



USP 800 Information

USP 800- What You Need to Know...

In roughly a year (July 2018), the USP Compounding Expert Committee will be implementing USP 800. This new chapter introduces new requirements for pharmacies designed to protect pharmacists, nurses, pharmacy technicians, and others from the potential carcinogenic and teratogenic effects of hazardous drugs. There are a number of key changes from USP 797.



Key Changes

Building on earlier regulations like USP 797 and 795, 800 focuses on hazardous drugs (HDs) and occupational safety surround them. More specifically it deals with the product transport, product storage, compounding, preparation, and the administration of parenteral products.

- The elimination of compounding small volumes of HDs in areas where non-HDs are prepared.
- Closed-system transfer devices are now required in the administration process of HDs in order to minimize exposure to nurses who administer these drugs to patients.
- Negative pressure environments must always be used in the preparation of HDs. (cleanroom or a dedicated containment segregated compounding area that is vented to the outside with at least 12 air changes per hour) This includes receipt, unpacking and storage.
- Updated definition of HDs set by NIOSH that include drugs in any of 6 categories: carcinogenic drugs, teratogenic drugs, reproductive toxins, drugs with organ toxicity at low doses, genotoxic drugs, or new drugs that mimic existing HDs.
- Nurses are now required to use a CSTD when administering HDs to patients

What Does This Mean to You?

How does this change effect your processes? There are a number of things that will have to be done in order to meet USP 800 and SBB Testing & Certification is here for you.

Current hoods BSCs and clean rooms will need to have their airflow re-balanced to a specific high and low pressure limit. (*Currently, there is no high pressure limit.*) Also, negative pressure enclosures will have to be engineered for the storage of HDs. In most cases, this means that re-engineering of the HVAC system is in order.

SBB Testing & Certification can help you become USP 800 compliant. Our group of technicians do more than just test your equipment, they help you solve your problems. So if you don't believe that your room or BSCs will be USP 800 compliant or you have questions regarding the changes, contact us below and we can help.

For the full USP 800 chapter please visit USP's website.

<http://www.usp.org/usp-nf/notices/general-chapter-hazardous-drugs-handling-healthcare-settings>

About Us

At SBB Testing and Certification we offer more than simple pass and fail. We believe in an unparalleled customer service and technical support system. When failures occur our highly trained technicians work with you to provide solutions and fix problems quickly and efficiently.



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