

Saint Francis Hospital and Medical Center

Cleanroom Renovation for USP <797> and USP <800> Compliance A CASE STUDY

In the summer of 2014, Saint Francis Hospital and Medical Center in Hartford, CT, was facing new State of Connecticut, Department of Consumer Protection Sterile Compounding inspection process requirements, as USP <797> standards related to pharmacies preparing compounded sterile preparations (CSPs) became state law.



**SMILOW CANCER HOSPITAL
YALE-NEW HAVEN**
AT SAINT FRANCIS

114 Woodland St • Hartford, CT 06105

- Licensed for 617 beds and 65 bassinets • Major teaching hospital
- Largest Catholic hospital in New England • Member of Trinity Health - New England, an integrated health care delivery system that is a member of Trinity Health, Livonia, MI

With USP <797> standards becoming state law and USP <800> requirements on the horizon, the hospital undertook compliance as a key initiative.

Patient safety was the primary concern, but personnel protection during sterile compounding of hazardous drugs (HDs), a large portion of the Outpatient Cancer Center Pharmacy CSP production, was also top of mind.

Historical Overview

Saint Francis Hospital and Medical Center was founded in 1897. From the beginning, stakeholders recognized that improving health required innovation, affiliation, and strategic partnerships.

A corporate merger between Saint Francis and Mount Sinai Hospital was formalized in 1995. Today, groundbreaking technology helps Smilow Cancer Hospital Yale-New Haven at Saint Francis treat a wide variety of cancers.

A 2015 partnership between Saint Francis and Yale-New Haven Hospital greatly expanded access to outpatient medical oncology services and hematology at state, regional, and national levels.

It is within this culture of innovation that Saint Francis responded to the challenges presented by regulatory demands and strategic growth to transform its Outpatient Cancer Center Pharmacy into a state-of-the-art facility.

Challenges

Growth in the organization's oncology services, as well as more **rigorous compliance demands** at both national and state levels, made it challenging to maintain a consistently high quality of CSPs in the existing cancer center pharmacy.

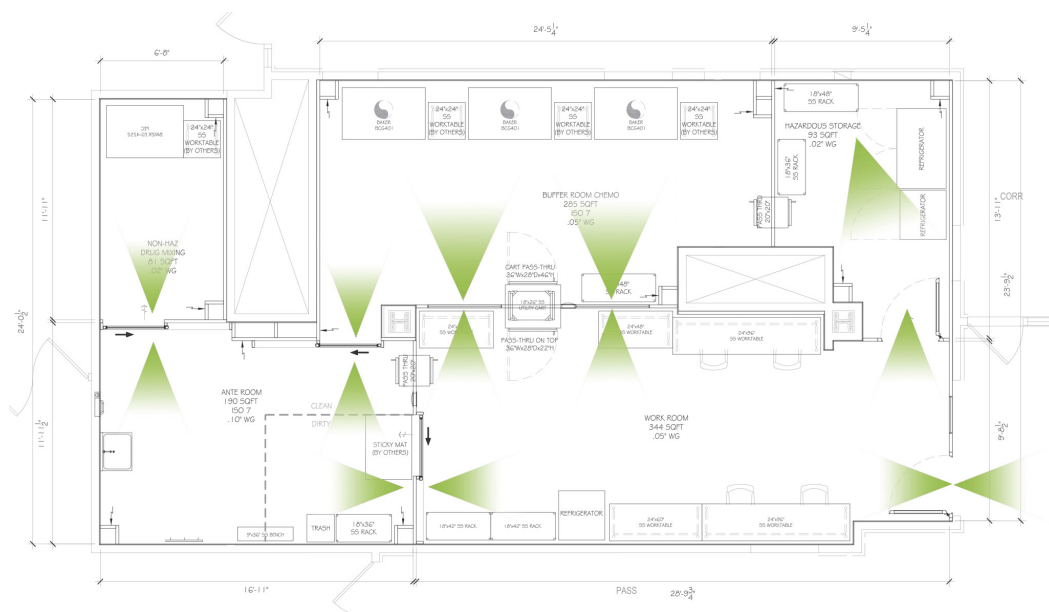
"The regulatory climate was the catalyst behind our decision to act," said Mike Culligan, RPh, Director of Pharmacy "but we were also very space constrained. This was our opportunity to improve product and personnel workflow, prepare for anticipated growth, and plan for future regulatory requirements."



Finding contiguous space large enough to house the pharmacy in close proximity to patients and clinicians, as well as optimizing the flow of products and people, was an early challenge. Exploration of where that space would be found involved additions to the team.

Gregory Katz, Pharm. D., Team Leader for Sterile Products, immersed himself in understanding the complex requirements of USP <797> and <800>, as well as new State of Connecticut, Department of Consumer Protection Sterile Compounding Inspection process demands.

“USP <800> standards describe practice and quality related to hazardous medications and are designed to protect healthcare personnel and the environment via defined processes that minimize exposure,” said Dr. Katz. *“We knew we needed to get ahead of the curve for the sake of our staff, our patients, and our organization.”*



An additional challenge was **finding a cleanroom supplier** to help the team meet regulatory requirements with **expertise and products** that they were confident would deliver a return on the hospital's financial investment and minimize disruption during installation.

“Cleanroom design and construction present challenges that require specific knowledge and experience outside the scope of most vendors,” said

Ronald Gorham, Associate Principal, Architecture, TRO, Boston, Massachusetts, the architect of record for Saint Francis since 1990. *“Our firm has worked alongside various clinical, operational, and financial stakeholders within Saint Francis to complete a number of projects. In this case, we knew we needed a vendor with not only products, but experience that is hard to find.”*

Solution

A Saint Francis team that included pharmacy **leadership and staff** began by **identifying gaps, researching options** for filling them, and **planning a new cleanroom design**.

Mr. Culligan and Dr. Katz worked closely with Kathleen Noone, Executive Director Oncology Service Line, and Bob Falaguerra, FASHE, CHFM, System Vice President Facilities, to **analyze space and workflow**. Patient care, staff efficiencies, and state and federal regulatory demands were top priorities.

Staff pharmacists and technicians from the compounding area of the pharmacy, as well as Infection Control and Oncology clinicians, also played essential roles throughout the project's planning and development processes.

Once the project gained momentum as a priority for the organization, Mr. Falaguerra enlisted TRO Design. TRO, an **architectural and engineering design firm with a focus on healthcare facility** planning, design, and operations, applied extensive experience in cleanroom design to the development of plans that met USP <797> requirements and forthcoming USP <800> requirements.



Because of the company's experience in design, engineering, and sterile manufacturing, Grifols was also brought into the process in its early stages.

*"Having a vendor like **Grifols** who understands industrial hygiene, aseptic processing requirements, and engineering controls was critically important to us."*—Robert Falaguerra, FASHE, CHFM.

Grifols is a global healthcare company with a more than 75-year track record of delivering solutions, services, and technical proficiencies deeply rooted in decades of engineering and the construction, operation, and monitoring of its own highly regulated manufacturing facilities.

When the team learned that Brigham and Women's Hospital in Boston was a Grifols customer and had a Misterium® cleanroom, they scheduled **a site visit** where they talked with Bill Churchill MS, R.Ph. FMSHP, Chief Pharmacy Officer, Brigham and Women's Healthcare. *"Identifying the right business partner is the single most important step for pharmacy leaders when considering the purchase of a new cleanroom,"* advised Mr. Churchill.

The Grifols Misterium **solution includes modular system components, consulting, conceptual and detailed engineering design, project management, construction, environmental monitoring, certification, and training.**

"Grifols worked collaboratively with our firm to leverage a collective familiarity with relevant regulations, workflow, and awareness of the consequences of poor planning and inferior product selections," said Mr. Gorham.

Using knowledge of what is required by USP and the state of Connecticut for compliance, the cross-functional team performed a gap analysis of existing space, compounding activities, and activities to determine changes needed to policies, space, workflow, airflow, and equipment.

Following the gap analysis, Grifols worked in concert with TRO and the internal Saint Francis team to perform a thorough evaluation of the oncology pharmacy workflow of people and product, space, and existing infrastructure. Several layouts were proposed for review and consideration by facilities and clinical decision-makers and influencers.

Once final floor plans and specifications were defined, a request for proposal (RFP) was issued in the May 2015 timeframe.

Results

"Our state Department of Consumer Protection Drug Control Sterile Compounding Inspection requirements for USP <797> are extensive. Our cleanroom meets all compliance criteria and we are confident we will continue to meet them for both <797> and <800>. Compliance is a journey and we are on the right path."—Mike Culligan, RPh, Director of Pharmacy.



The new cleanroom offers proximity to care providers and has nearly tripled the space for better workflow, greater productivity, and an environment conducive to training. The large anteroom facilitates good workflow and meets USP <797> and USP <800> requirements.

Grifols Misterium design and construction and the development process executed by the collaborative teamwork of internal stakeholders, TRO, and Grifols **minimized disruption and facilitated a streamlined installation and implementation.**

The Misterium fully flush wall and ceiling panels, heat-welded sheet vinyl flooring, and flush-fit, integrated windows and doors are able to withstand aseptic cleaning.



Coved joints prevent accumulation of dust and dirt, and specially designed light fittings are airtight and flush to the ceiling. And, the environment now includes monitoring of temperature, humidity, particles, and pressure differentials.

"Our successful outcomes are due in large part to the collaboration of our own team, Grifols, and TRO," said Mr. Culligan. "The value of a collaborative partnership when planning and executing a pharmacy and cleanroom renovation that prepares an organization for regulatory scrutiny cannot be emphasized enough."

About Grifols US Hospital Division

Grifols i.v.TOOLS® is our suite of scalable, specialized solutions for hospitals and clinics, as well as regional and national compounding centers. Our offerings include next-generation compounding robotics, cleanroom design, consulting services, IV workflow management software, high-density drug inventory carousels for cleanrooms and investigational drug service operations, and more.

Grifols' proficiencies are deeply rooted in decades of engineering and the construction, operation, and monitoring of our own highly regulated manufacturing facilities. Worldwide, Grifols serves organizations in more than 100 countries and employs more than 14,000 people.



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