

Adapting to New Hazardous Drug Requirements

How will USP <800>, effective December 1, 2019, be implemented in your research setting?

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Disclaimer

Anita Austin, MBA-HM, RRT, CCRP, CHRC

I have no relationships to report.

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I currently serve on the Utah State Board of Pharmacy. This presentation does not reflect the opinions of the Utah Board of Pharmacy or Licensing Division.

Which option best describes your site? (select all that apply)

- Academic Medical Center
- Hospital-based Research
- Independent Research Organization
- Contract Research Organization

How would you categorize your site's readiness for new USP <800> requirements?

- I have never heard of it.
- I have heard of it, but we are not ready.
- We are ready.

Overview of United States Pharmacopeia (USP) <800>

- Emphasis on caregiver safety
- Policy and Procedure updates-know your local laws/rules
- Training and medical surveillance
- Annual review of Hazardous Drug List
- Medication process- receiving, storage, compounding and dispensing
- Dispensing final dosage forms
- Audit and monitor for compliance
- Assessment of Risk (drug)

Assessment of Risk

➤ **Investigational New Drugs**

Toxicological data are often incomplete or unavailable for investigational drugs. However, if their mechanism of action suggests that there may be a concern, it is prudent to handle them as hazardous drugs until adequate information becomes available to exclude them. (NIOSH 2016)

➤ **Drugs on NIOSH Table 2 and 3**

Completed dosage forms for counting and repackaging
Alternative containment strategies and work practices

Impact of USP <800> on Research

- Increased cost per study
 - Increased pharmacy fees
- Increased sterile and non-sterile compounding requirements
 - Increased facility and equipment costs
 - Transport training and fees



Compliance Program Elements

Written Policies and Procedures

- Review of policy and procedures for compliance with USP <800>

Training and Education

- Assist with training materials

Auditing and Monitoring

- What to audit and monitor for compliance



Resources

- NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings 2016
<https://www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.pdf?id=10.26616/NIOSH PUB2016161>
- ASHP Guidelines on Handling Hazardous Drugs
<https://academic.oup.com/ajhp/article/75/24/1996/5248544>
- National Association of State Boards of Pharmacy
<https://nabp.pharmacy/boards-of-pharmacy/>
 - USP <800>
<http://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare>