

Summary

USP 797 was enacted in January 2004, and is beginning to be implemented in health-system pharmacies. Its requirements have caused concern for facilities compounding sterile products. This brief is intended as an internal overview of the document, and an explanation of what it means (and doesn't mean) to Baxa customers. Review also the PowerPoint presentation made by Eric Kastango at the February 5, 2004 Sales Meeting for further understanding of USP 797.

USP was written to improve the compounding of sterile products. But, like any change, it has the potential to be misinterpreted, and thus feared. In general, USP 797 contains many procedural, training and quality assurance requirements that are not unreasonable for a quality IV operation.

The biggest misconception about USP 797 seems to be that a sophisticated "cleanroom" is required. This is simply not true. The "requirement" has been interpreted in many different ways, and is explained in more detail below.

USP 797 will be implemented as the US standard for sterile compounding, with ASHP and other industry guidelines following its lead. Once the initial concerns over the cost and difficulty in meeting 797's requirements have passed, patients and staff alike will be better off as a result. Our goal to help customers understand how to use Baxa products to comply with USP 797.

About the USP

The USP (US Pharmacopeia) is a private organization formed in 1820. Current members include many members of accredited schools of medicine and pharmacy, state medical and pharmacy associations, government agencies, consumer organizations and other prestigious health organizations.

The standards developed by USP are important for several reasons:

1. The Food, Drug and Cosmetic Act (and thus the FDA) recognizes the USP/NF (National Formulary) as the official compendia of US drug standards. There are hundreds of USP drug standards and all standards numbered less than 1,000 are enforceable by either individual State Boards of Pharmacy, or the FDA. The FDA does not routinely inspect individual pharmacies but may intervene in the case of injuries, a death, or a complaint.
2. USP/NF standards are often used as evidence of national standards in lawsuits.
3. The JCAHO (Joint Commission for Accreditation of Healthcare Organizations) has adopted these standards for use after July 1, 2004. JCAHO accreditation is the most universally recognized standard of US healthcare system quality. JCAHO accreditation is required for reimbursement through the national Medicare program and almost all state Medicaid (welfare) programs. It's difficult for a hospital to do business in the US coverage for elderly patients under Medicare.
4. Many State Boards of Pharmacy are adopting USP 797 for their pharmacy inspections that occur every one to three years.

Rumors abound about the requirements to meet USP 797. The remainder of this document clarifies the document's most important topics.

First, USP 797 is a number of things:

1. *Long.* It's 18 pages, including 13 using single spacing and a small text font. That's a lot of information to read but the concepts are not complicated.

2. *Paperwork and process intensive.* It would fill too much space to list all of the topics but it's reasonable to say that virtually every significant step of the sterile compounding process is covered in detail. See the Kastango presentation for more information.
3. *Intended to upgrade pharmacy admixture processes to reasonable precautions.* Some pharmacists will argue with a number of the requirements but the overall tone is to be proactive, scientific, comprehensive and effective. There is nothing in USP 797 that a pharmacy cannot implement with a "reasonable" amount of time and, in some cases, money.
4. *Specifies increasing controls based on risk.* CSPs (compounded sterile products) are classified into low, medium and high risk categories. Most CSPs prepared with/for Baxa products are in the low and medium risk categories.

But USP 797 is **not** some of the things that it's rumored:

1. USP 797 does NOT require sophisticated cleanrooms. This is a huge issue in the rumor mill. The guideline requires a separate area for compounding that meets a defined level of cleanliness. A brief explanation of standards will clarify the USP 797 cleanroom requirements. First, there are six levels of ISO (International Organization of Standardization) cleanrooms from ISO Class 3 to ISO Class 8.
ISO Class 3 equivalent to the former Class 1 designation allows a maximum of one particle (over 0.5 microns in size for all classes) per cubic foot. This cleanliness level is suitable for the ultimate clean room application such as microchip manufacturing.
ISO Class 5 (formerly Class 100) allows a maximum of 100 particles per cubic foot; which is the level for the typical laminar airflow hood that is required by USP 797 for the actual mixing area. Mixing IVs in a hood is nothing new.
ISO Class 8 (formerly Class 100,000) allows a maximum of 100,000 particles per cubic foot. This level is required for an IV preparation area/IV room.
There are a couple of other issues, such as an ante room for dressing, etc. but the Class 100,000 area is the primary requirement. In my experience, implementing the most basic steps of straightening up an IV room, coupled with a positive pressure air system, will result in a room with less than 10,000 particles per cubic foot. Getting an IV room to less than 100,000 particles per cubic foot is quite easy if you follow the simple USP 797 physical facility suggestions.
The net result of the USP 797 guidelines is to require mixing in a properly maintained laminar airflow hood (ISO Class 5) situated in a relatively clean room (ISO Class 8). For most pharmacies, this is neither difficult or unreasonable. In some cases, individual interpretations of this requirement have made them seem more onerous.
2. USP 797 is NOT a radical departure from what reasonable admixture programs should already be doing. There are many basic steps in quality sterile compounding that inpatient pharmacies have unfortunately not had the time, or interest, to implement. Regulatory agencies such as the FDA and State Boards of Pharmacy have long recognized this need. USP 797 simply puts the answers in a standard format for inspectors to check against.
3. USP 797 cannot be fully met by outsourcing. Any pharmacy will still have to make first doses, doses that are subject to change and many short expiration doses. Antineoplastic doses are an example of expensive doses, subject to change, that are difficult to outsource. Compounding can be minimized but not eliminated. A pharmacy will still have to comply with USP 797, even if they outsource most of their admixtures.
4. Isolators alone will not assure compliance with USP 797. Isolators are far too "clunky" and physically hard to work in to be productively used for medium-to-large institution workloads. Using an isolator only fulfills the physical structure requirements but none of the other personnel, training, expiration setting, and other process controls required by USP 797.