ENSURING USP COMPLIANT PHARMACY CLEAN ROOM PROJECTS

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OVERVIEW

This interactive presentation will highlight the USP 795, 797, and 800 regulations and their impact on compounding cleanrooms. Innovative solutions will be discussed as well as the significance of the design, construction, and commissioning phases.

OBJECTIVES

State the intent of the updated USP 795, 797, and 800 regulations.

Describe the steps required to make your compounding cleanroom USP compliant.

Explain how to identify a hazardous drug and determine if sterile or non-sterile compounding is required.

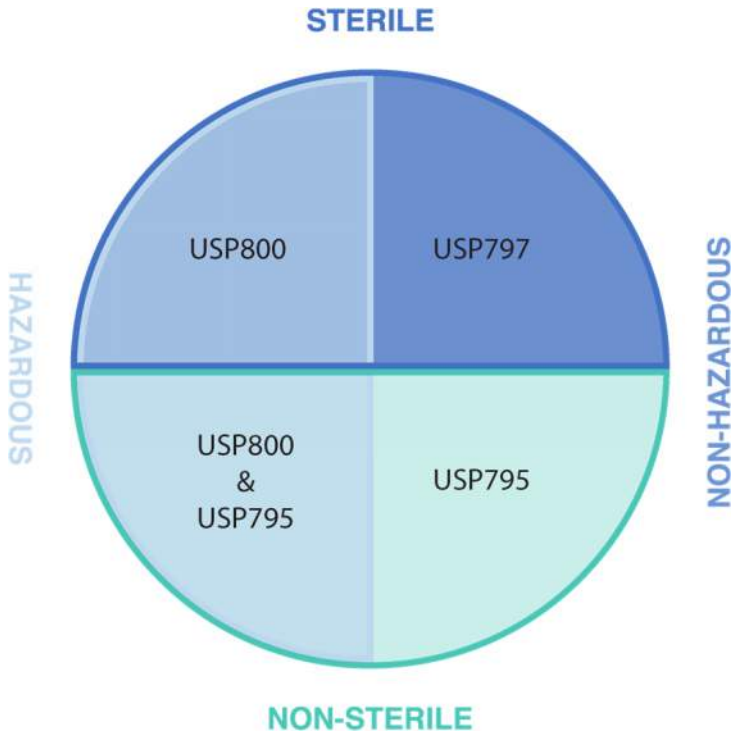
STERILE PREPARATIONS

- Compounded biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals that must be sterile when administered to patients
- Aqueous bronchial and nasal inhalations
- Baths and soaks for live organs and tissues
- Injections (emulsions, solutions, suspensions, etc.)
- Irrigations for wound and body cavities
- Ophthalmic drops and ointments
- Tissue implants

HAZARDOUS DRUGS

- Any drug defined as hazardous by NIOSH on the basis of:
  - Carcinogenicity
  - Teratogenicity or developmental toxicity
  - Reproductive toxicity in humans
  - Organ toxicity at low doses in humans or animals
  - Genotoxicity
  - New drugs that mimic existing hazardous drugs in structure or toxicity

USP ROADMAP


STERILE
USP800
USP797
HAZARDOUS
NON-HAZARDOUS
USP800
&
USP795
USP795
NON-STERILE

STERILE WILL BE OUR FOCUS

USP 797

Purpose is to describe conditions and practices that prevent harm including death due to:

- Microbial contamination
- Excessive bacterial endotoxins
- Variability in intended strength of the product
- Unintended chemical and physical contaminants
- Ingredients of inappropriate quality

USP 800

THE PURPOSE IS TO:

- Describe practice and quality standards …. To promote patient safety, worker safety, and environmental protection.

OVERLAP

- Currently there is overlap & conflict between 795-797-800
- USP is updating all 3 simultaneously to resolve
- Proposed effective date 12-1-2019
- But some states (like CA) are already using the new USP 800

STERILE HAZARDOUS – DRIVING THE CHANGE

- Worker safety – NIOSH / OSHA
- Cross contamination of medication

USP 797 TIMELINE

IMPORTANT UPDATES

Jul 2018

Proposed was posted for public comment

Nov 2018

Public Comment Period closed

Jun 1, 2019

Intended Publication Date

Dec 1, 2019

Anticipated Official Date

* The current published version of is official until the new Chapter becomes official.

USP 800 TIMELINE

IMPORTANT UPDATES

Mar 2014

First published for public comment

Dec 2014

Revised and presented for further public comment

Feb 2016

Revised again and published

Dec 1, 2019

Will be harmonized with USP 797; Becomes official

USP 795 TIMELINE

IMPORTANT UPDATES

Mar 2018

Proposed revision was posted for public comment

Jul 31, 2018

Public Comment Period

Jun 1, 2019

Intended Publication Date

Dec 1, 2019

Anticipated Official Date

*The current published version of General Chapter <795> in USP-NF is official until the new Chapter becomes official.

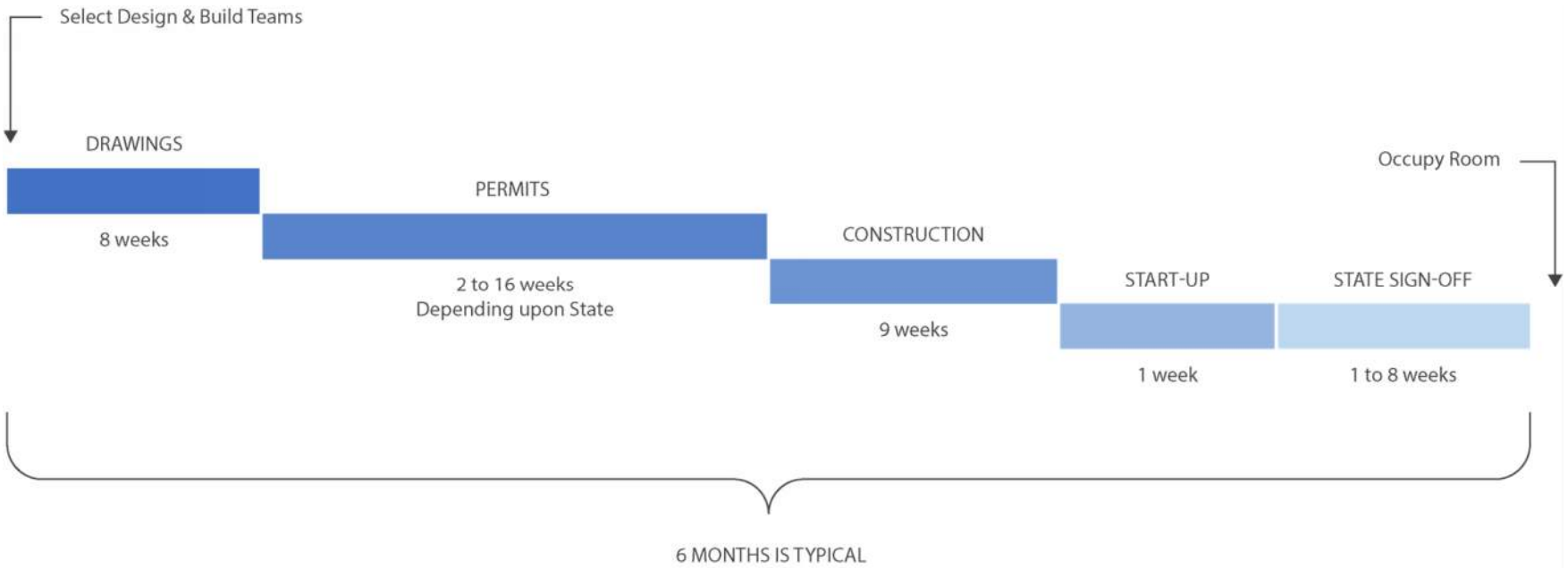
COMMON NON-COMPLIANT FEATURES OF OLDER ROOMS

- No clean / dirty designation in ante room
- HD room entrance is through non-HD room
- HD hood / room is not exhausted
- Finishes / furniture not monolithic / closed cell

COMMON NON-COMPLIANT FEATURES OF OLDER ROOMS

- Sink / eyewash in compound room
- Mechanical systems not dedicated
- Not able to maintain temperature, humidity, pressures
- Air change rate too low to meet ISO class

TIMELINE TO BUILD A NEW ROOM

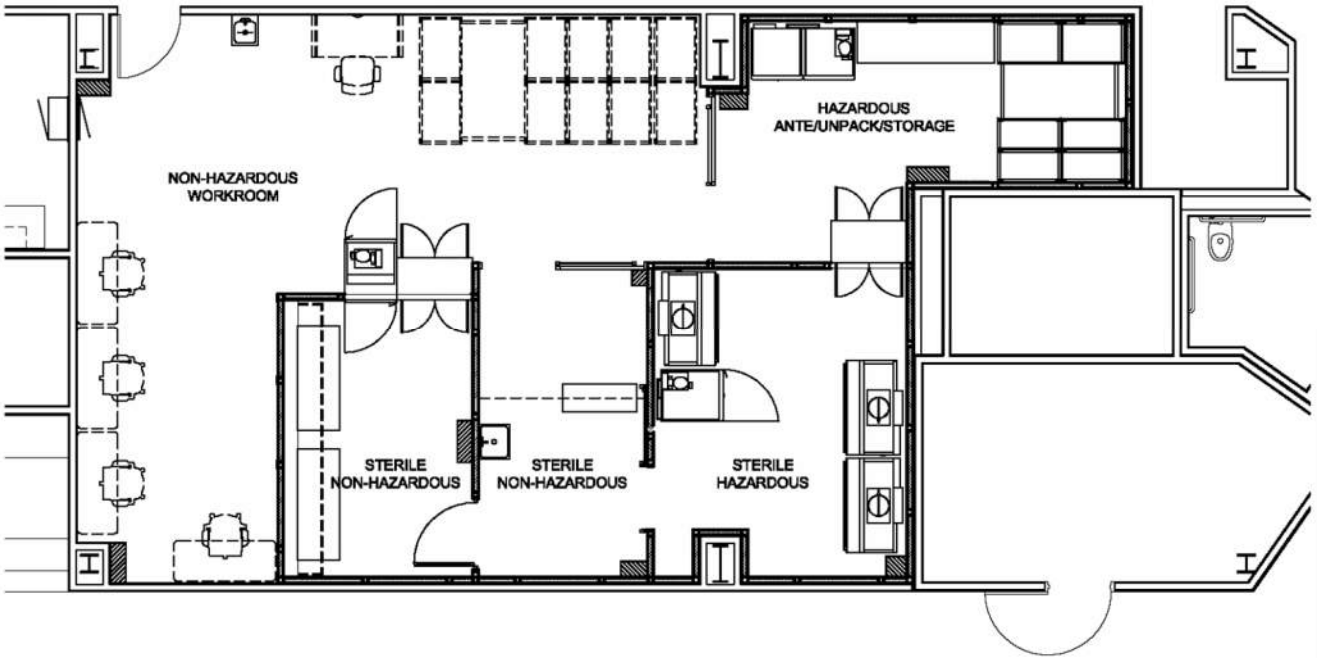


COMMON OPTIONS TO MAINTAIN OPERATIONS

- Build new compounding room elsewhere & keep existing operational during construction
- Shift workload to another room on campus
- Utilize temporary compounding room

ONE VERSION OF TEMPORARY

COMBINED USP 797 & 800



RECENT PROJECT

COMMISSIONING & CERTIFICATION

- What does this process look like?
  - Design
  - Installation
  - Operation
  - Functionality
  - Occupancy

COMMISSIONING & CERTIFICATION

- Common pitfalls during the process
  - Weather factored into the design
  - Maintainability
  - Pressure relationships to outside spaces
  - Noise, Vibration
  - Equipment
  - Validation processes

Thank You

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