LIFE SCIENCES CASE STUDY

Compounding Pharmacy Secures FDA Registration

CHALLENGE

A health system planned to design and build a centralized 503B manufacturing facility that met all relevant FDA and USP regulations.

SOLUTION

WorkingBuildings reviewed design and engineering plans, defined SOPs for the facility, facilitated communications with FDA, and oversaw construction, commissioning, and qualification.

RESULT

WorkingBuildings helped the client design and build a 503B compounding facility registered with the FDA and fully compliant with cGMP, USP <797> and <800>.

A large, not-for-profit health system in the southeast U.S. planned to centralize select compounding operations for over a dozen hospitals into a single facility for a greater level of control and quality services. The design of the facility would provide a highly controlled environment for the preparation of sterile dose units of both hazardous drugs and non-hazardous drugs, with engineering controls that aligned with the requirements of FDA 503B and United States Pharmacopeia (USP) <797> and <800>. The health system leaders engaged WorkingBuildings for help registering the facility with the U.S. Food and Drug Administration (FDA).

WorkingBuildings, a Trinity Consultants team, is a total solutions provider for complex facility projects and programs, helping clients avoid or resolve performance and regulatory compliance issues.

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CHALLENGE

The health system planned to open a centralized pharmacy service to compound and distribute sterile products that would otherwise be purchased commercially or compounded at its hospitals. After researching options and requirements for compliance, leaders decided to register the facility with the FDA as a 503-B. While its teams had significant experience in sterile compounding for hospitals, the client lacked expertise in the FDA registration process and Current Good Manufacturing Practice (cGMP) requirements.

The health system had already engaged an architect and an engineering firm, but it wasn't sure that it was moving in a direction that was consistent with FDA registration. In addition, cGMP guidance focuses on the end result, rather than prescribing how a compounding site should achieve that result, so the client turned to WorkingBuildings for help.

SOLUTION

The WorkingBuildings team began by evaluating the designs, the proposed processes, and engineering controls for the facility. WorkingBuildings also advised the client to schedule a Preoperational (Type C) meeting with the FDA—a step the client hadn't uncovered in its research into the FDA registration process. The meeting serves as preauthorization for how a 503B manufacturing facility will be built and provides assurance that the planned design and construction will result in a compliant facility.

To prepare for the meeting, WorkingBuildings partnered with the client to define a list of about 80 standard operating procedures that would help it meet cGMP requirements. Working hand in hand with the client's engineering team, WorkingBuildings leveraged its extensive experience in compounding pharmacies and regulatory compliance to identify potential issues and recommend corrections. WorkingBuildings also developed a Type C Briefing Book covering everything from individual room requirements to details of the proposed HVAC system.

RESULT

The partnership with WorkingBuildings allowed the client to catch errors in the design and engineering process, such as incorrect specifications for the chiller system and air handlers, and correct them before work on the facility began. By ensuring that materials, finishes, and systems, and the testing, cleaning, and certification processes were compliant—and verifying that with the FDA before construction kicked off—the client avoided building something that would have to be deconstructed should the FDA determine the facility was not in compliance. In addition, the clean construction protocols developed by WorkingBuildings ensured that construction teams built the facility in a way that reduced the risk of contamination after manufacturing began.

Together, these steps helped save significant time and money for the client. The end result was a fully compliant sterile drug compounding facility that not only could be registered as a 503B site but would also meet state board of pharmacy and USP <797> and <800> requirements.

> *Without WorkingBuildings, we most likely would have built something incorrectly and would have had to find the money to correct it and extend the process.*
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> **-Director of Pharmacy Services**

ABOUT TRINITY CONSULTANTS

Trinity Consultants, a leading global environmental consulting firm, provides services and solutions in the EHS Regulatory Compliance, Built Environment, Life Sciences, and Water & Ecology markets. Founded in 1974, Trinity has the technical expertise, industry depth, and capabilities to help clients achieve their goals across the natural and built environments.

HEADQUARTERS 12700 Park Central Dr, Ste 600, Dallas, TX 75251
P +1 800.229.6655 / P +1 972.661.8100

trinityconsultants.com