USP compounding compliance consulting

USP <795>, <797> and <800> compounding standards and regulatory requirements assessment and training

Gap analysis and compliance assessment services

Our experts will evaluate and provide a customized assessment of your United States Pharmacopeia (USP) <795>, <797> and <800> compounding services. We will provide a gap analysis of your current nonsterile, sterile, and hazardous medication compounding environments, safeguards, documentation and practices.

Upon completion of the assessment process, we will present our findings, identifying key observations, strategies and prioritized recommendations. This will guide the development of action plans to bring you into compliance with the USP standards, state regulations and leading practices.

Custom compliance-focused compounding training

Revisions to USP <795> and <797> significantly expand training, knowledge requirements and related documentation for all compounding pharmacy staff.

We have partnered with PCCA who can guide evaluation of your pharmacy's specific needs for sterile and nonsterile compounding training and collaborate to develop an agenda tailored to your facility's compounding SOPs and formulations. Didactic training is held virtually or in-person, and hands-on training is held onsite at your facility while accommodating shift scheduling.

The inherent risks of compounding

Compounded medications play a crucial role in healthcare, and medication compounding is often perceived as a simple, uneventful task, even by healthcare professionals. However, it's a risk-filled process that requires detailed procedures and highly trained staff.

Patients may be exposed to different levels of risk depending on whether the compounded medications are nonsterile, sterile or hazardous. Contaminants such as bacteria, fungi, or other microorganisms can potentially be introduced into these medications, leading to infections or other adverse effects in patients. Healthcare providers must exercise caution, adhere to best practices, and maintain a robust quality assurance program to ensure patient safety when using compounded medications.

Recent revisions to USP guidelines

As of Nov. 1, 2023, several updates to the USP <795> and USP <797> guidelines went into effect. These changes bring significant changes to the practice as well as compounding facilities.

Key changes to USP <795> guidelines

- Training and competencies
- Glove and garb requirements
- Master formulation record and compounding record

Key changes to USP <797> guidelines

- Personnel and settings affected
- The designated person(s)
- Immediate-use CSPs
- Preparation per approved labeling
- Who needs to be trained and how often
- Initial garbing competency evaluations
- Environmental monitoring requirements

To learn more, contact
PharmacyQuestions@vizientinc.com

As the nation's largest member-driven healthcare performance improvement company, Vizient provides solutions and services that empower healthcare providers to deliver high-value care by aligning cost, quality and market performance. With analytics, consulting and a robust sourcing portfolio, we help healthcare organizations improve patient outcomes and lower costs.