysis: HazMedSafety.com



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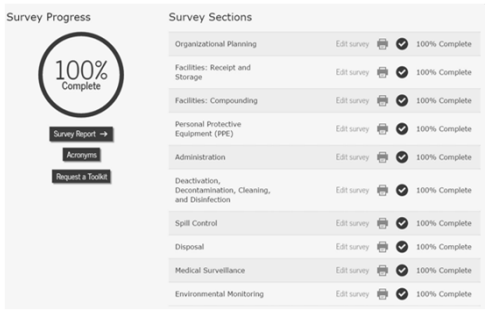
Gap Analysis: HazMedSafety.com



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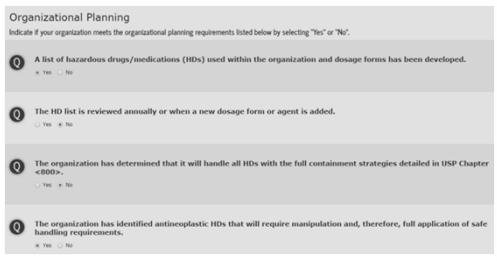
Gap Analysis: HazMedSafety.com



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Gap Analysis: HazMedSafety.com

Organizational Planning

Based on your answers, you indicated that you are 53% compliant with national regulatory requirements, recommendations, and best practices in this area.

Based on these answers, we recommend the following:

Which hazardous drugs/medications (HDs) are handled in this organization?

The current version of the National Institute for Occupational Safety and Health (NIOSH) list of hazardous drugs (HDs) (http://www.cdc.gov/niosh/docs/2014-138/pdfs/2014-138.pdf) is the required resource identified by U.S. Pharmacopeial Convention (USP) Chapter <800> to assist organizations in identifying HDs that the organization prepares, administers, or handles. The organization's list should correspond to what is actually used. Dosage forms should be included to help with identifying specific handling requirements. Dosage forms and the nature of handling must be considered to determine if full adherence to USP Chapter <800> containment requirements is needed, or if modified containment practices can be used, as determined by an assessment of risk (see *Safe Handling Practices for Hazardous Drugs*, Chapter 4). As new drugs (including investigational drugs) or dosage forms are adopted for use within the organization, criteria within the NIOSH list should be used to determine HD status. If insufficient information exists to determine HD status, the new drug should be considered hazardous until more information is available.

Decisions regarding assessment of risk

USP Chapter <800> defines containment strategies and work practices for HDs. Organizations must use all the containment strategies defined in USP Chapter <800> for active pharmaceutical ingredients (APIs) or any antineoplastic that requires manipulation, but may choose whether to implement all containment strategies within USP Chapter <800> for other HDs. An alternative to implementing all containment strategies and recommended work practices is to perform an assessment of risk for the HDs that may not require full implementation of all containment strategies. USP Chapter <800> allows this if drugs on the NIOSH list are final forms of compounded HD preparations or conventionally manufactured HD products, including antineoplastic dosage forms that don't require

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Gap Analysis: HazMedSafety.com

Personal Protective Equipment (PPE)

Based on your answers, you indicated that you are 73% compliant with national regulatory requirements, recommendations, and best practices in this area.

Based on these answers, we recommend the following:

Development of standard operating procedures (SOPs) that define PPE

The organization will need to decide on required personal protective equipment (PPE) for each activity. The most current National Institute for Occupational Safety and Health (NIOSH) list of hazardous drugs (HDs) defines required PPE by activity, but the list is limited to compounding and administration activities. U.S. Pharmacopeial Convention (USP) Chapter <800> provides added guidance for some activities, such as receiving of HDs and spill cleanup. The organization will need to make decisions based on best collective evidence and assessment of risk for the categories of HD that might be determined to carry a lesser degree of risk. Once decisions have been made, they should be incorporated into SOPs so that staff are aware of required PPE, and to support a consistent practice. Detailed guidance will be provided for recommended PPE by activity in *Safe Handling Practices for Hazardous Drugs*, Chapter 1.

Specific guidelines for PPE for each of these areas:

Receipt

Organizational procedures should direct required garb for receipt of HDs. Currently, USP Chapter <800> and the NIOSH List of Antineoplastic and other Hazardous Medications in the Healthcare Setting provides limited guidance as to required PPE. Consideration should be given to defining PPE for routine receipt of HDs, and for situations in which breakage might have occurred and exposure potential is more likely. Minimally, workers should wear chemotherapy protective gloves, and decisions should include whether one or two pairs of gloves should be used. Consideration should also be given to whether HDs are packaged in plastic. USP Chapter <800>

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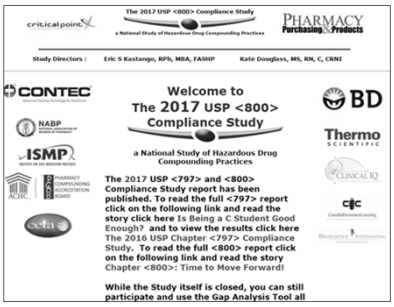
Gap Analysis: 800gaptool.com



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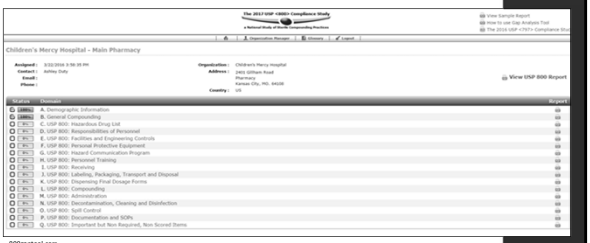

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TABLE 2

Chapter <800> PPE Compliance

	# of Responses	Compliance Rate
This location uses 2 pairs of powder-free, chemotherapy gloves that have been tested to ASTM standard 6978 when compounding any sterile or nonsterile HD formulations.	718	68%
Gloves used for HD compounding are inspected for physical defects before donning and periodically and are changed when torn, punctured, or contaminated.	854	93%
Hands are washed with soap and water after doffing (taking off) chemotherapy gloves.	718	79%
Gowns used for HD handling meet all of the following criteria: disposable, back-closing, long sleeved, closed cuffs that are elastic or knit, seamless or construction that prevents HDs from passing through; selected based on HDs handled and shown to resist permeability to HDs.	848	81%
Gowns are changed based on the following: per manufacturer's information on permeation OR every 2-3 hours of compounding AND immediately after a spill or splash.	847	74%
Disposable PPE (head, face, beard covers, gowns, sleeves, shoe covers) is used for HD compounding and is NEVER reused.	861	71%
Reusable PPE (such as goggles, full-face respirators, etc.) is decontaminated and cleaned after each use.	853	57%
This location's personnel (eg, nursing, interns, students, techs outside of the pharmacy) wear two pairs of chemotherapy gloves that have been tested to the ASTM standard 6978 AND gowns shown to resist permeability to HDs during the administration of antineoplastic HDs.	801	51%

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II. Action Plan Detail

The information contained in this section, **Action Plan Detail**, lists all of the action plan items within each domain that need to be addressed based on your responses to the gap analysis questions. To view the full detail of each question answered and your response please refer to Section III. Action Plan Detail by Trigger Question.

A. Demographic Information

None.

B. General Compounding

None.

C. USP 800: Hazardous Drug List

- As you evaluate new drugs, if the information available on the new drug is not sufficient to make a decision, then handle the drug as an HD.
- As you evaluate new drugs, if the information available on the new drug is not sufficient to make a decision, then handle the drug as an HD.
- Download a copy of the NIOSH Hazardous Drug. The 2014 list can be downloaded at: http://www.cdc.gov/niosh/docs/2014-138/pdfs/2014-138.pdf.

  Compile a list of the HDs handled at your location and review and update the list at least annually and whenever new HDs are handled at the location.

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Gap Analysis: What it can't do

- Show all complexities of the problem that may exist
- Implementation work
- Education to staff
- Minimize barriers to compliance

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Assessment of Risk

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NIOSH List

- National Institute for Occupational Safety and Health
- Updated every two years
- Three classifications
  - Antineoplastic
  - Non-antineoplastic
  - Reproductive only

https://www.cdc.gov/niosh/topics/antineoplastic/pdf/hazardous-drugs-list_2016-161.pdf

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http://blog.rmi.org/blog_2015_07_01_the_grid_is_at_a_fork_in_the_road

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Consider…

- Colchicine
- Fluconazole
- Paroxetine

https://www.laurieayers.com/consider-all-options/

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What Qualifies?

NIOSH Table 1: Antineoplastic

- Requires manipulation
  - Ex: crushing methotrexate tablets
  - Must follow all USP 800 precautions
- Final dosage form with no manipulation
  - Ex: counting methotrexate tablets
  - Perform assessment of risk for these agents

NIOSH Table 2 and 3:

Non-Antineoplastic and Reproductive Only

- Can perform an assessment of risk for all items
  - Unless using active pharmaceutical ingredients (API)

http://qctimes.com/counting-pills/image_b52bc2d6-1964-11de-96db-001cc4c002e0.html

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Consider These Actions

- Receipt from wholesaler
- Transport to storage
- Storage
- Transport to and from:
  - Compounding areas (sterile and non-sterile)
  - Dispensing area
  - Prepacking area
  - Administration area
  - Offsite area
- Deactivating, decontaminating, and disinfecting compounding and administration areas
  - Including spills
- Administration
- Disposal
- Education of staff

Improving Safe Handling Practices for Hazardous Drugs. Joint Commission Resources. 2016.

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Assessment of Risk: Tips

- Prioritize your concerns and implement those first
- USP 800 is not just a "pharmacy issue"
  - Begin partnering with nursing managers and educators
- Be reasonable when deciding how to handle items on Table 2 and Table 3

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Non-Sterile HD Compounding

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Non-Sterile HD Compounding

- Definition of Compounding:

Compounding	• Crushing tablets or opening capsules • Pouring oral or topical liquids from one container to another • Weighing or mixing components • Constituting or reconstituting powdered or lyophilized HDs • Withdrawing or diluting injectable HDs from parenteral containers • Expelling air or HDs from syringes • Contacting HD residue present on PPE or other garments • Deactivating, decontaminating, cleaning, and disinfecting areas contaminated with or suspected to be contaminated with HDs • Maintenance activities for potentially contaminated equipment and devices

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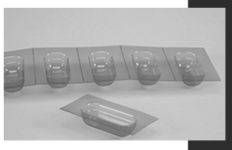
Repackaging

- USP 800 eliminates the ability to repackage tablets in packaging machines
  - Risk of crushing and exposure
  - Cytotoxic vs. hazardous
- Assessment of risk
- Buy unit dose
- Blister packaging



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http://shop.gohcl.com/default.aspx?page=item%20detail&itemcode=7079

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It's not just cleaning anymore…

- Deactivate
  - Renders the compound inert or inactive
- Decontaminate
  - Inactivating, neutralizing, or physically removing hazardous residue
- Cleaning
  - Process to remove contaminants from objects and surfaces using water, detergents, surfactants, solvents
- Disinfect
  - Inhibiting or destroying microorganisms

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Closing Thoughts

- USP 800 is a *minimum* requirement
- It is a supplement to USP 795 and 797 and does not replace it
- Sensitivity of messaging

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Questions

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