80 Oak Street, Norwood, New Jersey 07648 USA - Tel: 201-768-9501 - Fax: 201-768-9504

Designing your USP 797 and 800 compounding area

The new USP chapters describe practices and standards for pharmacy compounding. According to the type of drug that is compounded in your pharmacy, your lab will need to comply to USP 797 or USP 800.

Nicos Group, proud PCCA exclusive partner for the supply of modular compounding spaces, can be the answer you are looking for to be compliant with the new USP requirements and meet the upcoming deadlines. This guide will explain the minimum requirements that your

Picture 1 - Compounding Area for PCCA by Nicos Group

new facility will need to accommodate to be USP-compliant.

USP 800, regulating the handling of Hazardous Drugs (HDs) is the last standard introduced, and will become officially effective on December 1st, 2019. This guide will help you understanding the minimum requirements that your new facility will need to accommodate to be USP-compliant, so that your compounding lab transition will be smooth, well-informed and free of problems

Advantages of a modular system

From an architectural point of view, the cleanroom market offers different alternatives. Just to mention the main ones, there are:

- "**Stick-Built Cleanrooms**", built using standard building materials, with epoxied paint surfaces

- "**Soft-Wall Cleanrooms**", a lightweight, low cost solution where the hard walls are replaced by plastic curtains.

However, the industry experts agree that the best solution is a modular wall approach. There are several reasons that justify this. Here are the main ones:

- **GMP design for unique quality**
- **Flexibility**
- **Modularity**
- **Price optimization**

GMP design for unique quality: While a stick-built construction is just an adaptation of standard building materials, a modular system uses panels developed to be installed and used in cGMP and USP compliant facilities, guaranteeing a high resistance to cleaning agents, smooth and seamless connections between panels, coved connections at all 90 degrees corners and a clean and attractive appearance for the operator.

A modular panel has a "sandwich" structure, with a layer of insulating material (which is usually either rockwool or aluminum honeycomb) between two skins, for an overall thickness of 1 ¾". The skin material selected is the surface of the wall system that will be exposed: it is evident how the choice of its material is a key element in your project.

Nicos Group, thanks to its long experience, international nature and manufacturing flexibility, offers the widest selection of materials in the North American market, ranging from powder coated metal skins, UPVC coated skins with cold-welded joints, stainless steel, glass walls, or our signature HPL material. Click here to know more about our HPL panels

Flexibility: As the introduction of the new USP regulations show, the pharmaceutical compounding is a field prone to changes. In such a fast-paced environment, you want to make sure that your compounding lab is easy to modify, both in terms of little details (i.e. the addition of a receptacle at the last minute during the installation of the system) and in terms of future major renovations: while a stick-built system is fixed and does not allow you to modify the shape of it over time, a modular system allows you to enlarge your compounding space, changing the layout of your rooms, or even moving the entire lab in a new locations. Do not forget that you are working inside your pharmacy, if you want to modify the facility, you want to do it in a clean way! Only a modular system, with properly designed panels allows you to obtain a satisfactory result.

Price optimization: if the upfront cost of a modular system can be higher, compared to the alternatives mentioned above, when you factor-in the durability and the quality of the materials used, the low amount of maintenance required,

Picture 2 - Compounding area by Nicos Group

the speed and expertise in completing the installations by factory-trained installers, the overall cost becomes comparable and in some cases even lower, for a much higher quality system.

Modularity: Each project is custom-made for the needs of the specific customer. That means that there are no constraints in terms of minimum or maximum dimensions, locations and quantity of receptacles, doors, windows or any other cleanroom item. However, at the same time the manufacturing process is based on the same prefabricated panel, that is replicated each time with the needed small modifications, to offer you one of the shortest lead times on the market.

USP Design

The following is a brief and intuitive list of the minimum requirements that you will need to meet to have your compounding space up and running. We also included some "nice to have" elements, in case you want to go the extra mile, and show your customers that you did not only meet the requirements, but you went beyond them, to offer the best compounded preparations.

1.1 USP 797 design (Sterile, non-hazardous)

USP 797 means Sterile.

Sterile means that you will need to place your Primary Engineering Control (PEC, a device that

provides a defined and controlled ISO Class 5 environment for compounding CSPs.) in the ISO 7 buffer room of the cleanroom suite, with a positive relative pressure and at least 30 ACPH (Air Changes per Hour, the measure of the air volume added to a room divided by the volume of the room). The integrity of the room is protected by the presence of an ISO 8 ante-room, with positive pressure and at least 20 ACPH. The arrows in the layout below (Figure 1) help you understand the direction of the airflow. The goal here is the protection of the drug: you do not want to have air coming from the outside to potentially contaminate your sterile preparation.

USP 797	
Buffer room	Ante-room
ISO 7, positive pressure, 30 ACPH	ISO 8, positive pressure, 20 ACPH
Why positive pressure? To protect the Sterile compounded drug from being potentially contaminated	

As a recommendation, we suggest to also have a prep-room, between the ante-room and the buffer room, to reduce potential contamination to the products. However, this is not a requirement for USP 800

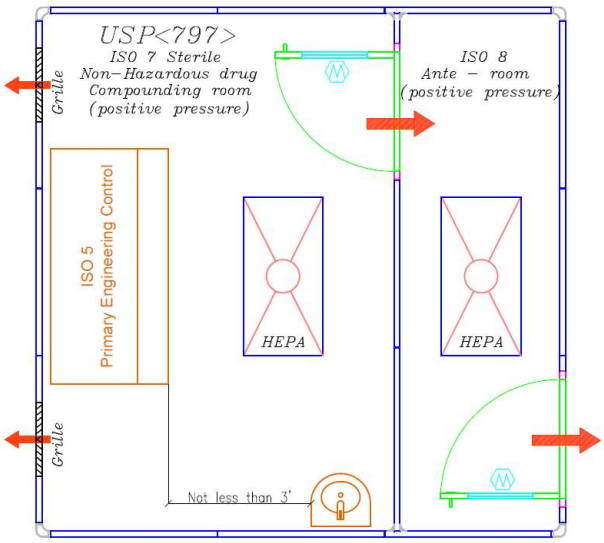

Figure 1 - USP 797

2.2 USP 800 design (Sterile, hazardous & Sterile, non-hazardous)

If you handle any of the drugs listed in the NIOSH (National Institute for Occupational Safety and Health) list, you will need to comply with USP 800. You should always keep in mind that these drugs must be handled in a way that promote patient safety, worker safety, and environmental protection. Therefore, to comply with USP 800, you need to have a negative pressure inside your buffer room, so that the hazardous particles can be externally exhausted rather than having access to the pharmacy environment.

If you are dealing with hazardous, non-sterile preparations, you only need one room, with no ISO classification (so the air can freely access the room through doors and air grilles). Technically the negative pressure can be guaranteed by an externally vented PEC only, but we suggest to vent the room through an independent system, to guarantee a higher reliability over time.

Based on the type and concentration of hazardous particles exhausted and the local rules, you may need to HEPA filter the exhausted air, to avoid potential contamination of the open environment (as shown in the design below, Figure 2)

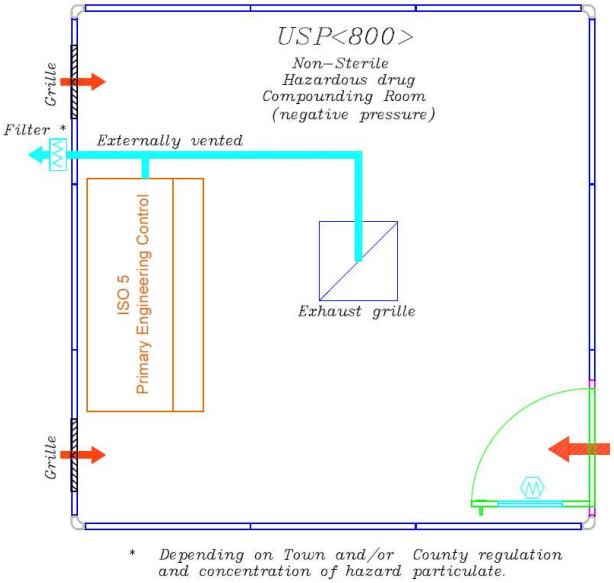

Figure 2 - USP 800, non-sterile

USP 800 – non sterile	
Buffer room	Ante-room
No ISO classification, negative pressure	Not needed
Why negative pressure? To promote patients and workers safety, and environmental protection	

When your preparations are both Sterile and Hazardous, you will need the ante-room + buffer room design we already saw in the 797 section, with two big differences: the buffer room must now keep a negative pressure (30 ACPH needed), and the ante-room needs to keep an ISO 7 air quality, with positive pressure (30 ACPH needed). (Figure 3)

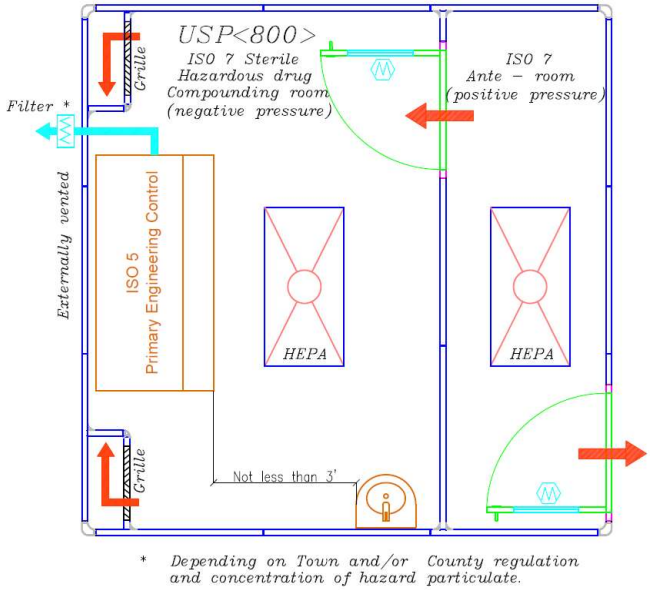

Figure 3 - USP 800, Sterile

USP 800 – sterile	
Buffer room	Ante-room
ISO 7, negative pressure, 30 ACPH	ISO 7, positive pressure, 30 ACPH

As a recommendation, we suggest to also have a prep-room, between the ante-room and the buffer room, to reduce potential contamination to the products. However, this is not a requirement for USP 800.

Please, keep in mind that the designs for Sterile facilities are intended to be used when the final compounded preparation is a category 2 CSP. In case of a category 1 CSP (shorter BUDs) the PEC can be placed in a unclassified area.

In any case, for USP 797 and 800, a differential pressure visual monitor is always required.

1.2 USP 795 design

If your final product is not Sterile nor Hazardous, you do not need a cleanroom environment to perform your compounding activities. However, in order to ensure the safety of your patients and the overall quality of your compounding pharmacy, we suggest to still predispose a cleanroom-like environment, with a supply of HEPA filtered air, and positive pressure in the room, as in the design below (Figure 4)

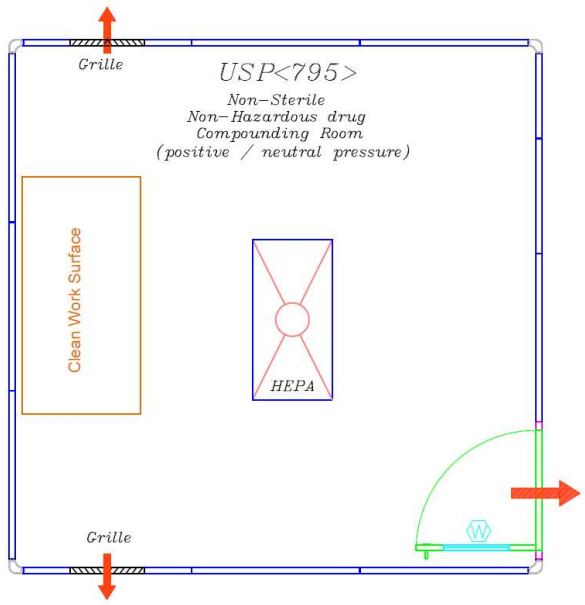

Figure 4 - USP 795 (recommendation)

Lorenzo Gazzola, Product Manager at Nicos Group