Viable Air and Surface Sampling Under USP <797>: What the Data Is Meant to Tell You

Viable air and surface sampling are often treated as a second thought. Results are reviewed, levels are checked, and the program moves on until there's exceeded an action level. But USP <797> never intended viable monitoring to be a passive exercise. When used correctly, it's one of the most valuable tools for understanding whether your cleanroom controls are actually working during real compounding conditions.



What viable monitoring is really measuring

Viable air and surface sampling are not just about counting microorganisms. They are indicators of how well multiple systems are functioning together:

- Room design and airflow
- Cleaning and disinfection practices
- Personnel movement and behavior
- Workflow discipline under pressure

Sampling occurs during dynamic operating conditions, which means results reflect reality—not

best-case scenarios. That's why viable monitoring often reveals patterns that wouldn't be visible through policy review or training records alone. But so many sterile compounders "cheat" the system. Resist the urge! Excursions only make your practices better.

Why results sometimes feel unpredictable

Many organizations describe viable monitoring results as "random." In most cases, they aren't.

What feels unpredictable is often the result of:

- Inconsistent traffic patterns
- Variable staffing or shift coverage
- Workflow changes that weren't formally assessed
- Aseptic technique drift over time

When results are reviewed in isolation, they feel confusing. When they're trended and discussed in context, they start to make sense.

USP <797> expects insight, not perfection

USP <797> does not expect zero recoveries or flawless months. It expects:

- Ongoing monitoring
- Awareness of environmental performance
- Appropriate investigation
- Documented response

Inspectors are not looking for a spotless record. They are looking for evidence that the organization understands its data and uses it to maintain control.

Avoiding viable monitoring, or minimizing its importance, often creates more regulatory risk than addressing results directly.

The leadership role in viable monitoring

Viable air and surface sampling is not just a technical activity—it's a leadership one.

How leadership frames monitoring determines whether teams see it as:

- A valuable tool, or
- A box check

Strong programs establish expectations early:

- Results are data, not judgment
- Investigations focus on systems, not individuals
- Responses are proportional and documented
- Trends matter more than single events

When leadership remains calm and consistent, teams are more likely to report issues, follow procedures, and engage with the process honestly.

Using trends to strengthen control

A single viable result can raise a question. Trends answer it.

Trend analysis helps organizations understand:

- Whether certain rooms are more challenged than others
- If specific activities correlate with higher recoveries
- Whether changes to cleaning agents or schedules are effective
- How seasonal or operational shifts impact the environment

This is where viable monitoring becomes powerful—not as a compliance checkbox, but as a management tool.

Air and surface sampling work together

Air and surface sampling are most meaningful when evaluated together.

Air results provide insight into:

- Environmental control
- Room recovery
- Personnel activity

Surface results provide insight into:

- Aseptic technique
- High-touch risk areas
- Workflow discipline

Looking at one without the other limits the story the data can tell.

Turning monitoring into confidence

Viable monitoring under USP <797> should reduce uncertainty—not increase it.

When programs are designed thoughtfully and reviewed consistently, monitoring:

- Builds confidence in cleanroom performance
- Supports proactive decision-making
- Demonstrates regulatory maturity
- Protects patients and staff

At Parasol, we help organizations move beyond simply “doing” viable monitoring and toward using it to calmly, defensibly, and effectively maintain control.