USP <800> FAQS

OVERVIEW

USP <800> Hazardous Drugs – Handling in Healthcare Settings will create numerous opportunities and challenges for compounding pharmacies. The FAQs below provide general information and guidance. Letco Medical highly recommends that **any** healthcare professional engaged in compounding read and understand the chapter. The following links are resources for USP <800> and the NIOSH Hazardous Drug List 2016:

- The International Academy of Compounding Pharmacists – IACP members login to receive discounted pricing: 2017 USP on Compounding Reference Book https://iacp.site-ym.com/store/ViewProduct.aspx?id=10200318
- Unites States Pharmacopeia: USP Compounding Compendium https://store.usp.org/OA_HTML/usp2_ibeCCtpSctDspRte.jsp?section=12587&minisite=10020
- National Institutes of Occupational Safety and Health: NIOSH Hazardous Drug List 2016 (PDF) https://www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.pdf

FREQUENTLY ASKED QUESTIONS

Q: What is USP <800> and why does it matter?

A: USP chapters numbered under <1000> are **enforceable as regulatory guidance** by federal statute as well as many state boards of pharmacy Practice Acts. USP <800> is a **work place safety standards chapter** that provides **best practice standards** for the handling (i.e., receipt, storage, compounding, dispensing, spill containment and/or disposal) of Hazardous Drugs. OSHA, FDA, state workplace safety agencies, and state boards of pharmacy can use USP <800> for regulatory guidance.

Failure to comply with USP <800> exposes owners and/or facility managers to significant fines and liability, as the personnel who work directly with drugs determined by the National Institute of Occupational Safety and Health (NIOSH) to be hazardous may be exposed to the drugs' harmful effects. See the NIOSH Hazardous Drug List 2016 for full list of hazardous drugs: https://www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.pdf

Q: Who is affected by USP <800>?

A: **ALL** facilities that store, handle, **compound**, and/or administer Hazardous Drugs, including, but not limited to, hospitals, pharmacies, medical practitioners, veterinarians, outpatient oncology clinics, etc.

Q: When does USP <800> take effect?

A: December 1, 2019. Note that new USP <795> Non-sterile Compounding and USP <797> Sterile Compounding revisions will go into effect the same date.

Q: What drugs are covered by USP <800> and the current NIOSH Hazardous Druglist?

A: Hazardous Drugs are separated into three categories, as outlined below, with a few of the more commonly compounded drugs in each category noted.

- Antineoplastics: Fluorouracil, methotrexate, mitotane
- Non-antineoplastics: Cyclosporine, estradiol (and other estrogens), methimazole, phenytoin, progesterone, tacrolimus
- Non-antineoplastics that primarily have adverse reproductive effects: HCG, colchicine, fluconazole, oxytocin, testosterone, tretinoin]

Note: This is not an all-inclusive list. A complete list of drugs may be found at: https://www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.pdf.

Q: Does USP <800> require any special equipment or facility designs?

A: **Yes –** USP <800> requires several strategies, including but not limited to:

- **Containment Primary Engineering Control (C-PEC):** Also known as a powder hood, glove box, or other similar device where the compounding takes place. C-PEC may require direct venting via HEPA filter to outside of the building, depending on drugs compounded. Even if not vented to outside, the exhaust from the C-PEC must occur through a HEPA filter. Refer to USP <800> for full list of acceptable C-PECs and selection based on compounding operation.
- **Containment Secondary Engineering Control (C-SEC):** Referred to as the **negative pressure room,** where all C-PEC devices must be located inside of the C-SEC. In addition, the C-SEC **must** be physically separated from other preparation areas within the facility, and must be vented outside of the building.
- **Personal Protective Equipment (PPE):** All masks, gowns, gloves and other personal equipment designed to protect the worker from any direct contact with hazardous drugs. Certain PPE, such as gloves, **must** meet specific standards for use with hazardous drugs. Refer to USP <800> and NIOSH Hazardous Drug list for detailed requirements.

Q: May existing equipment on hand, such as capsule machines, be used in both the non-hazardous and hazardous drug compounding labs?

A: No. General Chapter <800> states that "…disposable or clean equipment for compounding (such as mortars and pestles, and spatulas) must be dedicated for use with HDs." This refers to equipment (or parts of equipment) that come in direct contact with HDs.[1]

Equipment that does *not* come in direct contact with HDs may be shared between HD and non-HD compounding areas provided it is deactivated, decontaminated and cleaned before it is removed from the HD area.[1]

Equipment used in HD compounding must be operated in the C-SEC unless it is operated as a closed system (e.g. certain mixers, terminal sterilization using an autoclave or convection oven).[1]

Q: Is special training required for USP <800>?

A: Yes. Some of the key requirements include:

- All personnel who handle hazardous drugs **must** be trained based on their job function
- Training **must** occur **before** the employee independently handles hazardous drugs
- Effectiveness of training competencies **must** be demonstrated by each employee
- Competency **must** be reassessed every twelve months

Refer to USP <800> for full details of training requirements.

Q: Are there any unique requirements for policy and procedure manuals or standard operating procedures ("SOPs")?

A: USP <800>, like any new guidance, will require a thorough review of current polices and procedures, as well as SOPs, with requisite updating to ensure operations uphold the standards of practice in the chapter.

Q: Are there any exemptions from compliance with USP <800> regarding handling of hazardous drugs?

A: Final dosage forms that do not require additional manipulation other than counting or repackaging are the only hazardous drugs that are exempt from USP <800> requirements.

Please note, "…concentrated solutions of [hazardous drugs] (i.e. hormone concentrates) are an HD API that is further manipulated into a final dosage form and is subject to the containment requirements in <800>." [2]

Q: Does Letco Medical provide support for USP <800> related questions?

A: Yes. The Letco Professional Services team works closely with customers and the Letco Sales team to provide guidance on how to meet USP <800> requirements in the most cost effective manner. You may contact the Letco Professional Services team directly at 877-538-2679 (877-LETCORX) or via email at compounding@letcomedical.com.

In addition, Letco Medical offers a substantial line of products and services to meet your compounding needs, including those related to USP <800>. The Letco Sales team can assist with the selection of supplies and equipment used to build out and operate an <800> compliant facility including modular rooms, hoods, and mandated personal protective equipment.

[1] USP <800> Hazardous Drugs – Handling in Healthcare Settings
[2] Frequently Asked Questions: <800> Hazardous Drugs – Handling in Healthcare Settings – question 54 - http://www.usp.org/frequently-asked-questions/hazardous-drugs-handling-healthcare-settings