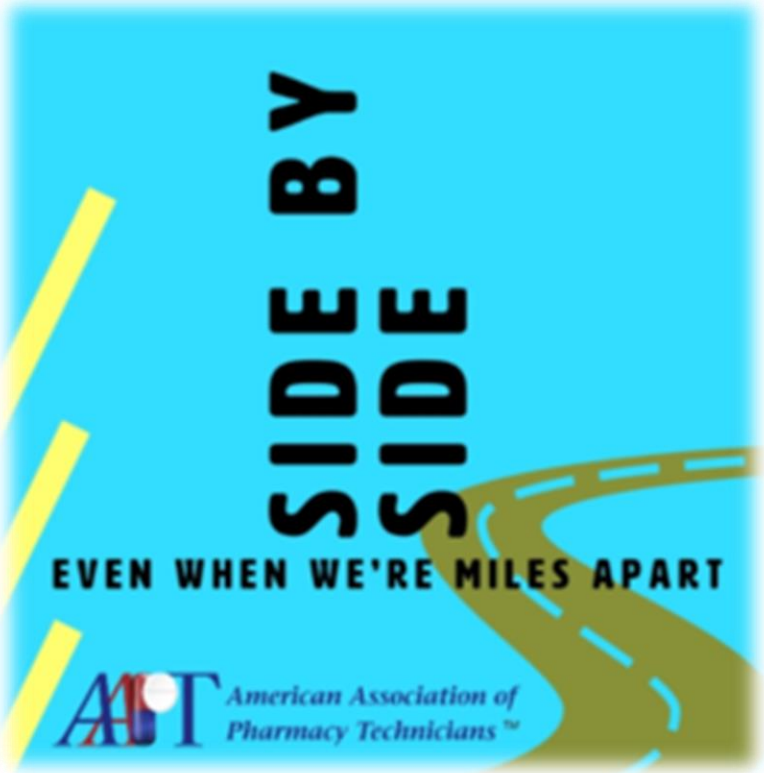
Sterile Compounding: A Refresher



AAPT National Convention 2020

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THEN

NOW!

Objectives

1. Describe building blocks of safe compounding

2. Outline temporary policy regarding personal protective equipment (PPE) practices for sterile compounding

3. Discuss sterile compounding in the time of COVID-19

Building Blocks of Safe Compounding

The most important strategies pharmacies should keep in mind to stay safe and compliant in their compounding activities~

1. Know the contents and status of USP Chapter <797>
2. Know your state regulations
3. Know accreditation standards
4. Practice full compliance to protect staff & for patient safety
5. Qualify & Requalify staff- include staff outside of pharmacy in appropriate training
6. Consider advanced training for the designated person who oversees sterile compounding
7. Evaluate environmental monitoring reports & take action based on the results
8. Use FDA resources

Know the Content & Status of USP <797>

USP <797> has not changed since 2008

- 12/1/2019 was intended official date of revised chapter
- Several pharmacy groups filed appeals to USP Chapter
- Key topics covered in the appeals included:
  - Beyond-Use Date (BUD) provisions
  - Removal of Alternative Technology provision
  - Applicability to veterinary practitioners

BUD

Current definition of BUD: The date (or time) beyond which the drug must not be stored.

- Sell by/use by dating – does not include infusion time

Future definition of BUD: The date or date and hour after which the CSP must not be used, because its required quality characteristics (e.g., sterility, strength, purity) cannot be ensured.

Beyond-use dating for CSPs according to Risk-Level			
Risk Level	BUD at Room Temperature (20 to 25° C)	BUD under Refrigeration (2° to 8° C)	BUD with Frozen Storage (-25 to -10° C)
Immediate Use	1 hour	N/A	N/A
Low Risk with 12h BUD	12 hours	12 hours	N/A
Low Risk	48 hours	14 days	45 days
Medium Risk	30 hours	9 days	45 days
High Risk	24 hours	3 days	45 days

Revised <797> (published June 1, 2019)

- Category 1
  - ≤ 12 hours at CRT
  - ≤ 24 hours in a refrigerator
- Category 2
  - Aseptically processed, no sterility, only sterile starting components
    - 4 days at CRT
    - 10 days in a refrigerator
    - 45 days in a freezer
  - Aseptically processed, no sterility, one or more nonsterile starting component(s)
    - 1 day at CRT
    - 4 days in a refrigerator
    - 45 days in a freezer

Know State-Specific Regulations

USP<797>  Federal  State

Pharmacies need to follow the more stringent regulations, which may be on the state side.

Know Accreditation Standards

The Joint Commission

Practice Full Compliance

Safe sterile compounding depends on several factors

- use of personal protective equipment
- closed system drug-transfer devices (CSTDs)
- surface wipe sampling
- other best practices

Qualify & Requalify Staff

Core competencies needed to fulfil safe compounding requirements

- Training
- Guidance in policies & procedures

Consider Advanced Training

- helps compounding pharmacies meet optimal safety and reliability in compounding practices
- helps the pharmacy comply with the most stringent practices

Evaluate Environmental Monitoring

Clean Room ~ Clean Staff

Use FDA Resources

https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding

ugs / Guidance, Compliance, & Regulatory Information / Human Drug Compounding

Human Drug Compounding

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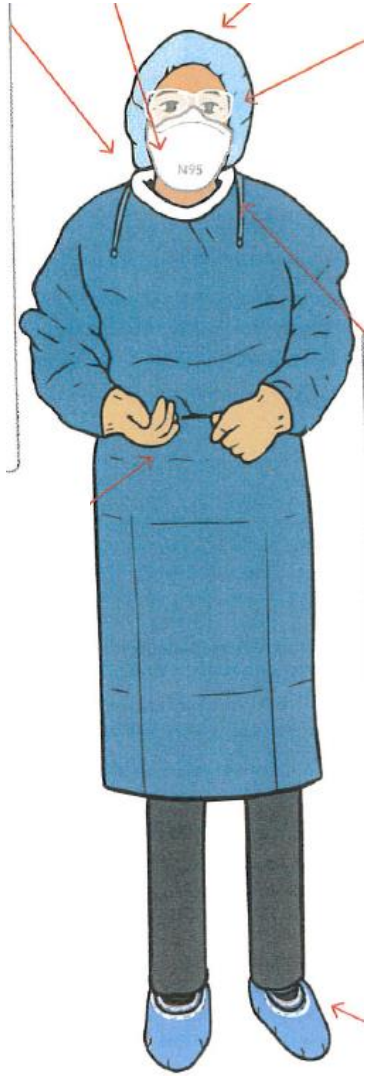
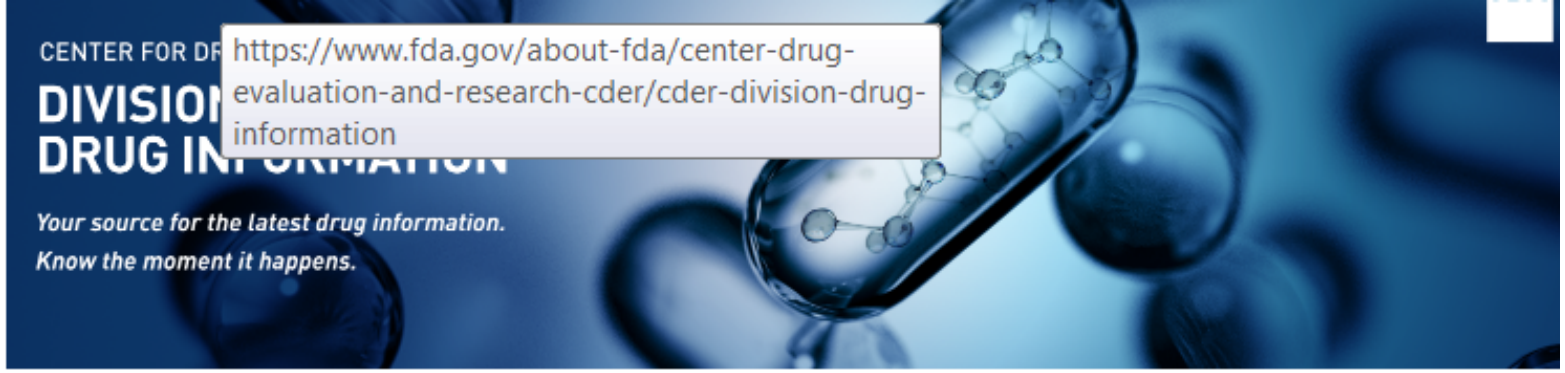
Compounding is generally a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. Although compounded drugs can serve an important medical need for certain patients, they also present a risk to patients.

FDA's compounding program aims to protect patients from unsafe, ineffective, and poor quality compounded drugs, while preserving access to lawfully-marketed compounded drugs for patients who have a medical need for them.

Questions? Email FDA's compounding team at compounding@fda.hhs.gov.

Temporary Policy Regarding PPE practices for Sterile Compounding





FDA Updates Temporary Policy Regarding Non-Standard PPE Practices for Pharmacy Compounders During the COVID-19 Public Health Emergency

Today, the FDA issued an update to its guidance for pharmacy compounders that experience shortages, due to the COVID-19 public health emergency, of the personal protective equipment (PPE) they typically use to compound human drugs that are intended or expected to be sterile. In the update, FDA has clarified that drugs can be compounded under the policy in a segregated compounding area that is not in a cleanroom, when the following beyond-use dates are utilized: up to 12-hours for product stored at room temperature, and up to 24 hours for products stored refrigerated. These beyond use dates aim to reduce the risk of contamination.

FDA adopted this policy to help assure patient access to needed medicines and to reduce the risks of compounding when standard PPE are not available. FDA wants to ensure that health care professionals are aware of this guidance and the potential for greater contamination risk when compounded drugs are prepared without standard PPE or within segregated compounding areas. FDA encourages health care professionals who purchase compounded drugs to engage with compounders to balance these risks and the need for compounded products for patient care.

Contains Nonbinding Recommendations

Temporary Policy Regarding Non-Standard PPE Practices for Sterile Compounding by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency

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Guidance for Industry

April 2020
Updated May 14, 2020

The compounder:

a. employs the mitigation strategies as described below to reduce the risk of product contamination related to compounding when compounding is performed without standard PPE; or

b. employs terminal sterilization where standard PPE is not used, as long as basic garbing expectations (e.g., hairnet, clean garment, non-sterile gloves, other appropriate coverings) are followed.

The compounder:

a. keeps a record when compounding is performed without standard PPE;
b. keeps a record when there are changes in the sterilization approach (e.g., from aseptic processing to terminal sterilization); and
c. documents mitigation strategies in a new or updated standard operating procedure.

PPE Reuse-

- Use unused PPE that has expired
- Reuse masks during same shift
- Don non-sterile gloves if sterile gloves not available
- Do not reuse booties/use dedicated clean room shoes if booties unavailable

SCRUB ZONE

Loafer Shoe, 8, M, Women's, White, Plain Toe Type, 1 PR

Item # **13J230** Mfr. Model # **Energize** Catalog Page # **N/A** Catalog Group # **G8870** UNSPSC v8 # **46181605**

Your Price

$28.45 / pair

Shipping Weight **1.2 lbs.**

Country of Origin **China** | *Country of Origin*

Note: Product availability is real-time updated a

- Temporary policy on PPE practices applies to pharmacy compounders regulated under section 503A. It does not apply to outsourcing compounding pharmacies registered as 503B, which are subject to Current GMP requirements and under which different PPE considerations apply
- NOT exempt from ((parts of) section 501 of the FD&C Act:

Performing aseptic manipulations with exposed skin or hair in International Organization for Standardization Class 5 (ISO 5) areas

Engaging in aseptic processing wearing critical gown components (e.g., gloves) that are non-sterile

Putting on gowning apparel in a way that may cause the gowning apparel to become contaminated

Engaging in aseptic processing after leaving the cleanroom and reentering from a non-classified area without first replacing gowning apparel (e.g., mask, goggles, foot covers, gloves)

Failing to disinfect or change gloves frequently enough given the nature of the operations to prevent contamination

Sterile Compounding in the Time of COVID-19

COVID-19

At the time of this presentation recording…

- ensure that every effort is taken to minimize the risk for drug contamination especially with COVID-19 induced shortages in PPE

- focus on aseptic technique as well as cleaning and disinfection of the critical surfaces where sterile compounding is conducted-more frequent disinfection-diligent about cleaning- extra documentation

- review how state rules & requirements are temporarily adjusting to PPE shortage

- limited beyond-use dates

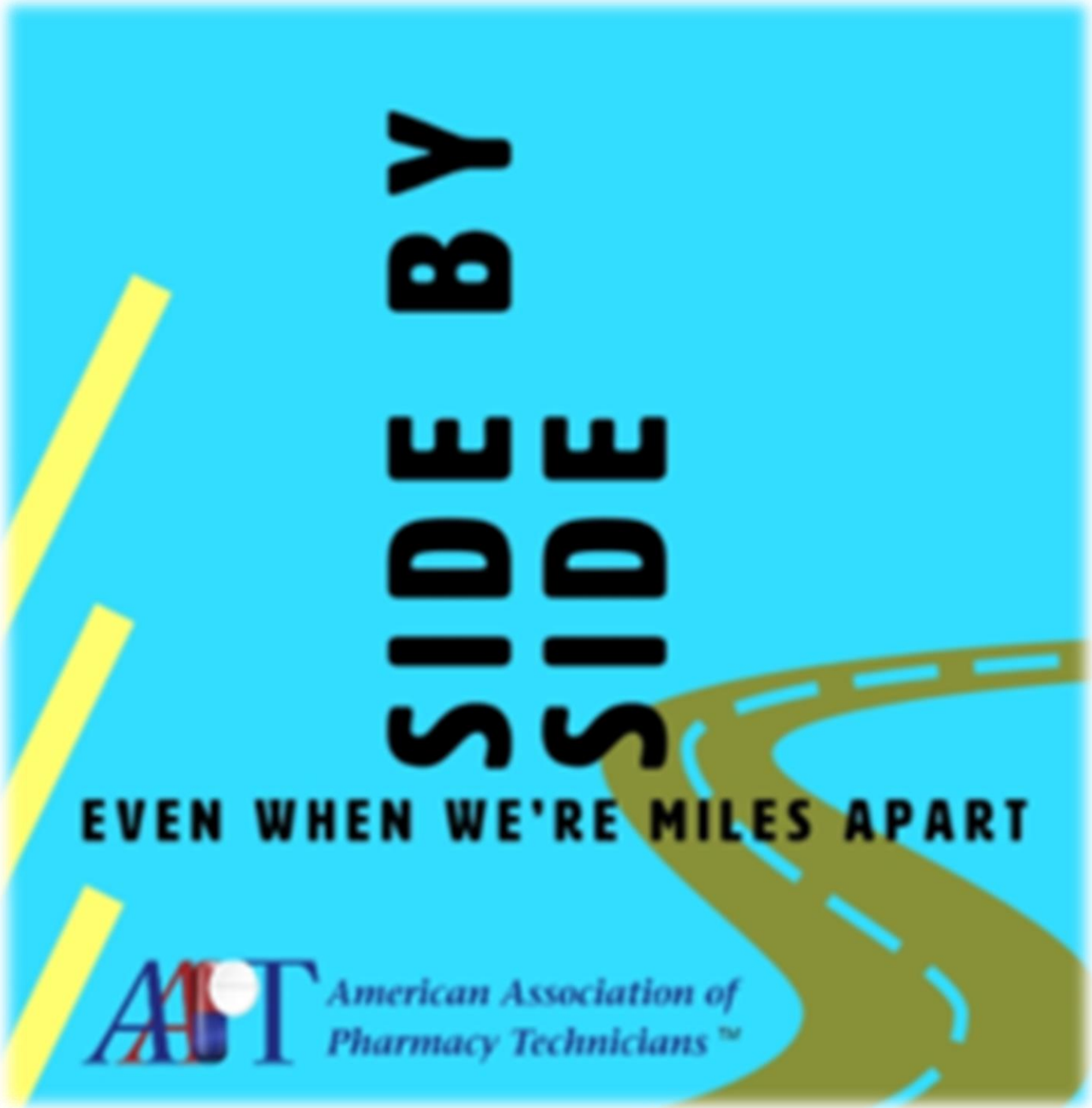
BUD

- USP supports risk-based discretion related to BUD of critically short supply drugs required to care for ventilator patients.
- USP establishes standards but does not enforce them
- https://www.usp.org/compounding for updates

COVID-19

COVID-19 demand for certain compounded sterile drugs that are in short supply-

- relevant sterile IV drugs listed on the FDA shortage list are drugs needed to induce or maintain sedation, neuromuscular blocking agents used for rapid intubation & analgesia to maintain comfort for patients under mechanical ventilation
- 503A pharmacies should be compounding for named patients only; not in large quantities requiring manufacturing quality control standards



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Reference Page

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2. Kienle's 10 New Building Blocks of Compounding Safety, June 9, 2020 https://www.pharmacypracticenews.com/Operations-and-Management/Article/06-20/Kienle-s-10-New-Building-Blocks-of-Compounding-Safety/58410?sub=C9EB874D42DD916B0AD19FCAA7AD6637ED8F73562C40939E6FE04B39D32F49&enl=true&dgid=--DGID--&utm_source=enl&utm_content=1&utm_campaign=20200609&utm_medium=button