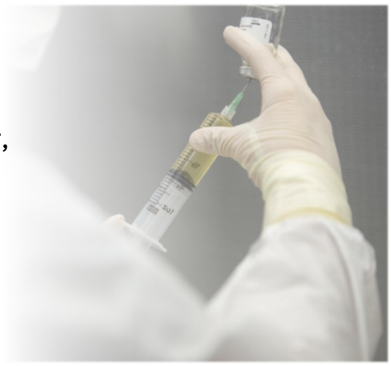
CriticalPoint
a trchealthcare brand

CriticalPoint Pearls of Knowledge — December 2024

Compounding and Compliance: Where are we one year later?

Introduction



Sterile compounding facilities and pharmacy compliance have evolved significantly in the nearly 35 years since the ASHP National Survey conducted in 1991.[1] Compounding quality assurance activities and patient safety are the cornerstone of the pharmacy profession. However, unfortunate incidents of the past have shaped the future of pharmacy. This has caused multiple organizations, from private to regulatory, to govern and harmonize standards in pharmacy practice. In this month's Pearl, we discuss what the official implementation of USP <797> looks like in pharmacies one year later.

CriticalPoint asks class alumni how their first year went

We followed up, via survey, with former attendees of our 2022 and 2023 training classes. A kind thank you to all who participated and were willing to share their thoughts and developments in preparing for the official chapters. A clear picture emerged of common challenges, successes, and experiences. CriticalPoint has identified the top three challenges in pharmacy compliance as personnel competencies (and all that goes with it), documentation practices, and environmental monitoring.

Anticipating the new standards pays off by preparing early through training and education

Our respondents prepared their pharmacies and teams during the era of the revised 2019 version and then the proposed 2021 version. Because this latter version included many of the new requirements now part of the official chapter, there were fewer surprises when implementing organizational policies and procedures. As a result, the prepared and informed pharmacies generally received no findings during state board of pharmacy (SBOP) inspections during 2023. Hospitals seeking continued accreditation through The Joint Commission (TJC) also performed well during inspection.

Respondents also implemented operational and design best practices that had been recommended by industry experts—actions that paid off, as many of these best practices have since become a standard "must" in the official <797> . One respondent noted, "I realized we've implemented more of these recommendations than I initially thought. Our leadership was very supportive of implementing all the changes, especially since our regulatory body endorsed them."

Developing relationships between pharmacies and boards of pharmacy makes all the difference

In conversations with regulators and inspectors, CriticalPoint does not sense that regulators have a punitive mindset when it comes to inspections. This view was confirmed in the survey feedback: "SBOPs and accrediting bodies realize there is still a learning curve but recognize the efforts and improvements made in individual pharmacy practices." Respondents felt that inspectors were not trying to "catch" them, which made them more comfortable sharing their practices and challenges. As a result,

inspections were perceived as more collaborative, leading to any findings being akin to action plans for continual improvement in safety and compounding practices.

Pharmacy compliance and challenges reveal a (mostly) prepared compounding facility

The surveyed CriticalPoint alumni noted that inspections uncovered very few major findings. Typical findings included facilities that were in the middle of a remodel, inappropriate hardware or items within compounding spaces, and competency-frequency issues. Many pharmacies mentioned that the most scrutiny involved staff competency. Addressing the connections between standard operation procedures (SOPs), training, and competencies was described as the most significant undertaking. However, when executed properly, it substantially eased inspectors' concerns.

Documentation across all disciplines seemed to be a persistent theme. In the area of facility design, the emphasis was largely on certification reports and ensuring that all the necessary documentation was in place. A few respondents shared that a number of their rural pharmacies lack the resources to implement IV workflow management software (IVWMS) and still document operations, training, and competencies manually though paper form or basic spreadsheet programs. Although tracking competencies and other operational matrices can be performed manually, most found this method cumbersome and a burden on administrative labor.

Preparing and administering competency is harder than preparing and administering medication

Despite feeling comfortable with understanding the new competency framework, respondents expressed that executing these requirements proved more strenuous than expected. They found that developing an evaluation cadence for large health networks demands planning and an unexpected amount of program management. From both the evaluator's perspective and from the performer's, the actions necessary are technically involved and hard to train with any staff census.

Because program management is so involved, respondents have come up with a solution by creating teams to take specific steps within competency programs. This has lightened the burden that may have once fallen on one or even a few leadership members. Designated persons and other similar roles delegated from leadership have identified tasks and are responsible for review of failures and successes, incubation and analysis, training and documentation, and the performance evaluation and collection of viable sampling. The outstanding challenge is having all of these moving parts work harmoniously, seem sensible as a program, and comply with the chapter's prescribed frequency and details.

Summary

Pharmacies must remain constant in preparing for and implementing the significant changes needed to meet USP compliance. As inspections continue in the coming months, it's clear that competency evaluations and documentation will be a challenge to implement effectively.

A key focus is ensuring personnel competency and training protocols satisfy the chapter and meet regulatory expectations. CriticalPoint recommends pharmacies develop leadership teams and key staff members who work together to implement changes with the goal of continuous improvement in operational standards and documentation within their organization. USP standards are minimum standards and are too broad to address the needs of an individual facility. Implement best practices and adopt more "shoulds" where it makes sense for your organization. Drive drug quality and patient safety by aiming for operational compliance rather than compendial compliance.

References

[1] ASHP National Survey of Hospital-based Pharmaceutical Services 1991-1992 https://academic.oup.com/ajhp/article-abstract/50/7/1371/5180837

The United States Pharmacopeial Convention, Inc. – Revision Bulletin. November 2019

The United States Pharmacopeial Convention, Inc. USP <797> Pharmaceutical Compounding—Sterile Preparations. 2024.

The United States Pharmacopeial Convention, Inc. <800> Hazardous Drugs-Handling in Healthcare Settings. United States Pharmacopeia Originally published in 2020.