WorkingBuildings Case Study

Compounding Pharmacies Ensure Cleanroom Compliance

Challenge

A large, multi-site U.S.-based healthcare system needed to ensure compliance with USP compounding standards in dozens of new and existing compounding pharmacies and infusion centers.

Solution

WorkingBuildings provided regulatory compliance, commissioning services, design reviews, gap analysis, and remedial design solutions across a wide range of projects. WorkingBuildings also provided off-site monitoring and assisted with maintenance planning and emergency response planning.

Result

Working as an extension of the healthcare system's design and construction team, WorkingBuildings streamlined compliance as well as construction, improving the experience for end users and ensuring that the pharmacy team can focus on what's most important—the patients they service.

A U.S.-based network of hospitals and medical facilities has demonstrated commitment to ensuring sterile compounding safety, regulatory compliance, and patient and staff safety. This healthcare system has engaged WorkingBuildings since 2014 to provide cleanroom consulting services, commissioning services, design reviews, gap analysis, and remedial design solutions for USP <797>, <795>, and <800> compliant compounding pharmacies across its network.

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Challenge

Compounding pharmacies must adhere to the United States Pharmacopeia (USP) compounding standards, which in November 2022 published revised versions of chapters <797> (sterile preparations) and <795> (nonsterile preparations). The revisions, which expand quality and safety measures to minimize risk for patients and pharmacy personnel, also address enforcement of USP <800>, which focuses on the safe handling of hazardous drugs.

While some of the requirements in the revised chapters are new, the healthcare system's focus on compliance is not. The system first partnered with WorkingBuildings to ensure the safety and efficiency of its facilities in 2014, when it acquired multiple compounding sites and infusion centers amid increasing decentralization of healthcare delivery. Spanning the more than three dozen projects, WorkingBuildings has helped this healthcare system bring new and existing sites into compliance regarding the required engineering controls in the USP standards.

Solution

The WorkingBuildings team kicked off the partnership with this client by visiting each compounding and infusion location and conducting a gap analysis to identify the current state and the steps needed to meet USP standards. Each cleanroom is subject to specific temperature, humidity, and HVAC standards as well as requirements for architectural details and finishes able to withstand frequent cleaning as outlined in the USP compounding standards. The team held weekly calls to evaluate the progress at each site.

Throughout the initial engagement covering more than a dozen clinical sites—and in dozens of projects since—members of the WorkingBuildings team leveraged their extensive clinical and regulatory experience and expertise in mechanical systems, architecture, and engineering controls to help the facilities identify and close gaps necessary for compliance with the USP standards. The WorkingBuildings teams work alongside the architects and general contractors, supporting regulatory requirements in the design phase and ensuring that components have been installed correctly and function as intended as part of construction quality control during the construction phase.

Along the way, WorkingBuildings not only identified potential issues but also recommended corrective actions. In some cases, for example with HVAC systems in existing facilities, the team identified when existing systems could be reused with minor upgrades, when systems needed to be enhanced, and when they needed to be replaced entirely. In other instances, the team leveraged its deep understanding of day-to-day cleanroom operations to improve the end user experience—including laying out process flow diagrams and reviewing drawings to weigh in on the location of work tables, sinks, pass-through windows, and primary engineering controls—at the beginning of the project, before construction began. Once a site was operational, WorkingBuildings supported the pharmacy team and other team members to maintain the space and ensure continued compliance with support in the required ongoing facility maintenance and environmental monitoring (EM) analysis.

As part of the ongoing partnership, WorkingBuildings continues to provide all the cleanroom locations with off-site monitoring; maintenance and emergency response planning; coordination of certification efforts; and addressing compliance issues if they arise.

Result

Leveraging WorkingBuildings' experience in USP <797>, <795>, and <800>, compliance activities, and expertise in mechanical and engineering systems, the team has helped the healthcare system design cleanroom spaces more efficiently. The team created a 60-item checklist for success and identified multiple configurations for various cleanroom suites across the network—everything from low-volume infusion centers in rural settings all the way up to high-volume cleanrooms within a large health system. WorkingBuildings published design guides outlining room-specific engineering control requirements, architectural and mechanical details all the way down to the type of silicone sealant, epoxy paint type, and flooring required for the cleanroom spaces.

By defining these configurations and providing a framework for the future, the team has been able to not only streamline design and construction but also leverage lessons learned from other projects to reduce risk for this healthcare system. For example, while the USP chapters include several example layouts, the team identified some flaws in these proposed configurations that could lead to environmental monitoring failures. WorkingBuildings was able to avoid these issues by adding an extra dry anteroom separating the particle-generating activities of handwashing and gowning from the ISO7 compounding room. Preventing these types of failures means avoiding the associated costs, which can include fees for additional terminal cleaning due to EM failures or lost revenue due to HVAC system downtime. Most importantly, preventing these failures allows the healthcare team to provide uninterrupted, valuable patient care to a critical population.