ARTICLE

3 Automation Strategies for USP <797> Compliance

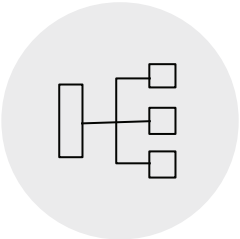
In November of 2023, new revisions to USP <797> became official. The updates include more stringent requirements for personnel training, cleaning and garb, increased frequency of microbiological air and surface sampling, and new beyond-use date (BUD) assignments for compounded sterile preparations.

Hospital-based compounding pharmacies have been working diligently to ensure their sterile compounding operations comply with these new revisions. However, change is never easy and many health systems have encountered numerous challenges on their USP <797> journey. Partnering with an expert in IV clean room processes and automation like Omnicell can help you successfully navigate USP <797> complexities, accelerating compliance while maximizing operational efficiency and patient safety.

The following are three key areas to consider on your path to USP <797> compliance and some examples of how Omnicell is providing health systems with valuable guidance.

1

Choosing the Right Compounding Category



The revised chapter divides compounded sterile preparations (CSPs) into three groupings: Category 1, Category 2, and Category 3. Each of these categories is primarily based on the levels of environmental control necessary for compounding, the probability for microbial growth during storage, and the time period in which the compound must be used.

Category 1 CSPs require the fewest environmental controls, but the compounds must be used within a matter of hours, while Category 3 CSPs require the highest level of environmental controls (e.g. cleanrooms, buffer rooms, increased testing), but have the longest BUDs – up to 120 days frozen (aseptically processed with sterility testing).

Choosing the right category for your hospital-based IV room operation is a foundational component of successfully complying with USP <797>.

Most of Omnicell's IV Compounding Service customers fall into Category 2 compounding. Our team of experts support evaluation of the proper category based on each pharmacy's goals for patient care. Finding a balance across clinical, financial, and operational needs factor into this decision.

For example:

- Design or construction of sterile compounding cleanroom
- Cost of necessary personal protective equipment (PPE)
- Increased sterility testing options and associated costs
- Change management for staff
- Strategies to manage drug inventory through shortened BUDs

For example, one of Omnicell's academic medical center customers initially evaluated transitioning to a Category 3 compounding facility, but ultimately decided against it based on the operational challenges of a shared cleanroom space for Category 2 and Category 3 compounding which was highlighted by Omnicell clinical strategists.

Conversely, a health system in the Northeast is planning to advance from a Category 2 to a Category 3 compounding facility with the implementation of a new cleanroom and an upgrade to the new IVX Station robot.

Balancing clinical, financial, and operational goals to select the best compounding category is key to USP <797> compliance.

2

Finding the Best BUD Balance

Once you've identified the CSP category for your operation, another key consideration is setting optimal BUD assignments for CSPs within that category. For example, BUDs in Category 2 can range from 4 days (room temp)/10 days (refrigerated)/45 days (frozen) all the way up to 45 days (room temp)/60 days (refrigerated)/90 days (frozen), depending on the preparation environment, sterility of starting ingredients, and types of sterilization techniques used. Optimal BUD assignments find the balance between maximizing effective BUDs while minimizing operational costs.

There are many strategies to consider to find your BUD balance including:

1. Adjusting your production schedule to minimize waste
   - Analyzing utilization data
   - Finding the optimal days on hand
   - Implementing automation to manage soon to be outdated stock

2. Experimenting with different sterility testing options:

- USP <71> sterility testing — the industry's gold standard and a cost-effective approach
- Sterility Testing via rapid microbial methods — provides multiple options with faster turnaround times

3. Leveraging multiple storage conditions to maximize dating

Our team will help you determine what is most effective for your pharmacy and maximize dating based on those criteria.

For example, the previously mentioned academic medical center decided to leverage rapid sterility testing to better support its needs with beyond-use dating while remaining a Category 2 compounding facility. Conversely, a Mid-Atlantic health system successfully leverages USP <71> sterility testing as a Category 3 compounding facility.

Optimal BUD assignments balance between maximizing effective BUDs while minimizing operational costs.

3

Adopting a Flexible Approach

A final and important consideration for operationalizing USP <797> is to keep an open mind. The industry is still learning what works best in this new regulatory environment. It is important to experiment and adapt until the process is optimized for your needs to provide the best patient care. Some initial strategies may not work out as anticipated and will require you to change course. Omnicell's expert team uses data and best practices across its customer base to help you assess production adjustments, protocol mix, batch sizes, quarantine processes, and more to continually adapt your program to achieve desired outcomes.

For more information on how Omnicell can support USP <797> compliance visit **Omnicell.com/iv-room**

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