

From concept to completion

How one healthcare company's vision for expanding its laboratory capabilities went from whiteboard to reality with the right laboratory product and distribution expertise.

This spring, GenCure, a subsidiary of BioBridge Global, was ready to announce the good news. Its biomanufacturing facility at the VelocityTX Innovation Center in San Antonio was now fully operational. The cGMP-compliant, biomanufacturing space is an extension to what GenCure and BioBridge Global already are doing – supporting the use of cells and tissue to save and enhance lives. The expansion allows for the production of consistent, clinical-grade, adult stem cells on a large scale – stem cells needed to bring potential new therapies through early to late phase clinical trials, and then to be available for routine prescribing, according to the organization.

Michael Fiske, MS, vice president, GenCure Biomanufacturing Center, said the project called for a high degree of collaboration and lab expertise. GenCure would need high-tech laboratory equipment to be delivered and installed at the site within a condensed timeframe, and it would need a flexible distribution partner willing to have boots on the ground during the build to help coordinate the effort.

Based off previous experience, Fiske reached out to Thermo Fisher Scientific for its combination of innovative Thermo Scientific-branded equipment and Fisher Healthcare's distribution experience for a consultation on the project. "I have now built and validated five cGMP clinical manufacturing facilities. Each case used a significant amount of Thermo Scientific equipment. So, from my perspective, why mess with a good thing?"

Needs assessment

GenCure's vision for the expansion was to distinguish itself in the stem cell therapy field with technology to scale up processes to



produce commercial amounts of material. "Our expansion needed to add cleanroom space," Fiske said. "Not only larger cleanroom space, but also large-scale Thermo Scientific equipment for the expansion of cell therapy production."

After an in-depth needs assessment, GenCure opted to outfit its laboratory space by utilizing Thermo Fisher's breadth of laboratory products, from biological

safety cabinets to centrifuges and cold storage equipment. (see list on page 42).

Along with the equipment came a team of experts needed for the complex installation. The biggest challenge of the expansion was having so many moving parts occurring simultaneously. The project involved three components:

- › The renovation of an old, on-site warehouse by the development firm Texas Research and Technology (TRTF).
- › The fabrication of cleanrooms by G-CON Manufacturing, Inc. located in College Station, Texas.
- › The supply chain management of laboratory equipment and its installation by Fisher Healthcare.

Thermo Fisher devoted several team members to the project to have a constant presence at the build site, including a business development manager, a lab products specialist and a Fisher Healthcare account executive.

Typically, lab equipment is moved into a space that's clean, sterile and ready to go – it's simply a matter of "plug and play." In the case of GenCure's custom project, the lab equipment had to be received, validations conducted by Unity Lab Services and then stored offsite at a nearby temporary warehouse before installing at the correct time in GenCure's custom space. Having access to Thermo Fisher's team members from the detailed needs' assessment to complex installation process

allowed for experts to be pulled in for detailed, highly-technical conversations as needed throughout the project. Because of the condensed timeline, this proved critical to the success of the project.

“So, you had this three-pronged approach to pulling the facility together,” said Fiske. “It had to be run concurrently, and then completed at the same time so we could put it all together in one piece. The project management aspects of that were probably some of the most challenging I’ve ever had to deal with.”

New possibilities

The finished facility was well worth the effort. The biomanufacturing



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center includes an initial 6,700 square feet of clean-room production space, expandable to 14,000 square feet, and a 2,500-square-foot development lab, along with office and meeting space. The clean rooms are sized for a wide range of production volumes, up to a series of 250L bioreactors. The facility was also designed to be compliant with almost all the regulatory guidance and regulations across the globe. The biomanufacturing space is compliant with FDA regulations, EU Annex 1 and PMDA (Grade A, B, C,

D). “This facility is one of the highest levels of compliance that you can possibly get, which allows us the flexibility to be able to manufacture things that go into basically any market,” said Fiske.

There are already discussions on expanding the facility. “We have additional space that we can add clean-room space to, and so we are evaluating what types of equipment we will need for that space,” he said. “So, for any future expansions we will definitely be talking to, and partnering with, Thermo Fisher.” ■

Fisher Healthcare assisted GenCure in outfitting its custom lab with a cross section of high-tech Thermo Scientific equipment, IQ and OQ validation services, including:

- › Thermo Scientific™ 1300 Series A2 Class II, Type A2 Bio Safety Cabinets to be used in processing and cell culturing.
- › Heracell VIOS 160i CO₂ Incubator with 100% copper chambers.
- › TSX Series refrigerators and freezers for storage of high value samples and materials.
- › Sorvall Legend XFR Centrifuges, high performance equipment used for general processing in the cell culture, microplate, bioproduction space.
- › CryoPlus™ LN₂ storage and Cryomed™ Controlled-Rate Freezer for cryopreservation to ensure cell line viability.
- › Sorvall BIOS 16 Bioprocessing Centrifuges for high quality harvesting, separation and purification bioprocessing methods that require run-to-run reproducibility and traceability, and an enhanced capacity of up to 16 liters.