

Taking USP <797> Best Practices into the New Year: Resolutions for Sterile Compounding Success

As the calendar flips to a new year, sterile compounding teams have a unique opportunity to reflect, reset, and recommit to excellence. The revised USP <797> standards, effective November 2023, introduced significant changes that impact every aspect of compounding—from facility design to personnel training. Now is the perfect time to turn these requirements into sustainable habits. Think of them as your New Year's resolutions for compliance and patient safety. Here are 6 resolutions for 2026!



Resolution 1: Align Your Facility with the Right Category

USP <797> replaced risk levels with Category 1, 2, and 3, each tied to environmental controls and beyond-use dating (BUD).

- Category 1: ISO Class 5 PEC in an unclassified segregated compounding area; short BUDs.
- Category 2: ISO Class 5 PEC in ISO Class 7 buffer room; longer BUDs with robust controls.
- Category 3: ISO Class 5 PEC in ISO Class 7 buffer room; enhanced controls and the longest

BUDs.

Action Step: Audit your space and workflows. If you're aiming for longer BUDs, ensure your cleanroom meets Category 2 or 3 requirements. This resolution sets the foundation for everything else.

Resolution 2: Make Environmental Monitoring a Habit

Monitoring isn't just a compliance checkbox—it's your early warning system against contamination.

- Category 1 and 2: Monthly surface sampling and semiannual air sampling.
- Category 3: End of batch and weekly surface sampling and monthly viable air sampling.

Action Step: Create a monitoring calendar for the year. Assign responsibilities, document results, and trend data. Proactive monitoring prevents small issues from becoming big problems.

Resolution 3: Invest in People

USP <797> emphasizes competency and accountability. Assessments in hand hygiene, garbing, and aseptic technique are mandatory.

Action Step: Schedule training now. Use tools like fingertip sampling kits and media-fill tests to verify skills. Empower your designated person(s) to lead these efforts—they're your compliance champions.

Resolution 4: Upgrade Your Cleaning Program

Spores are resilient, and alcohol alone won't eliminate them. USP <797> requires sporicidal disinfectants for the monthly clean. Verify that the agents and supplies used in the primary engineering controls are sterile.

Action Step: Review your cleaning and disinfecting SOPs. Are you using the appropriate agents? Are surfaces staying wet for the full dwell time? Train staff on why these details matter—they're critical for patient safety.

Resolution 5: Document Everything

If it's not documented, it didn't happen. Logs, SOPs, and certificates of analysis are your best defense during inspections.

Action Step: Audit your documentation process. Digital tools can simplify recordkeeping and reduce errors. Make documentation part of your daily routine, not an afterthought.

Resolution 6: Build a Culture of Continuous Improvement

Compliance isn't static—it evolves. Encourage feedback, share audit results, and celebrate wins. A culture of accountability and learning ensures your team stays ahead of regulatory changes.

Action Step: Hold quarterly compliance review sessions. Use these sessions to identify gaps, set goals, and recognize achievements.

Looking Ahead

The new year is more than a date change—it's a chance to transform compliance into confidence. By adopting these resolutions, you'll not only meet USP <797> requirements but exceed them, creating a safer environment for patients and a stronger foundation for your pharmacy.

Ready to start strong? Parasol Medical offers solutions that simplify training, monitoring, and documentation—so your team can focus on what matters most: safe, sterile compounding.