USP 797/800 Pharmacies: Architectural and MEP Strategies to Assure Compliance

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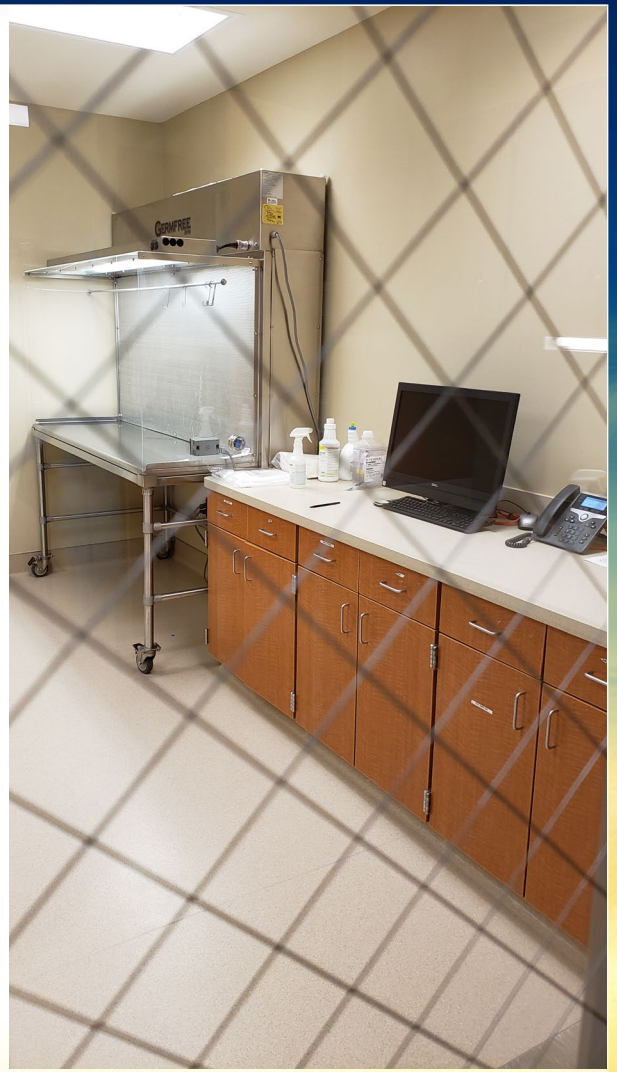
1. USP 797/800 Pharmaceutical Compounding Standards
2. Case Studies – Examples of Renovation Projects
3. Architectural, MEP, Facility Requirements and Key Details
4. Summary



What is USP?

The United States Pharmacopeial Convention (USP) is a non-profit organization that establishes standards for medicines, dietary supplement products, and ingredients.

USP does not enforce its own standards, rather the FDA and local government agencies adopt and enforce the USP standards and regulations.

Not all state Pharmaceutical Boards specifically require the following of USP <797> and <800>

For example in Texas – **THHSC (Texas Health Human Services Commission)** has additional information regarding requirements that aren't stated in USP <797> and <800>

See §133.163. Spatial Requirements for New Construction

(x) Pharmacy suite

Other codes - **FGI and ANSI** requirements

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Key Differences: 795 vs 797 vs 800

- **USP 795_Pharmaceutical Compounding – Nonsterile Compounding:** describes requirements for the compounding process, facilities, equipment, components, documentation, quality controls and training to promote patient safety.
- **USP 797_Pharmaceutical Compounding – Sterile Compounding :** helps to ensure patients receive quality preparations that are free from contaminants and are consistent in intended identity, strength and potency. It describes a number of requirements, including responsibilities of compounding personnel, training, environmental monitoring, storage and testing of finished preparations.
- **USP 800: Handling of Hazardous Drugs – Sterile & Non-sterile hazardous compounding :** provides standards for safe handling of hazardous drugs to minimize the risk of exposure to healthcare personnel, patients and the environment. PPE & monitoring; *standards apply to all personnel who compound HDs preparations and all places where HDs are* ***prepared, stored, transported,*** *and* ***administered****.*

What is the purpose of USP <797> and <800>?

USP <797> was established to “ensure patients receive quality preparations that are free from contaminants and are consistent in intended identity, strength and potency”.

USP <797> Protects Patients from contaminants

USP <800> was established to provide “standards for safe handling of hazardous drugs to minimize the risk of exposure to healthcare personnel, patients and the environment”.

USP <800> Protects Staff and Patients from hazardous drugs

NAVIGATING THE CURRENT REGULATIONS

MUST vs *SHOULD*

*Used when an obligation is a **Requirement***

Example

A sink **must** be available for hand washing

An eyewash station **must** be readily available

Refrigerated antineoplastics **must** be stored in a dedicated refrigerator in a negative pressure area with at least 12 ACPH

The ante-room **must** have a line of demarcation to separate the clean side from the dirty side

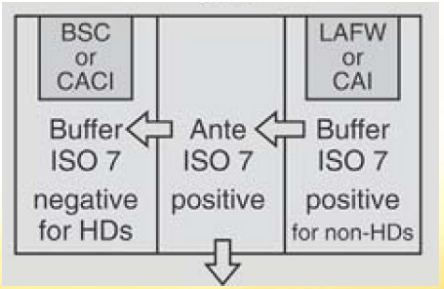
*Used as a **Recommendation/Best Practice***

Example

Refrigerators in negative pressure buffer rooms **should** have an exhaust located adjacent to the compressor and behind the refrigerator

Lines of demarcation **should** be inlaid flush into flooring material, and should not create crevices.

Both sterile HD and nonsterile HD compounding	A separate room for sterile and nonsterile compounding is recommended



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ASSESSMENT & WALK-THRU

Learn how to efficiently review your facilities for USP compliance, and develop tools to effectively analyze your current compliance

Explore how to manage user expectations, set realistic goals, align those goals with existing culture and future growth

Identify key challenges of implementation and determine how to meet them

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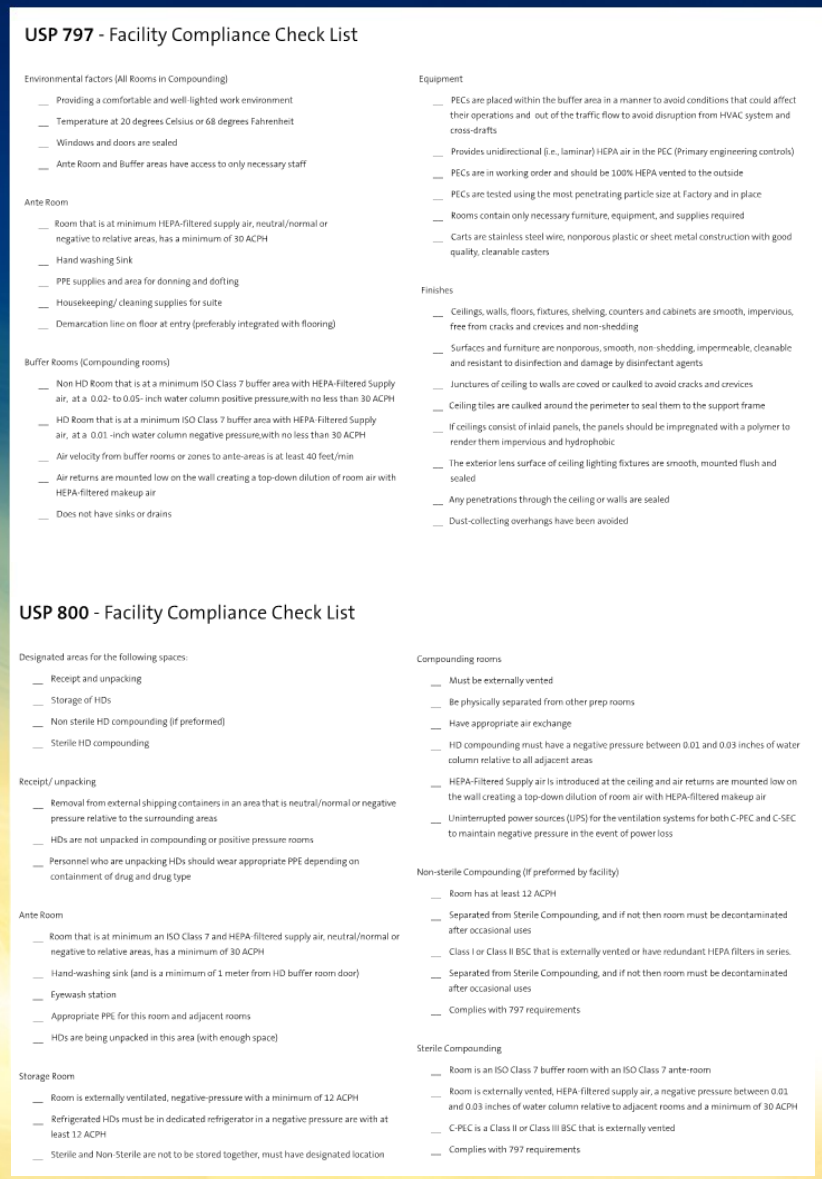

USP 797 - Facility Compliance Check List

Environmental factors (All Rooms in Compounding)

- Providing a comfortable and well-lighted work environment
- Temperature at 20 degrees Celsius or 68 degrees Fahrenheit
- Windows and doors are sealed
- Ante Room and Buffer areas have access to only necessary staff

Ante Room

- Room that is at minimum HEPA-filtered supply air, neutral/normal or negative to relative areas, has a minimum of 30 ACPH
- Hand washing Sink
- PPE supplies and area for donning and dofting
- Housekeeping/ cleaning supplies for suite
- Demarcation line on floor at entry (preferably integrated with flooring)

Buffer Rooms (Compounding rooms)

- Non HD Room that is at a minimum ISO Class 7 buffer area with HEPA-Filtered Supply air, at a 0.02- to 0.05- inch water column positive pressure,with no less than 30 ACPH
- HD Room that is at a minimum ISO Class 7 buffer area with HEPA-Filtered Supply air, at a 0.01 -inch water column negative pressure,with no less than 30 ACPH
- Air velocity from buffer rooms or zones to ante-areas is at least 40 feet/min
- Air returns are mounted low on the wall creating a top-down dilution of room air with HEPA-filtered makeup air
- Does not have sinks or drains

Equipment

- PECs are placed within the buffer area in a manner to avoid conditions that could affect their operations and out of the traffic flow to avoid disruption from HVAC system and cross-drafts
- Provides unidirectional (i.e., laminar) HEPA air in the PEC (Primary engineering controls)
- PECs are in working order and should be 100% HEPA vented to the outside
- PECs are tested using the most penetrating particle size at Factory and in place
- Rooms contain only necessary furniture, equipment, and supplies required
- Carts are stainless steel wire, nonporous plastic or sheet metal construction with good quality, cleanable casters

Finishes

- Ceilings, walls, floors, fixtures, shelving, counters and cabinets are smooth, impervious, free from cracks and crevices and non-shedding
- Surfaces and furniture are nonporous, smooth, non-shedding, impermeable, cleanable and resistant to disinfection and damage by disinfectant agents
- Junctures of ceiling to walls are coved or caulked to avoid cracks and crevices
- Ceiling tiles are caulked around the perimeter to seal them to the support frame
- If ceilings consist of inlaid panels, the panels should be impregnated with a polymer to render them impervious and hydrophobic
- The exterior lens surface of ceiling lighting fixtures are smooth, mounted flush and sealed
- Any penetrations through the ceiling or walls are sealed
- Dust-collecting overhangs have been avoided

USP 800 - Facility Compliance Check List

Designated areas for the following spaces:

- Receipt and unpacking
- Storage of HDs
- Non sterile HD compounding (if preformed)
- Sterile HD compounding

Receipt/ unpacking

- Removal from external shipping containers in an area that is neutral/normal or negative pressure relative to the surrounding areas
- HDs are not unpacked in compounding or positive pressure rooms
- Personnel who are unpacking HDs should wear appropriate PPE depending on containment of drug and drug type

Ante Room

- Room that is at minimum an ISO Class 7 and HEPA-filtered supply air, neutral/normal or negative to relative areas, has a minimum of 30 ACPH
- Hand-washing sink (and is a minimum of 1 meter from HD buffer room door)
- Eyewash station
- Appropriate PPE for this room and adjacent rooms
- HDs are being unpacked in this area (with enough space)

Storage Room

- Room is externally ventilated, negative-pressure with a minimum of 12 ACPH
- Refrigerated HDs must be in dedicated refrigerator in a negative pressure are with at least 12 ACPH
- Sterile and Non-Sterile are not to be stored together, must have designated location

Compounding rooms

- Must be externally vented
- Be physically separated from other prep rooms
- Have appropriate air exchange
- HD compounding must have a negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas
- HEPA-Filtered Supply air Is introduced at the ceiling and air returns are mounted low on the wall creating a top-down dilution of room air with HEPA-filtered makeup air
- Uninterrupted power sources (UPS) for the ventilation systems for both C-PEC and C-SEC to maintain negative pressure in the event of power loss

Non-sterile Compounding (If preformed by facility)

- Room has at least 12 ACPH
- Separated from Sterile Compounding, and if not then room must be decontaminated after occasional uses
- Class I or Class II BSC that is externally vented or have redundant HEPA filters in series.
- Separated from Sterile Compounding, and if not then room must be decontaminated after occasional uses
- Complies with 797 requirements

Sterile Compounding

- Room is an ISO Class 7 buffer room with an ISO Class 7 ante-room
- Room is externally vented, HEPA-filtered supply air, a negative pressure between 0.01 and 0.03 inches of water column relative to adjacent rooms and a minimum of 30 ACPH
- C-PEC is a Class II or Class III BSC that is externally vented
- Complies with 797 requirements

REVIEW FOR COMPLIANCE

- CHECK LIST per 797/800
  - Architectural, MEP, Operational
- Assess the deficiencies
  - Document & Photograph facility
- User group discussion to determine initial needs
  - Must vs Should
  - Life of Project
- Working with Turnkey Solutions/Vendors

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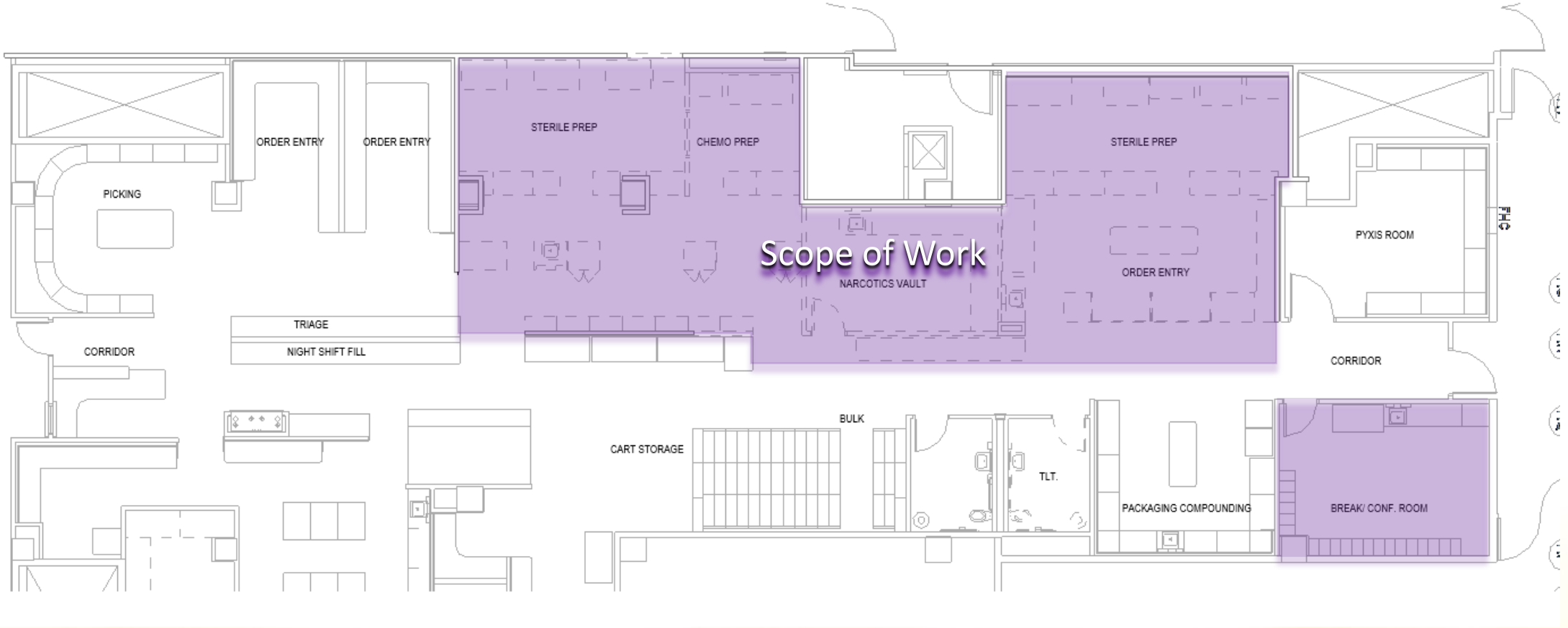
CASE STUDY 1

PROPOSED DEMO PLAN



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PROPOSED PLAN

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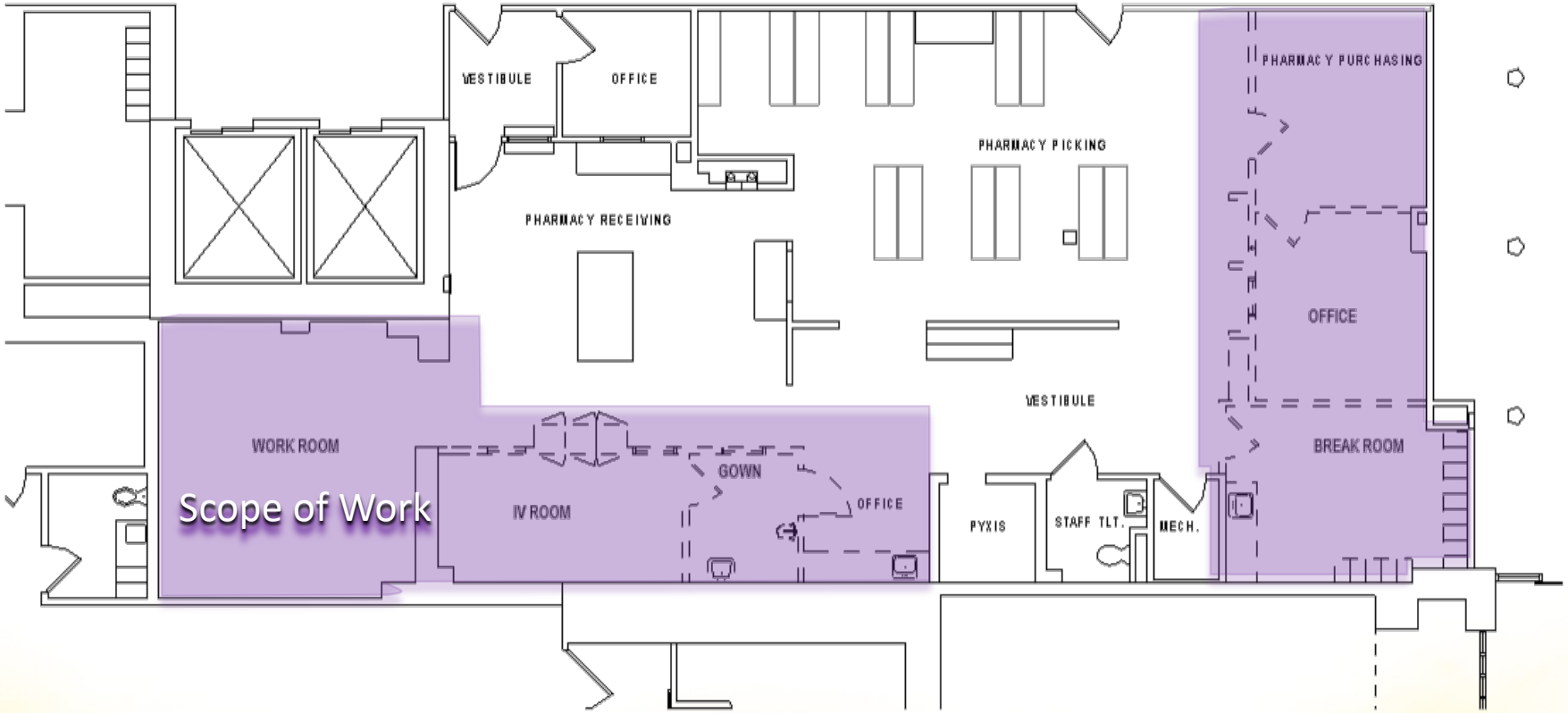
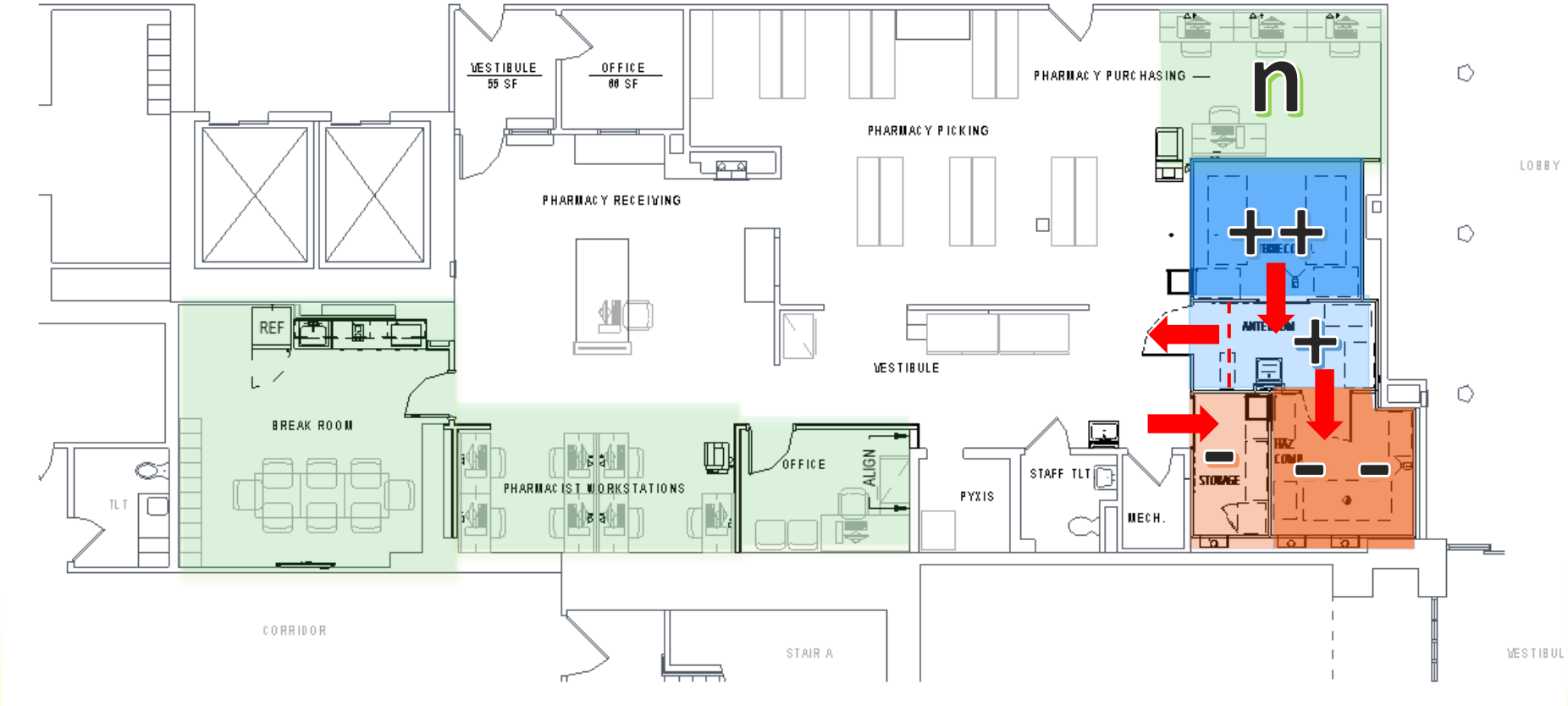
CASE STUDY 2

PROPOSED DEMO PLAN



PROPOSED PLAN



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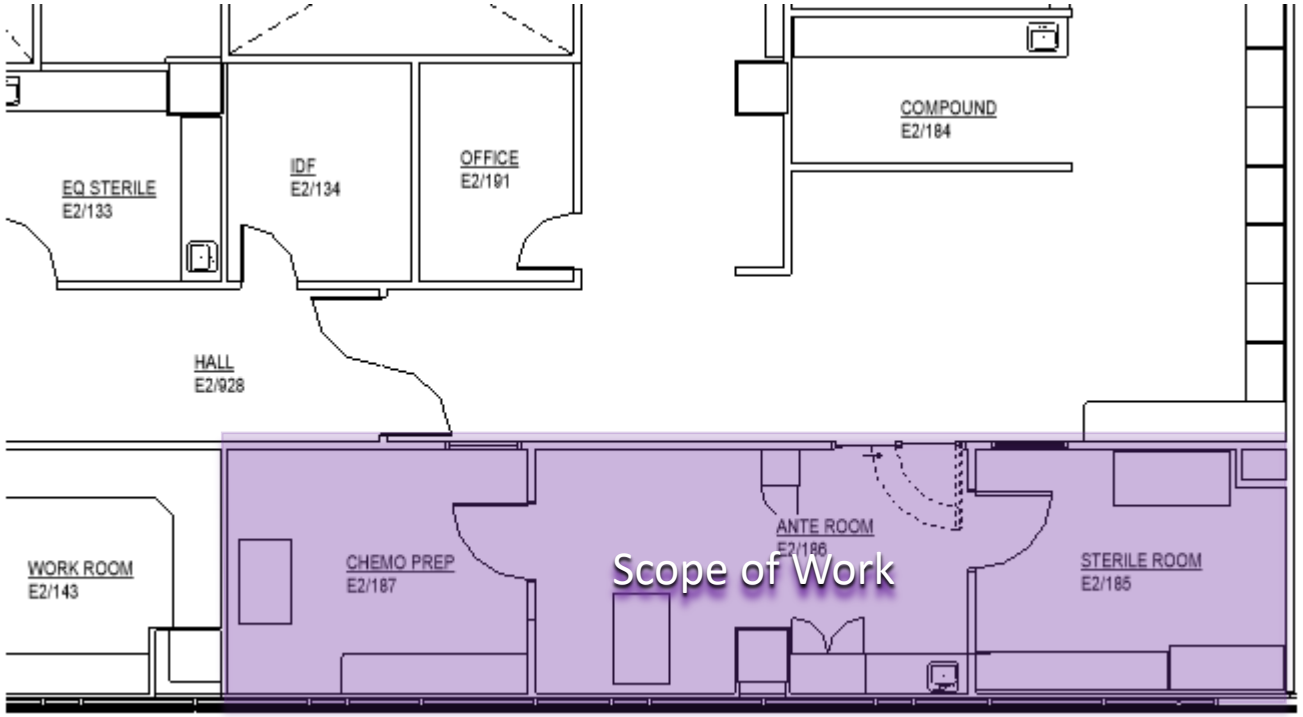
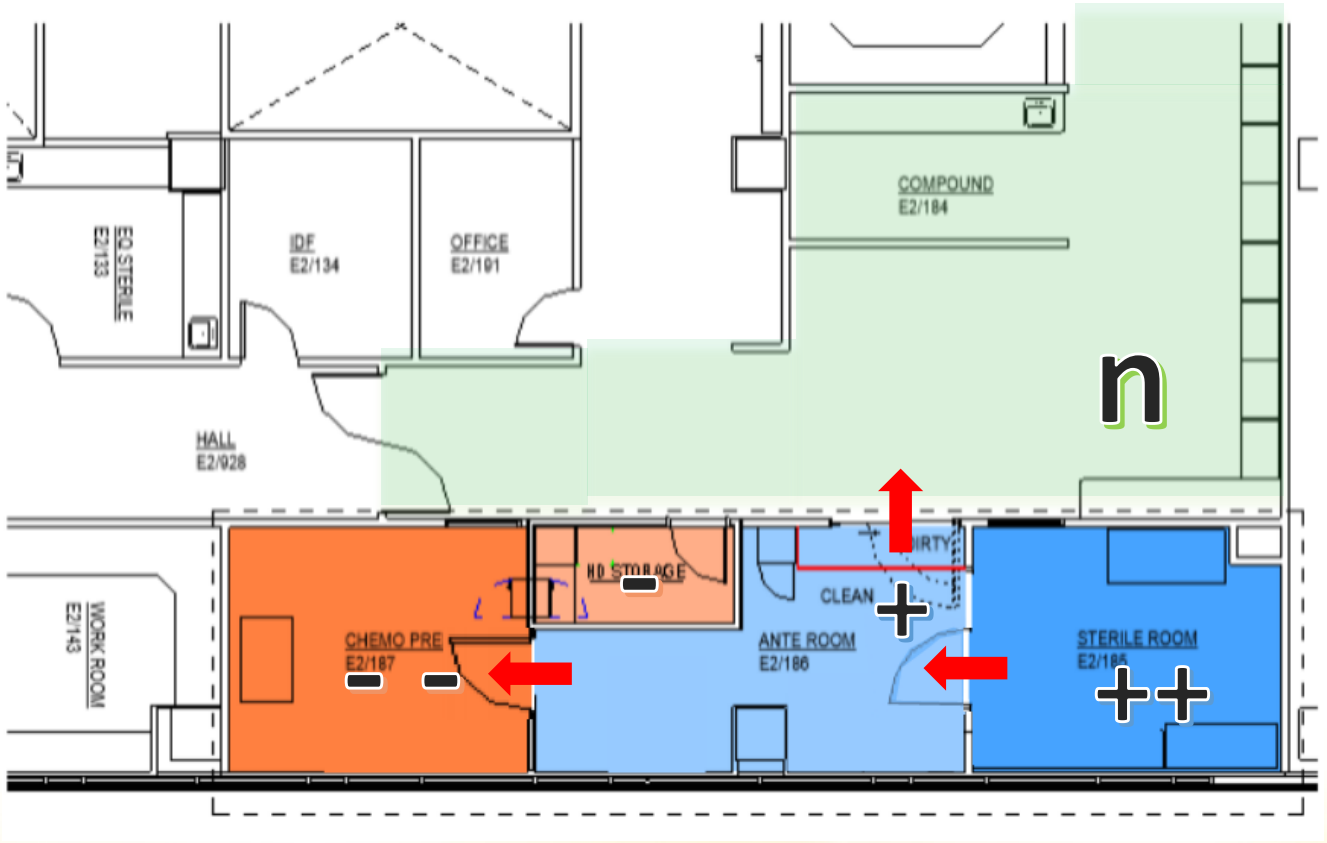
CASE STUDY 3

PROPOSED DEMO PLAN



PROPOSED PLAN



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Summary

TAKE AWAYS

- Air Change Requirements – 30 ACH min in Ante, Sterile, and HD Compounding Rooms, 12 ACH min in HD Storage Room – Best Practice New Dedicated AHU
- Pressurization Requirements – Min 0.02” w.c. Positive in Ante and Sterile Compounding Rooms. Min 0.02” Negative in HD Compounding Rooms. Min 0.01” to 0.03” Negative in HD Storage Room
- Controls/Monitoring - Keep it simple?
- Door design with direction of flow (Positive, Negative, Neutral)
- Door Operators - Best practice handsfree wave technology
  - Sliding doors can provide solutions in tight spaces and comply with pressure flow
  - Doors must accommodate equipment

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TAKE AWAYS

- Temperature and Humidity Requirements – 68 degrees F or cooler with a relative humidity of less than 60% RH
- Filtration Requirements – All air serving ISO classified rooms shall pass through HEPA filters – Best Practice to locate them at the end devices with laminar airflow
- Low Return/Exhaust Grilles – Whenever return or exhaust grilles are installed locate them down low on the wall – In HD storage room locate low exhaust behind refrigerator near compressor
- Exhaust Requirements – Separate hood exhaust from all other building exhaust systems
- Equipment Location – obstruction of LR, Future planning – add' l hoods coordinate MEP requirements

TAKE AWAYS

- Lighting – Utilize gasketed clean room style light fixtures with cleanable surfaces
- Maintain a properly sealed room - Seal or Gasketed access panels, other components that penetrated the walls/ceilings etc.
- Eyewash Requirements – Use ANSI approved eyewash and meet tempered water requirements between 60-100 degrees F by using a mixing valve
- Sinks – make sure the washing requirements – Best Practice Single Scrub sink with Integral eye wash
- Have the spaces Commissioned/Certified prior to substantial completion
- Be careful with third party vendor package solutions

TAKE AWAYS

- Drug receipt / unpacking process for hazardous drug/Hazardous drug storage needs – receiving through final dosage form
- LOD – Line of Demarcation- Donning/Doffing
- Segregated compounding area – sterile vs non-sterile
  - *Dedicated segregated Anterooms – hazardous vs non-hazardous

*Determine what Best Practices components were desirable for better patient outcomes and improved process flow to maintain safety of Staff and Patients.

TAKE AWAYS

- Avoid potential dust collectors – caulking corners vs coved corner conditions
  - Flooring and wall finishes, Coved conditions
  - Monolithic integral flooring with coved base
  - Ceiling with coved transition to wall
  - Surfaces in the SCA should be smooth, impervious, free from cracks and crevices, and non-shedding so they can be easily cleaned and disinfected
- Cleaning Storage – supply closet for HSKP equipment
- THHSC to adopt FGI 2018
- Official December 1, 2019 – USP 800

MEP Items from THHSC

(iii) A hand washing fixture with hands-free operable controls shall be in the preparation room and within five feet of each entrance to the hood room or chemo-hood room. Hand washing fixtures and floor drains are not allowed inside the hood room or chemo-hood room.

(C) All penetrations in the walls and ceilings shall be sealed.

(D) The door from hood room shall swing into the preparation room. The door from preparation room shall swing into the chemo room. The door from preparation room shall swing into pharmacy.

(B) When fume hoods are used for chemotherapy, the air/fumes shall be exhausted directly to the exterior. The hood exhaust shall not use the building exhaust system. When more than one fume hood is in the same hood room and the work stations face each other, at least six feet must separate work area openings.

(D) All air entering the IV solutions area for the preparation room, hood room and chemo-hood room shall be HEPA filtered.

FGI 2018

2.1-4.2.2 Pharmacy Areas

* **2.1-4.2.2.1 Dispensing facilities.** The following shall be provided:

A2.1-4.2.2.1 Dispensing facilities. Dispensing facilities should meet all applicable requirements of:

a. USP <795>: Pharmaceutical Compounding—Nonsterile Preparations

b. USP <797>: Pharmaceutical Compounding—Sterile Preparations

c. USP <800>: Hazardous Drugs—Handling in Healthcare Settings

(1) A room or area for receiving, unpacking, and inventory control of materials used in the pharmacy

(2) Work counters and space for automated and manual dispensing activities

(3) An extemporaneous compounding area. This shall include a sink and counter space for drug preparation.

(4) An area for reviewing and recording

(5) An area for temporary storage, exchange, and restocking of carts

(6) Security provisions for drugs and personnel in the dispensing counter area

FGI 2018

2.1-4.2.3 Sterile Work Areas

* **2.1-4.2.3.1 General.** Where sterile work areas are provided, they shall meet the requirements in this section.

A2.1-4.2.3.1 General. Sterile work areas should meet the requirements of USP <797>: Pharmaceutical Compounding—Sterile Preparations and USP <800>: Hazardous Drugs—Handling in Healthcare Settings as applicable.

(1) Layout. The pharmacy shall be laid out to preclude unrelated traffic through the intravenous (IV) and hazardous drug IV preparation rooms.

(2) Where robotic systems are used in the preparation of IV solutions in either the positive pressure IV preparation room or the negative pressure hazardous drug IV prep room, the robotics shall be separate systems and shall not pass from one room to the other.

2.1-4.2.3.2 IV preparation area. If IV solutions are prepared in the pharmacy, a sterile work area with a laminar-flow workstation designed for product protection shall be provided.

(1) The laminar-flow workstation shall include a nonhydroscopic filter rated at 99.97 percent (HEPA), as tested by dioctyl phthalate (DOP) tests.

(2) The laminar-flow workstation shall have a visible pressure gauge for detection of filter leaks or defects.

FGI 2018

* **2.1-4.2.3.3 Hazardous drug IV preparation room.** A separate room shall be provided for preparation of hazardous drug IV admixtures under a Class II (Type A2, B1, or B2) or Class III biological safety cabinet.

A2.1-4.2.3.3 Hazardous drug IV prep room

a. Biological safety cabinets are classified according to biosafety levels established by the Centers for Disease Control and Prevention. See the CDC document "Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets."

b. The hazardous drugs IV preparation room should meet the requirements of USP <800>: Hazardous Drugs—Handling in Healthcare Settings.

***2.1-4.2.8.7 Hand-washing station.** A hand-washing station(s) shall be provided either in an anteroom or immediately outside the room where open medication(s) are prepared.

A2.1-4.2.8.7 A hand-washing station(s) should be in accordance with:

a. USP <795>: Pharmaceutical Compounding—Nonsterile Preparations

b. USP <797>: Pharmaceutical Compounding—Sterile Preparations

c. USP <800>: Hazardous Drugs—Handling in Healthcare Settings

THANK YOU

COMMENTS / QUESTION/ NEED HELP

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Learning Objectives:

We covered the basic Architectural and MEP requirements for hospital pharmacy clean rooms and explain how to work within the parameters of USP 797/800 compounding pharmacy standards to achieve the best outcome for day one compliance.

Best practices to navigate the current standards, different alternatives to meeting the standard, and associated pros and cons of each will be discussed.

Discussed how to approach USP 800 requirements for hazardous drug storage to help hospital pharmacies prepare for this new standard anticipated to become official December 1, 2019.