Trinity Consultants | SafeBridge® Regulatory & Life Sciences Group

WORKING® BUILDINGS

## 1 Read, read, and re-read

Read the entire, newly revised ***USP 797*** compounding standards and make sure you understand the distinctions between the old and new. While you're at it, throw out and delete any copies of the old USP compounding standards. Also, all sites affected by the USP compounding standards must also spend time understanding the FDA ***Insanitary Conditions at Compounding Facilities*** guidance document published in November 2020.

## 2 Commissioning begins at the design phase

Engage an expert commissioning firm to review cleanroom design, adjacencies, finishes, equipment selection, and HVAC design early in the design phase. Also, consider the presence of a construction quality control expert for your next cleanroom construction project. The proper application and installation of cleanroom equipment and finishes are critical to preventing compliance issues in your classified spaces.

## 3 Separation is critical

If your cleanroom suite contains a negative pressure hazardous drug (HD) buffer room, design the classified area with a separate wet and dry anteroom to isolate the particle-generating activities and aerosols of the wet anteroom from the negative pressure area of the HD buffer room.

## 4 Build in a cushion

USP 797 provides the minimum recommended air changes per hour (ACPH) for various classified spaces. Instead of building to the minimum ACPH, design with at least a 20% higher factor to accommodate for filter loading, staff, and volume of products compounded. Air Handling Unit design for these spaces is especially challenging. These spaces are the worst of all worlds from a design perspective, constrained by small size, high ACPH, tight temperature and humidity requirements, pressure relationships, interlocks to other equipment, and other challenges. The design team is tasked with making decisions on system types including utility selections (chilled water vs DX), outdoor design conditions, indoor environmental conditions, and building automation types. Frequently, these decisions are made based on minimum code criteria or guidance provided with USP standards. These minimum requirements often fall short of the end user's needs, resulting in space that is not able to operate under compliant conditions and requiring costly renovation or equipment replacement.

## 5 Monitor and review trends

Understand the relationship between certification reports, test and balance trends, and personnel environmental monitoring trends. Create a committee at the facility or system level to monitor and review trends. If possible, engage the expertise of a microbiologist as part of the review process.

## 6 Choose your BSC wisely

Type 2 A2 biosafety cabinets (BSCs) are typically sufficient for the majority of HD compounding activities and needs. While Type 2 B2 BSCs are effective for providing 100% exhaust when working with highly volatile agents, they also introduce additional challenges to the mechanical and exhaust design, such as potential failure of the unit, resulting in the entire cleanroom going out of compliance. Therefore, be sure to determine whether a Type 2 B2 BSC is necessary or whether a Type 2 A2 BSC will satisfy your facility's need.

## 7 Save Time on Acceptable Surface Limits

Do you know that many drug manufacturers have already developed Acceptable Surface Limits (ASL) for their drugs? Check with the drug manufacturer to obtain an ASL that can be used to compare quantitative sample analysis results to assess employee exposures and effectiveness of cleaning procedures. And remember, one ASL does not fit all HD's. If an ASL is not available, a conservative ASL can be developed from the inhalation Occupational Exposure Limit (OEL), which should be more readily available from the Manufacturer.

## 8 Perform Risk Assessments and Protect Worker Health

Health and Safety staff should perform qualitative risk assessments of the facility to evaluate the potential for employee exposure at all stages of the hazardous drug (HD) life cycle: receiving, compounding, administration, patient care and waste disposal. Be sure to include a review of HDs paths in the facility, focusing on the greatest exposure potential and the strength of the control system in place, prioritizing high-risk tasks throughout the facility. Qualitative risk assessments result in effective plans for sampling and analysis of HDs that drive continuous improvement in control systems and worker protections.

## 9 Review Hazardous Drugs Annually

The landscape of new drugs evolves rapidly, so be sure to annually review the list of HDs used in your facility. Updates are made periodically to the NIOSH Hazardous Drug Lists, so your facility's HD list should represent the most current NIOSH definitions of HDs. If you are handling drugs in development in clinical trials, use the NIOSH definition to help categorize new drugs. Aside from an annual review of your facility's HD list, be sure to annually review and update all Standard Operating Procedures (SOPs) as well.

## 10 Conduct Hazardous Drug Sampling and Analysis

Sampling and analysis are recommended every six months. Review your list of HDs and categorize by potency and usage. Prioritize HDs that are the most potent and most used in your facility, and sample for these HDs every six months. Tracking these results will allow you to evaluate your control systems and cleaning effectiveness and provide a baseline of historic HD levels. In circumstances where there is potential for aerosolization of drug, consider air sampling in addition to surface sampling.


# Countdown to USP 797/800 Compliance: 10 Things to Do Now