SUFFOLK

# Making medicines: “A team sport”

How Suffolk collaborated with Vertex, subcontractors to build the company’s cGMP facility in six months

WHITEPAPER

# Challenge

Vertex Pharmaceuticals was moving its headquarters in a real estate deal that would spark a downtown transformation. The company needed a state-of-the-art advanced research and cGMP (current Good Manufacturing Practice) facility and turned to Suffolk to execute the scope.

## The Team

SUFFOLK

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# Background

In a move that signaled the rise of the city's Seaport District as an innovation and real estate hub, Vertex Pharmaceuticals announced in 2011 that the company would move its headquarters from Cambridge, Mass., to Boston's Fan Pier. Newspapers described the deal at the time as the one of the largest office deals in recent memory and a "watershed in Boston's campaign to court the biotechnology industry." Plans called for Vertex to move in to two 18-story buildings totaling 1.1 million square feet in late 2013 or early 2014, with an option to expand into a third to be built there.

As part of that project, Suffolk performed extensive renovations and upgrades to an existing 60,000 square-foot building and converted it into Vertex's advanced research and cGMP (current Good Manufacturing Practice) facility. The project took place in two phases, with the first phase taking 11 months and the second phase happening over the course of six months. Phase 1 involved substantial MEP upgrades and structural modifications to accept the installation of high-tech capital equipment, with Phase 1 focusing on the build out of laboratory and manufacturing space. The Phase 1 renovation also developed seven main areas including a kilo laboratory, drug development areas, space for a Continuous Processing Rig (CPR), laboratories, environmental rooms, a controlled warehouse space, utility areas, office and support space, and a remote warehouse located about 300 feet away from the main building. The sustainable, state-of-the-art facility also used 100 percent heat recovery from lab and process exhaust to preheat incoming outdoor air.

Meeting the standards of biotech manufacturing took diligent planning and coordination, extensive digital modeling and tracking, and overall sophistication in science and technology construction.

The finished CPR area

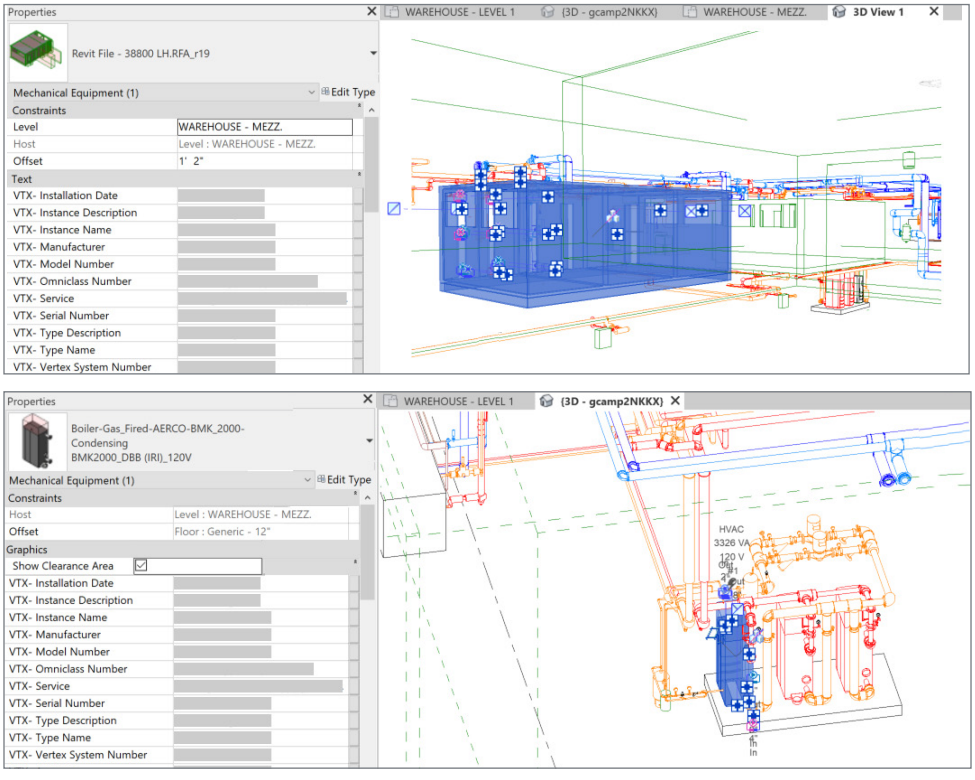
# Solution

## Plan early, plan often: P&IDs

The Suffolk team had six months to build Vertex's cGMP facility and knew there was a lengthy validation process ahead, so the team moved quickly to coordinate design elements and get all equipment on site. One of the most essential elements in design for a cGMP facility are thepiping and instrumentation diagrams, or P&IDs. These diagrams show the piping and related components of a physical process flow. Ultimately, these diagrams become a bible for proper commissioning of all systems, detail piping and equipment labeling in the field and documentation process as part of Electronic Turnover Packages (ETOPs) development and close out. That preparatory work eventually results in streamlining the validation process, facilities management and future compliance inspections. In a manufacturing plant where lifesaving drugs require production and storage, accurate P&IDs are crucial.

Suffolk's project management staff collaborated closely with Vertex, the design team, and subcontractors to ensure all P&IDs were followed during the construction process. The team established all labeling and naming conventions for every system early on, during the preconstruction and design phase, they were able to use that information to inform all phases of the building lifecycle: operations and maintenance manuals, ETOPS, piping and equipment labeling, commissioning efforts, model asset tagging efforts, and much more. If an error occurred during the labeling process, that one change would trigger major updates to the entire system and affect all these processes. Knowing that waterfall effect, the Suffolk team prioritized teamwork in the early stages and extra diligence in tracking and communicating any potential changes to all stakeholders, including subcontractors who played key roles in developing and providing all required information.

Sample BIM model assets detail product description information.



## Details, details, details—in modeling and facility management

Suffolk's digital twin of the building served many purposes before, during, and after construction. Before beginning construction, the team digitally scanned the building to get a sense of the existing conditions. Data from that scan went into Suffolk's model of the building and showed various utility and structural conflicts that weren't shown in the construction documents. For example, the team was building on a mezzanine, which extended over a corridor, and within the corridor was a floor-to-ceiling wall not shown in the documents. Thanks to the scanning and modeling exercise, the team understood what and how to demolish the wall ahead of time. The scan also uncovered massive existing drain lines and sprinkler mains, all of which was incorporated into the model and properly coordinated.

The model also became a platform that Vertex could use for facility management. When the Suffolk team and its subcontractors modeled an asset or object, such as an air handling unit, they created a clickable tag with info on each asset within the model. That level of detail isn't typical on construction projects, so Suffolk set expectations with subcontractors early on and offered trainings with the company's VDC staff. All assets were tagged, down to every pipe. Vertex staff had information on the submittal reference, the last inspection date, and any other data they needed for successful facility management in conjunction with the P&IDs and ETOPs.

## The build process

To further prepare for the sprint schedule, Suffolk procured the four massive air handling units and the modular chiller that fed the space at the outset of the project. The team also secured the racks that eventually held the manufactured pharmaceuticals, since the placement of those racks determined the location of the large ductwork and controlled many other elements of the facility's mechanical systems layout.

The building under renovation was a large warehouse space, which had bar joists running across the ceiling. Those joists were designed to handle the snow load on the building, but not much more; the engineering drawings called for hanging all the piping from the joists, which included six-inch chilled water lines. Suffolk's field staff realized the roof joists wouldn't be able to support the load, so they went back to the model and determined it was best to support the water lines from the floor. Those supports were planted from the floor like field goal posts, with vertical posts and a horizontal bar. Now, instead of hanging from the joists and risking a collapse, posts ran up from the bar, which clamped to the piping to hold it in place.

All hands were on deck to make sure the project was a success: MEP specialists to coordinate the air handling and heating and cooling systems; project management staff to manage volumes of paperwork from beginning to end; and field operations staff to track installations, labeling, inspections, and scheduling in the field.

## Validation and commissioning: A tale of teamwork

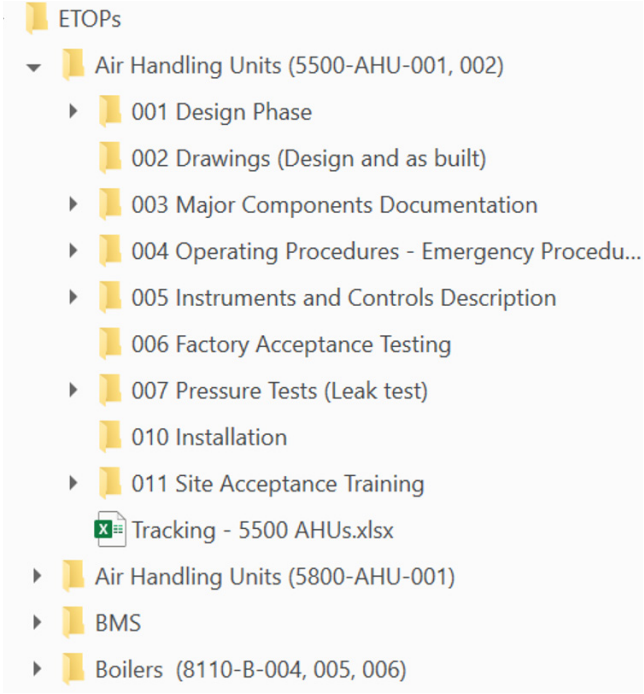
One of the largest components of a building a cGMP facility is the validation and commissioning process. As construction was underway, Suffolk's project management staff were working hand-in-hand with Vertex's commissioning and validation groups on all the paperwork to get the equipment up and running.

While construction efforts were taking place, the Suffolk and Vertex teams collaborated to create Electronic Turnover Packages (ETOPs). Suffolk's staff coordinated with Vertex's commissioning leadership to create a template and what they wanted contained in the folder system, which helped collect the right data and documents. Suffolk provided detailed operating and maintenance manuals for all equipment early on, which also included specific P&ID information. Examples of detailed documentation included lab waste piping welding certifications, a comprehensive equipment startup and verification checklist, hydro testing verification, a chilled water loop flush report, and much more.

## A sample of the ETOPs folder system

Monitoring temperature and humidity was also critical, as those measures affect both manufacturing and storage of the pharmaceuticals. The team installed sensors throughout the building for temperature tracking, humidity control, and constant monitoring, which was crucial for the validation process and turnover of the facility—part of the validation process was to maintain specific temperature limits for about one week in order to pass. Suffolk's team became an extension of the Vertex commissioning group, and the collaboration paid off: when the field staff was ready to turn over the newly renovated space, the commissioning process was nearly complete.

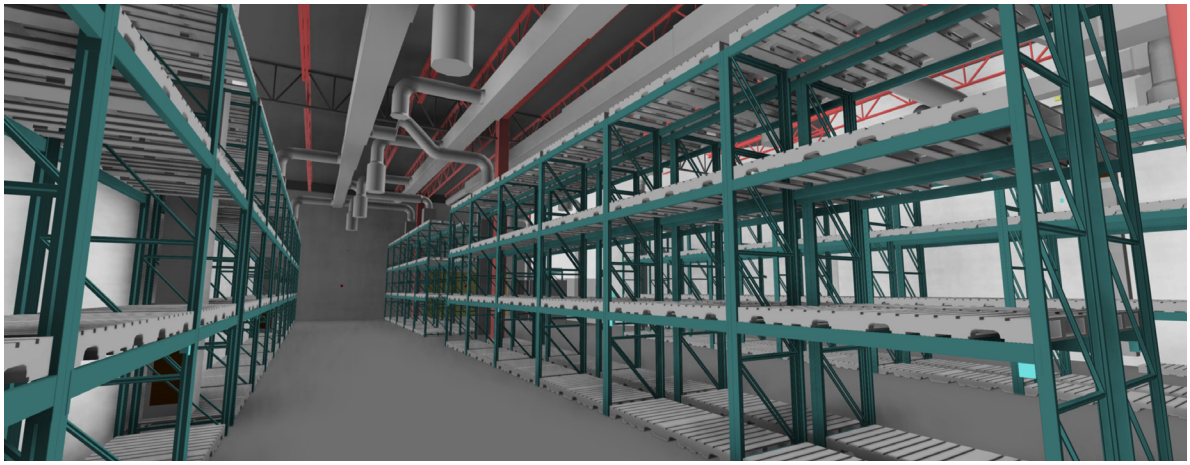
A sample of the ETOPs folder system



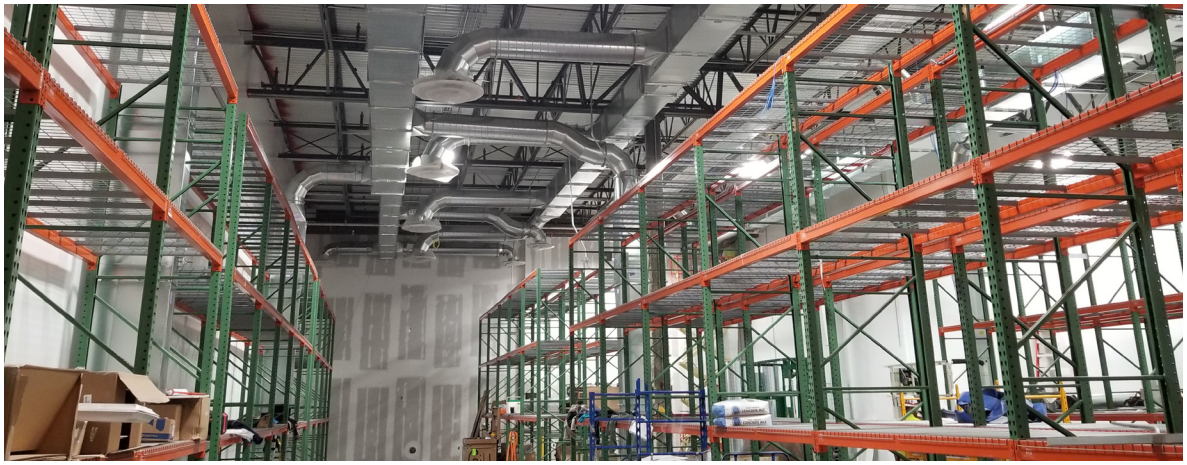

The mechanical penthouse for the cGMP facility

# Conclusion

From model...



...to reality



A short schedule didn't mean less work for the construction team; it actually meant more preparation, diligence, and collaboration applied to each stage, especially given the lifesaving products Vertex was gearing up to manufacture at the facility. Suffolk worked through all phases with a high attention to detail and teamwork at the forefront.

As Vertex CEO Jeffrey Leiden said at the opening of the new headquarters in February 2014, "Making medicines is a team sport that requires hundreds of people working together for many years." That statement applied to both the construction of the building, which was designed to continue developing a new Vertex cystic fibrosis treatment, and the medicines that would help lives for many years to come.

**Here's how you can connect with our life sciences experts:**

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