



MediZap

Advanced Sterilization

Uncovered – New USP 797 Sterile Compounding Guidelines Insider Perspective

As of Nov. 1st, 2022, USP 797, “Pharmaceutical Compounding - Sterile Preparations,” was published, and one year later, on Nov. 1st, 2023, compliance with these new regulations was enforced. Upon extensive review of new guidelines, the industry and subject matter experts across regulatory consulting were left with some open questions.

Two of the most salient and common areas that colleagues within the 503A compounding pharmacy industry focused on were Beyond-Use Dates (BUDs) and Lot size restrictions. MediZap has been at the forefront of addressing these concerns and has worked to understand further and provide context and recommendations around these areas based on 503A customer interviews, regulatory consultant meetings, attendance at conferences: Association Society of Health-System Pharmacists (ASHP) with USP in-person meetings, the American Academy of Anti-Aging Medicine (A4M), and as a sponsor of the Alliance for Pharmacy Compounding (APC) with in-person attendance at both Owners Summits and Compounders on Capitol Hill. On top of that, we’ve had extensive research and engagement with industry leaders PCCA, Eagles Analytical, and Fagron.

Many gaps are filled by reading the published Dec. 11th, 2023 [USP 797 FAQs](#)

In addition to the USP document sourced in-person by MediZap titled [“Compounded Preparation Monographs”](#)

Lastly, MediZap has a position on [USP 797](#) downloadable in our Learning Resource Center.

MediZap’s unique methods by terminal sterilization by irradiation through E-Beam | X-Ray opens possibilities to solve for perceived constraints in the highlighted topics above. To hear MediZap’s opinion and guidance, please reach out for an initial dialogue and presentation on these topics.

