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A compounding compliance team at an academic medical center

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Abstract

Purpose: Highly publicized safety issues arising from poor sterile compounding practices in facilities around the United States have garnered substantial attention in recent years. This attention has led to increased scrutiny of health systems by regulatory bodies, new regulatory requirements, and changes to existing regulations or their interpretation. Health systems are often resource constrained, and the added work resulting from this scrutiny challenges pharmacy departments in meeting regulatory requirements and United States Pharmacopeia chapter 797 standards for sterile compounding. This article describes the creation of a dedicated compounding compliance team (CCT) and the team's responsibilities in support of pharmacy operations in achieving compliance with those standards.

Summary: Visits to our organization by several regulatory bodies resulted in findings that required substantial work in order to achieve compliance with sterile compounding standards. Given the number and complexity of findings and the need for timely resolution, it was felt that specialized staff were needed to understand, evaluate, and correct identified deficiencies and help the already overburdened staff and leadership comply with existing standards. A CCT was formed, and work was simultaneously initiated on ensuring proper credentialing and training of all compounding staff, development of standard operating procedures, improvements in facilities, environmental monitoring, equipment certifications, practice auditing, and documentation. Key activities of the team included strategic planning, building relationships, communicating with stakeholders, self-education, and record keeping. Key partners included environmental services, facilities, and infection prevention and control personnel and departmental staff and leaders.

Conclusion: The formation and collaborative work of a CCT at an academic medical center was successful in changing the culture of the organization and achieving compliance during visits from several regulatory agencies.

Keywords: collaboration; compliance; planning; regulatory; sterile compounding; training.

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