



USP <797> <800> STERILE COMPOUNDING

Overview & Trends Prior to Revision Implementation

WHY USP<797>?

- Earlier efforts were unsuccessful since USP 1206 was voluntary and initial USP<797> was confusing and not comprehensive
- Reduce or prevent harm to patients resulting from bioburden, endotoxins and other contamination of compounded sterile products
- The guidance represents a process to gain a documented state of control over pharmacy operation and performance
- Final revision in November of 2023 is now the standard of practice

WHY USP<800>?

- Implement a Quality System that creates a documented state of control over the pharmacy
- Outline containment strategies for Hazardous Drugs HDs
 - Facility and Engineering Controls
 - Protective Equipment
 - Work Practices
- Promote worker and patient safety through protection from exposure to HDs
- Provide a framework to assess the risk of HDs



USP <797> <800> NOVEMBER 2023

- Continued emphasis on Pharmacy Management Responsibility for Quality System with defined components
- Addresses deficiencies, contradictions and ambiguities
- Invest in a Quality Assurance System now or pay the “penalty” later approach
- Microbial and Chemo Wipe Testing/Trending to demonstrate control over the pharmacy cleaning, material and personnel work flow
- State Boards, JCAHO and others have adopted as the standard of practice and are inspecting to the standard



MANAGEMENT STRATEGIES

- Document your plan
- Define the resources needed to implement your plan
- Develop a process to investigate excursions and maintain the pharmacy in a documented state of control
- Focus on changing staff compounding culture
- Full Commitment from Management and Personnel
- Utilize specialized providers that can manage and report testing data as a tool to implement Quality System requirements



QUALITY ASSURANCE PROGRAM



HOW QUALITY SOLUTIONS CAN HELP



**Certification &
Environmental
Testing**



**Environmental
Monitoring (EM)
Kits**



**Facility Design
and Assessment**



**Personnel
Training &
Assessment
Support**

Quality System and Compliance Consulting



EM KITS

- Provide Kits and Reports to self perform routine environmental sampling
- Support your in-house testing with incubation and enumeration of test samples





ENSURING A RETURN ON THE COST OF QUALITY

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