USP <797> Contamination Control: Where Best Practices Make the Difference

USP <797> sets clear expectations for preventing contamination in sterile compounding—but compliance alone doesn't guarantee control. True contamination control depends on how consistently best practices are applied in daily operations, especially in three high-impact areas: garbing and hand hygiene, material transfer, and cleanroom behavior.

While engineering controls matter, people and processes ultimately determine success.

Garbing & Hand Hygiene: The First and Most Critical Barrier

USP <797> is explicit: personnel are the primary source of contamination in cleanrooms. Skin cells, clothing fibers, and microorganisms are continuously shed—even when staff feel "clean."

Best practice programs go beyond teaching garbing order. They:

- Emphasize *why* each step matters
- Reinforce proper technique through routine observation
- Treat glove sanitization as an ongoing practice, not a single event

Key best practice:
Garbing and hand hygiene should be assessed routinely—especially after workflow changes, staffing turnover, or process drift.

Material Transfer: Where Good Intentions Go Wrong

Material transfer failures are rarely dramatic. They're subtle:

- A missed dwell time
- A wiped item placed on an unclean surface
- Recontamination from not wearing gloves

USP <797> expects materials to enter controlled spaces in a way that preserves environmental state of control, not compromises it.

Best-practice organizations:

- Standardize the agent and method
- Define where items can and cannot be staged
- Train staff to recognize hidden contamination pathways

Key best practice:
Material transfer should be treated as a defined process—not an informal task.

Cleanroom Behavior: The Invisible Risk

Talking, rushing, unnecessary motion—these behaviors don't feel risky, but USP <797> recognizes their impact on particle generation and airflow disruption.

Cleanroom behavior must be:

- Explicitly defined
- Modeled by leadership
- Corrected in real time

Key best practice:
Behavioral expectations should be included in training, observation, and feedback—not left to interpretation.

Pulling It Together: Contamination Control as a System

Garbing, transfer, and behavior are interconnected. Weakness in one area can undermine the others.

Organizations that succeed treat contamination control as:

- Cultural
- Trainable
- Measurable

Not just audit-driven.

Final Thought

USP <797> compliance is the starting line. Let your viable sampling be your guide. Best practices

keep you in control long after inspections end.