



Investing In The Future Of Manufacturing

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Investing In The Future Of Manufacturing Manufacturing biologics is a highly complex process that employs living cells to serve as mini-factories to produce medicines. These therapeutics are thousands of times larger and more complex than relatively simple molecules like aspirin. In fact, the process is so involved that up to half of a regulatory application for a new biologic is focused on the exact manner in which it is manufactured.

In the more than 45 years since Genentech kick-started the biotechnology industry and began inventing processes and technologies to commercially manufacture biologics, we've discovered how to make these medicines efficiently at scale and deliver them as quickly as possible to patients with serious and life-threatening conditions.

Today we are using protein engineering to make even more complicated types of antibodies, such as bispecifics that enable simultaneous binding to two different disease targets. And in 2021 our global Genentech and Roche manufacturing network produced more than 55 million vials of medicine for patients around the world.

Genentech's new Clinical Supply Center is at the forefront of a modern manufacturing evolution.

- Jeff Davis, executive director, Clinical Supply Center



Approaching the Clinical Supply Center.

While four decades ago it was challenging to produce even grams of these transformational medicines - and our focus was on scaling up into huge 25,000-liter bioreactors - a core component of the future of manufacturing is set to play out on a much smaller-scale, modular and more nimble stage with an even bigger impact.

“Genentech’s new Clinical Supply Center is at the forefront of a modern manufacturing evolution, says Jeff Davis, executive director, Clinical Supply Center. “Keeping pace with the increasingly personalized nature of health care, it presents a new model for small-batch manufacturing that enables speedier bench-to-bedside delivery of clinical trial medicines and more agile production of potential therapeutics for smaller patient populations, including those with rare diseases or specific biomarker-driven subtypes of cancer.”

Genentech has invested more than \$250 million in this innovative biologics facility, which is the latest example of our long-standing commitment to our California operations as well as our dedication to environmentally responsible manufacturing practices.

A PEEK INSIDE THE CLINICAL SUPPLY CENTER

The new facility will produce the investigational medicines from Genentech's Research and Early Development group for delivery to patients in clinical trials.

The production process starts by putting a small vial of cells into a bioreactor along with proprietary media that serves as their sustenance as they grow and divide into larger and larger populations. They will eventually become the active drug substance that is ultimately packaged and administered to patients.



Monitoring conditions in the bioreactor to promote optimal cell growth.

The Clinical Supply Center has been designed to leverage process improvements developed in-house that significantly increase the concentration of therapeutic proteins while improving flexibility and speed, and reducing our environmental footprint. We continuously optimize for what the cells need to thrive through artificial intelligence and new digital technologies and, as a result, we're able to produce the investigational medicines faster.

These bioreactors are located in a contained manufacturing area within a single open space production floor – known as a “ballroom”. The design of this flexible, modular space allows us to rapidly reconfigure equipment for various scenarios and scales. It only takes a matter of hours to pivot from producing one medicine to another – as compared to days, weeks or even months in traditional manufacturing facilities.



Initiating the purification process that will extract the proteins needed to make medicines.

It may sound surprising, but single-use technology is a more eco-friendly option for biologics manufacturing.

- Dante Lee, Genentech senior director, Production Support

ADVANCING SUSTAINABLE MANUFACTURING

The Clinical Supply Center enables us to produce smaller volume batches of more clinical trial medicines at unprecedented speed with less impact on the environment. For example, we line the bioreactors with single-use soft plastic bags so the cell material doesn't touch the metal. This eliminates the need to clean and sterilize the bioreactors after each manufacturing run, which significantly reduces the amount of water, steam and chemicals we use. This innovative approach means the Clinical Supply Center uses 28% less water compared to our other facilities.

“It may sound surprising, but single-use technology is a more eco-friendly option for biologics manufacturing. Not having to clean or generate steam means we can significantly cut back our energy, water, and chemical use, which is critical given our location in drought-prone California.” said Dante Lee, Genentech senior director, Production Support. “None of our plastic goes to landfill. We are currently recycling, downcycling or converting used materials into energy as well as exploring new circular economy solutions to further reduce our environmental impact.”

In the Clinical Supply Center, we are using 25% less energy overall and sourcing 100% of our electricity from renewable sources, including onsite solar generation. Sustainability is top of mind for us whether we are developing new processes or building new facilities – in



Single-use technology reduces the amount of energy and water used in the facility

manufacturing and beyond. We built the Clinical Supply Center with sustainably-sourced materials and have earned LEED Gold certification from the U.S. Green Building Council, a rare achievement for a manufacturing facility. We've also signed up all our manufacturing sites to the U.S. Department of Energy's Better Climate Challenge. This connects us to other companies around the country where we can share best practices and lead by example in our commitment to ensuring a sustainable future.



Collaboration space where employees can connect outside the manufacturing floor.

We've made significant progress toward reducing Genentech's overall environmental footprint. The Clinical Supply Center is an important example of how we are advancing toward our goals to reduce our greenhouse gas emissions by 40%, water use by 20%, total landfill waste by 20% and plastic waste by 20% at our South San Francisco campus by 2025. We are on a path to achieve true zero emissions by 2045.

After more than four decades at the forefront of biologics manufacturing innovation, Genentech is now at the vanguard of a new movement in manufacturing. The Clinical Supply Center is the flagship location for what will ultimately expand to become a core and integral part of our future manufacturing network, serving as a template for future small-batch, flexible production facilities.