

Medication Safety and Management USP 797 Compliance Services



Challenge: Meeting USP 797 Regulatory Guidelines

Regulatory standards and guidelines consistently challenge pharmacy owners and managers. New regulations can sometimes demand that operations and processes are modified to achieve and successfully maintain regulatory compliance with industry standards to ensure the safety of patients and staff.

A more recent requirement from the United States Pharmacopeia, USP 797, governs any pharmacy that prepares compounded sterile preparations. The regulation is designed to decrease the number of infections transmitted through pharmaceutical products, protecting both patients and staff from harm. Pharmacists must be prepared as they begin to be surveyed for compliance.

With limited time, resources and budgets, how can you effectively and efficiently prepare your pharmacy to best comply with USP 797 while continuing to safely maintain day-to-day pharmacy operations?

Medication Safety and Management USP 797 Compliance Solution

At AmerisourceBergen®, we understand the critical importance of maintaining the integrity and safety of medications that flow through your pharmacy, and the budget and resource constraints that challenge you each day.

We've leveraged our pharmaceutical distribution and services expertise to provide a comprehensive pharmacy consulting offering dedicated to helping you achieve all your patient safety, regulatory, and operational goals.

You can rely on AmerisourceBergen to deliver the pharmacy resources, expertise, and experience to help you successfully achieve compliance to the USP 797 guidelines and any of the regulatory requirements and standards to which you must adhere.



Here's how:

Through our three-step process including an assessment, design, and implementation phase, AmerisourceBergen can partner with you to identify what's necessary to comply with USP 797.

Step 1: Assess

Pharmacy consultants review your operations, processes and procedures, equipment monitoring, and clean room practices to determine your current compliance with the USP 797 regulations.

The assessment is scalable to include a combination of the following services:

- Determine risk level of products that are prepared and stored
- Evaluate current preparation areas, processes and written policies
- Evaluate space configuration, equipment, environmental monitoring procedures and workflow
- Review all documentation procedures and document examples
- Assess effectiveness of the IV Sterile Compounding portion of pharmacy's Quality Assurance program
- Assess pharmacist verification procedures
- Observe equipment accuracy monitoring, disinfecting, and clean up processes

The final deliverable includes a summary of findings and a recommended action plan to bring your pharmacy's compounded sterile products practices into compliance with the USP 797 standard.

Steps 2: Design

- Develop an action plan with responsibility assignments for complying with USP 797
- Evaluate equipment procurement options
- Review and update existing policies and procedures

Step 3: Implementation

- Outline a proposed training program and implementation plan to meet USP 797 standards
- Outline a Quality Assurance Plan for maintaining the Clean Room area that complies with regulatory standards

Should new construction be a necessary step toward compliance, AmerisourceBergen can work with you to design and build a clean room, including assistance with space configuration, equipment placement and storage area design.

As you begin to work toward compliance, we recommend that you review the criteria below to see if your compounding staff are in compliance.

Responsibilities of Compounding Personnel*

- Personnel are adequately educated, instructed, and skilled to perform their functions
- Ingredients have correct identity, quality, amount
- Open/partial containers are properly stored
- Minimize bacterial endotoxins
- Proper and adequate sterilization is used
- Equipment is clean, accurate, appropriate
- Potential harm from added substances considered
- Packaging is appropriate for sterility, stability
- Compounding environment maintains the sterility of pre-sterilized items
- Labels are appropriate and complete
- Beyond-use dates are appropriate and based on valid scientific criteria
- Correct compounding procedures are used
- Deficiencies in compounding can be rapidly identified and corrected
- Separate compounding from quality evaluation

* Taken from "An Update on USP Chapter <797> The New National Standard for Sterile Preparation," by Lawrence A. Trissel, B.S., FASHP, Director, Clinical Pharmaceutics Research, M.D. Anderson Cancer Center, Houston, Texas

AmerisourceBergen. The best medicine for healthcare.

At AmerisourceBergen, optimizing every process that contributes to the successful delivery of medications to the patient's bedside is our business and our passion. AmerisourceBergen combines the infrastructure and procurement expertise of a global leader in pharmaceutical distribution with the consultative savvy and best practices that have helped thousands of healthcare providers reduce errors, increase efficiency and save millions of dollars each year.

For more information on this and other AmerisourceBergen consulting solutions, contact us at 877-892-1254 or email at solutions@amerisourcebergen.com.