

CASE STUDY

ZERO PROBLEMS; ZERO COMPLAINTS



Northwell Health Relies on Modular Devices Inc.



Alfonso Traina
Vice President of Cleanrooms
~ *Modular Devices Inc.*



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Director, Capital Projects,
Corporate Facilities Services
~ *Northwell Health*

BACKGROUND AND INTENDED OUTCOME

Northwell Health is New York state's largest healthcare provider. It comprises 23 hospitals, 74,000 employees, and more than 700 outpatient facilities. The vast integrative healthcare network continually expands and upgrades facilities to improve the health of the patients and communities it serves.

In the fall of 2019, Northwell leadership assigned specific areas for upgrading, including the compound pharmacy in their Staten Island hospital. Great care and concentration had to go into the decision because of the protections needed for the life-saving work performed in this lab.

This location serves cancer patients who need individualized chemotherapy. Disruption for these patients and the more than 1,000 daily hazardous and traditional intravenous (I.V. medications) produced in this lab was not an option during construction.

Leadership landed on bringing in a vendor with a trailer that could convert into a lab. However, this trailer-chemotherapy lab had to come with an immaculate level of cleanliness. The mobile cleanroom had to provide incontestable evidence that it would be particulate-free and sterile to compound hazardous and non-hazardous pharmaceuticals and provide ample protection for staff and patients.

Equally as necessary, the self-contained unit had to ensure continuity of care. Tight timelines and stringent compliance were priorities. And a vendor had to assure seamless operations among logistical, productions, and entry requirements.

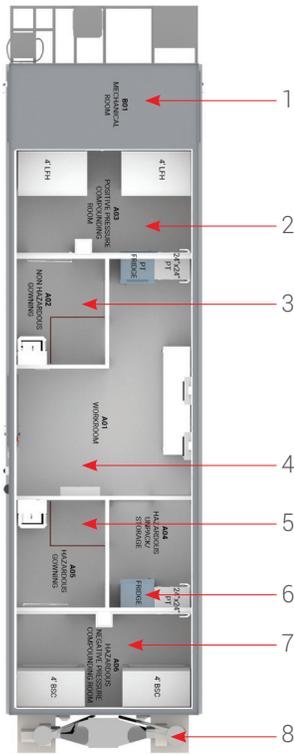
This case study analyzes the hospital leadership's decision to contract with a vendor to lease a cleanroom. It examines the criteria applied to choose a vendor and how the vendor addressed the challenges, complexity, and requirements of installing and servicing a modular relocatable compound pharmacy.

THE CHALLENGE

Construction is disruption, which is an anathema for a hospital. Leadership at Northwell Health wanted a short lead time to open a modular lab, while upgrading facilities. Beyond all the regulatory requirements that they must meet, the facilities staff wanted an environmentally friendly lab that minimizes a carbon footprint.

Otto VonEilbergh, director, capital projects, corporate facilities services, Northwell Health, now knows first-hand all the intricate details of moving a unit that is 14 feet wide and 60 feet long and

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1. Mechanical Room
2. Positive Pressure Sterile Non-Hazardous Compounding Room with (2) 4' Laminar Flow Hoods
3. Non-Hazardous Gowning Room with Eyewash
4. Main Workroom, Non-Classified Space, with Refrigerator and Interlocking Pass-through to Sterile Compounding Room
5. Hazardous Gowning Room with Eyewash Sink
6. Hazardous Unpack/Storage Room with Refrigerator and Pass-through to HZ Compounding Room
7. Negative Pressure Hazardous Compounding Room with (2) 4' BSC's
8. Redundant HZ exhaust

converting it into a high-tech, high-touch critical resource for a hospital. VonEilbergh managed the cleanroom installation, vendor details, and lab requirements.

"Getting a mobile unit through the streets and over the bridges in New York is a monumental undertaking. Various government entities require numerous permits and transport licensing," said VonEilbergh.

The facilities team required a leveled foundation that would hold more than a 60 thousand pound trailer. It needed sterile materials and an uninterrupted power and water supply. They also had a lengthy list of to-dos to prepare for the State Board of Pharmacy to commission the mobile lab for compounding pharmaceuticals. The team continually balanced the need for speed with a systematic, measured approach to safeguards.

Northwell could not perform all of the requirements mentioned above without a vendor. Moreover, they were installing the lab in the middle of an unprecedented pandemic.

"For much of 2020, New York was at the epicenter of COVID-19. Everything went toward increasing patient capacity and acquiring equipment while still installing a lab," said VonEilbergh. "To say we had challenges would be an understatement."

THE DECISION TO CONTRACT WITH MODULAR DEVICES INC.

The vendor requirements were numerous, which shortlisted the manufacturers. Northwell searched for a proven record in design, build, and certification of turnkey cleanroom installations. Vendors had to demonstrate how they could deliver a secure environment, uphold USP regulations, and maintain the production of compound pharmaceuticals with a written guarantee.

The clear choice became Modular Devices Inc. because of their vast experience in mobile labs, their array of services, and a complete understanding of the constraints and their plan on addressing them.

"The rental fees were reasonable for our marketplace," said VonEilbergh. "Their statement of work met our requirements for this high-revenue department."

Specifically, the chief pharmacy officer at Northwell Health applied the following criteria that solidified the contract with Modular Devices Inc.

PROVIDE A SUPERIOR PRODUCT

Northwell Health's mobile pharmacy was highly engineered and met all codes. It provided real-time data logging and an alarm for out-of-range temperatures, humidity, and pressures. Pollutants such as dust, airborne microbes, aerosol particles, and chemical vapors could not survive in this environment.

"Our modular units are pre-built at our factory and delivered as ready-to-use, negative pressure containment, and isolation rooms," said Alfonso Traina, vice president of cleanrooms, Modular Devices Inc. "The materials stand up to anything – marine-grade components, fiberglass, stainless steel. All the components can be boiled but not melted."

"This cleanroom worked for us in every way. Modular Devices Inc. exceeded our expectations – from the interlocking system that provided additional safety measures to providing the latest digital equipment," said VonEilbergh. "They seamlessly installed a sterile compounding pharmaceutical lab tailored to our unique needs. They met all the numerous New York regulations, including maneuvering a 60-foot trailer over the Verrazzano-Narrows Bridge."

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~ Northwell Health

DESIGN WITH THE CUSTOMER IN MIND

The pharmacy and facilities staff at Northwell Health noticed how the mobile unit on the concrete slab appeared nondescript. Upon initial inspection, they expected a 1980s infrastructure, but ended up walking through a sophisticated lab that looked like mission control at NASA. The well-laid-out design offered ergonomic functionality that delighted the pharmacy technicians.

“The bright white stainless covered every corner, exuding security and spotlessness,” said VonEilbergh. “The engineering team at Modular Devices Inc. also included smaller details that made big differences, such as the perfect placement for storage racks and digital displays.”

The engineers at Modular Devices Inc. applied its design-build method, which minimizes risk and expedites the project timeline by overlapping the design and construction phases.

DELIVER A FULL-SERVICE COMPOUND PHARMACY

“Modular Devices Inc. delivered on day one with turnkey capabilities. The only thing we had to do was turn on the water and connect the network and phones,” said VonEilbergh. “They provided an engineering timeline and coordinated with us four months ahead. Then, they delivered as promised.”

Modular Devices Inc. offerings didn't stop with the fully functioning lab. They also oversaw all maintenance and certification programs. With their partner firms, pharmacy staff has access to ongoing training and emergency service.

“With over 1,000 designs in our portfolio, our team at Modular Devices Inc. understood the production needs of compounding hazardous chemotherapy as well as the non-hazardous vitamin therapies,” said Traina. “We were committed to alleviating any burden for the patient and staff.”

ENSURE COMPLIANCE AND SAFETY

One of the most highly regarded areas of expertise for Modular Devices Inc. is ensuring compliance and certification with USP 797, the anticipated USP 800, and cGMP.

Before departing for New York, the cleanroom underwent a thorough quality control regimen and pre-certification. And upon completion of installation, Traina and the team prepared Northwell Health for inspection.

The mobile cleanroom met all regulations and codes, and the New York State Board of Pharmacy commissioned the lab. The commitment from Modular Devices Inc. didn't stop after inspection. The team remotely monitors the lab from their headquarters in Columbus, Ohio. From downing to chemotherapy production, Modular Devices Inc. looked at all angles to ensure excellent safety protocols.

“I was impressed with the airlocks and humidity control infrastructure. And I was pleased when I received a call from Alfonso saying check your pressures. Alfonso knew before we knew to review a setting,” said VonEilbergh. “They also supplied each room with a hands-free interlocking door with red and green light indicators to ensure the integrity of differential pressures.”

MAINTAIN FLEXIBILITY AND DEADLINES

Modular Devices Inc. are the only mobile cleanroom provider that offers standard and customized mobile cleanrooms equally suited as either short or long-term rentals or a purchased unit. The Staten Island location went with a lease agreement.

“Whether there is a need for a short-term solution to bridge the gap during an equipment change-out or upgrades, we'll deliver a turnkey solution quickly,” said Traina.

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The mobile cleanrooms came with 40% more space than other cleanrooms on wheels, providing more functional flexibility for personnel and workflow. Modular Devices Inc. can build their product in a fraction of the time as they control the entire production at their facility, eliminating delays caused by local permit approvals or subcontractor scheduling.

"Modular Devices Inc. met all deadlines and sped up the timeline," stressed VonEilbergh. "And all of this was done during COVID-19. They just stepped up and worked through it, just like we did at the hospital."

THE RESULTS

The can-do team at Modular Devices Inc. provided exact specifications for the interim mobile compounding pharmacy, and then delivered on every one of them. Northwell Health even incorporated many of the design elements into their system, such as putting your hand up to the light beam to enter an area, having a highly controlled pass-through for pharmaceutical carts, and implementing motorized doors rather than a hinged door.

Upon delivery, the New York Board of Pharmacy conducted an inspection and approved the unit to compound both hazardous and traditional I.V. solutions for patients.

Northwell Health received a one-stop vendor for everything and beyond for a cleanroom.

The products, services, and maintenance for the compounding pharmacy never faltered during the most tumultuous time for the hospital.

Although the hospital's upgraded areas are complete, the mobile unit is still in use today because leadership extended the lease. Modular Devices Inc. are actively monitoring the unit and providing support to the pharmacy technicians.

CONCLUSION

In a highly regulated, highly scrutinized industry during COVID-19, Modular Devices Inc. instilled trust, complied with all regulations, and exceeded expectations.

Modular Devices Inc. invested in up-front, customer-focused initiatives, such as certification and enhanced capabilities, which serve the full-spectrum needs of compounding pharmacies today and in the future.

"This was a hospital dealing with an overwhelming crisis. Their focus had to be on the patient, so our team did everything we could to lessen any burden and make sure the pharmacy department had everything they needed," said Traina.

"Alfonso and team were the bridge that allowed us no loss of volume and productivity," said VonEilbergh. "More than anything, we maintained continuity of care."