USP <797>: Where Compliance Breaks Down—and How to Close the Gap

USP <797> provides a comprehensive framework for sterile compounding—but it does not function as an operational playbook. Most organizations are not struggling because they are unaware of the requirements. They struggle in the space between what the chapter says and what daily practice actually looks like.

This is where compliance gaps emerge.



These gaps are not always the result of poor intent or lack of effort. More often, they stem from interpretation, variability, and incomplete operational translation of expectations into practice.

Below are four of the most common—and most impactful—areas where organizations fall short, along with practical strategies to close those gaps.

1. Viable Sampling: Activity Without Strategy

USP <797> requires environmental monitoring. What it does not fully define is how to design a program that demonstrates control.

As a result, many programs default to:

- Routine sampling without justification
- Site selection based on ease or habit
- Limited trending or retrospective review
- Inconsistent responses to excursions

The gap is not in performing sampling—it is in demonstrating why it matters.

A defensible viable sampling program should clearly answer:

- Why were these locations selected?
- What trends are being evaluated over time?
- How are results influencing decisions?

Practical Takeaways

- Document risk-based rationale for every sampling location
- Define what constitutes a meaningful trend before you need it
- Standardize investigation triggers and response expectations
- Ensure your program demonstrates decision-making—not just data collection

2. Competency Programs That Miss System Risk

USP <797> requires personnel competency—but it does not limit risk to compounding personnel alone.

Many programs focus narrowly on:

- Media fills
- Gloved fingertip testing

While essential, these assessments do not capture all contributors to contamination risk.

Critical gaps often exist in:

- Viable sampling personnel
- Cleaning and disinfecting staff
- Individuals reviewing data and making release decisions

Practical Takeaways

- Expand competency programs to include all roles that impact contamination control
- Assess not just task execution, but decision-making and understanding
- Align competency frequency and rigor with level of risk—not job title
- Ensure individuals performing sampling or reading plates are trained and evaluated for competency

3. Cleaning and Disinfecting: The Execution Gap

Most facilities have well-written cleaning procedures. Fewer have procedures that are consistently executed as written.

Common challenges include:

- Contact times that are not operationally achievable
- Inconsistent product use or sequencing
- Workflow conflicts that interfere with proper technique

The result is a familiar inspection finding:
“Observed practices do not align with written procedures.”

Practical Takeaways

- Ensure that required contact times are realistic in practice
- Observe staff performing cleaning to confirm true workflow alignment
- Standardize products and application methods to reduce variability
- Audit for consistency across shifts—not just during scheduled reviews

4. Policy-to-Practice Misalignment

This is the most common—and most inspection-visible—gap.

Organizations often have:

- Complete SOPs
- Defined procedures
- Documented expectations

But still have challenges during inspections due to:

- Variability between shifts
- Staff not following procedures exactly
- Disconnect between training and execution

Compliance is not demonstrated by documentation alone—it is demonstrated by consistent behavior.

Practical Takeaways

- Conduct direct observation audits of real practices
- Compare “what is written” vs. what is actually happening
- Reinforce training through hands-on verification—not just review
- Ensure leadership routinely validates execution—not just documentation

Closing the Gap: From Compliance to Defensibility

USP <797> compliance is not achieved by completing a checklist. It is achieved by building systems that are:

- Risk-based
- Consistent
- Operationally realistic
- Clearly justified

Organizations that succeed are able to answer not just *what* they do—but *why they do it, and how they know it works*.

Final Thought

The largest compliance gaps in USP <797> rarely involve missing requirements. They involve unclear interpretation and inconsistent execution.

Closing that gap requires intentional design—not just adherence.