Enhancing Pharmaceutical Innovation with 3D Printing

DEVELOPING HARDWARE FOR BIOMANUFACTURING

The production of pharmaceuticals, vaccines, and antibodies is a highly intricate and innovative process that relies on technology matching its level of complexity. The vessels used in the procedure, called bioreactors, are designed to carry out the required chemical processes key to this industry. Inside is a tank in which growing organisms are submerged and suspended in a liquid solution where they can perform their desired function with limited production of impurities. In order to ensure a consistent, high-quality output, bioreactors are designed to control internal environmental factors such as temperature, nutrient concentrations, pH, and dissolved gases; all of which can drastically affect the growth and productivity of the contained organisms if not carefully regulated.

HyPerforma DynaDrive Single-use Bioreactor
Courtesy of Thermo Fisher Scientific

One company at the forefront of this innovative technology is Thermo Fisher Scientific. Created in 2006 by the merger of Thermo Electron and Fisher Scientific, the company has a deep history and proven track record of working with laboratory equipment, chemicals, and other supplies often used in its industry. Regarding bioreactors specifically, Thermo Fisher offers a wide range of products, all perfectly suited for both cell culture and microbial fermentation applications that run the gamut of everything from process development, to clinical trials, and even large-scale commercial biomanufacturing. Along with numerous recent advancements in its industry, Thermo Fisher continues to push the envelope of innovation by exploring the addition of new technologies, such as additive manufacturing.

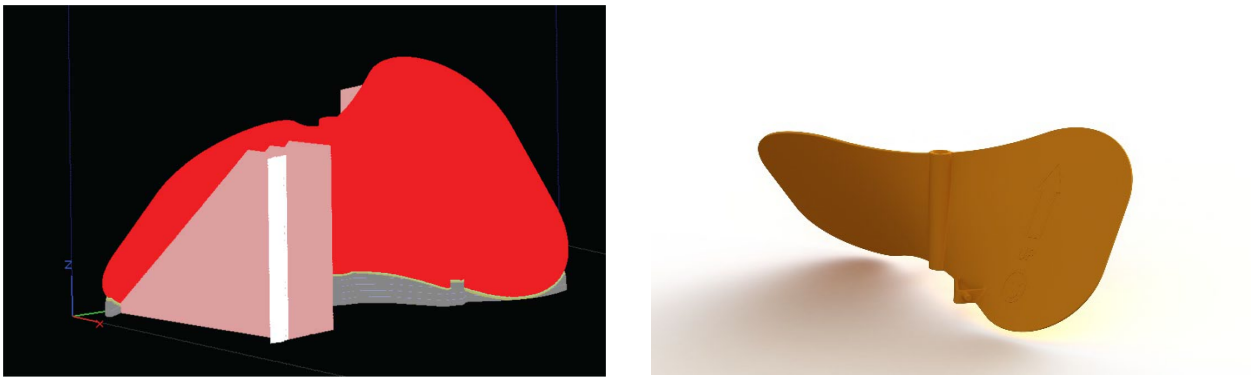
TRADITIONAL PRODUCT DEVELOPMENT GETS A BOOST

Historically, additive manufacturing has had a limited role among biopharmaceutical suppliers due to industry requirements on materials and practices. Stainless steel components are typically used and as a result, it was a major undertaking to switch over to the additive manufacturing's use of plastic-based materials. Prior to implementing additive manufacturing, Thermo Fisher relied on injection molding for low-volume manufacturing of customized components, which, while proven to be effective for developing high-quality parts, was also the source of challenges such as high costs of production and lack of rapid iteration in the design stage. While looking for an alternative solution, Thermo Fisher chose to partner with Stratasys due to its long history in the 3D printing industry. Implementation of this technology

provided the company a more effective means of prototyping. From here it was exposed to a plethora of new capabilities for quicker customization and sped up product development by 30-50%. Additive manufacturing not only contributed toward solving the company's technical challenges, but also provided a means to tackle their ISO compliance goals.

ADDITIVE'S ROLE IN HEALTHCARE COMPLIANCE

Due to implications for public health, products manufactured for use in the biopharmaceutical industry must go through rigorous testing by both the company and its customers before anything can move forward. These requirements can be even more disruptive when traditional manufacturing methods like injection molding are used, as users are required to build a new mold for every component before its usage is even confirmed. This makes for costly and time-consuming product development. Thermo Fisher is ISO13485 compliant and consequently, every part of their production process must be documented. As a result, additional time can be spent in the ideation phase, where the design can continuously change before considering the restrictions placed on it upon entering product development phase. Additive manufacturing can have a lasting impact on this process by speeding up product design with rapid iteration, allowing engineers to make changes on the fly, which ultimately saves money.



Insight and 3D Renders of bioreactor impeller (later printed in Ultem 1010) 19.4" x 10" – Support walls added to stop the part from warping
Courtesy of Thermo Fisher Scientific

Along with the advanced manufacturing capabilities of its 3D printers, Stratasys also produces a variety of materials with unique characteristics which can operate within a bioreactor and meet ISO certification. These materials include PC, ABS, and Ultem 1010. The first two (PC & ABS) are highly versatile, with accuracy, durability, and stability advantages for both prototyping and ancillary parts. Parts made with these materials can withstand mechanical functional testing and are created in drastically less time.

Conversely, Ultem 1010 contains unique characteristics that allow for contact with process fluids and other chemicals. This material is one of the strongest FDM thermoplastics, possessing high heat and chemical resistance, as well as thermal stability. Thanks to this it can withstand autoclave operations associated with sterilization and composite fabrication, as well as bioreactor's cell growth operations.

"We feel it important to push the limits of what we are able to do with additive in our environment. Not only for how we are using it, but also for sharing information about how we are using it. The more people that use additive manufacturing in our industry, the higher the acceptance rate by our customers is going to be. That will make it easier to do what we set out to do, make the world a healthier, cleaner and safer place."

Steven Kjar, Mechanical Engineer, Thermo Fisher Scientific

Technological advances like these continue to make additional innovation possible for Thermo Fisher and others in the industry. New biopharmaceutical technology is being developed with supporting components that are purely additively made, making additive manufacturing a widespread technology that will work for everyone. There will always be more questions to answer, but the engineers at Thermo Fisher continue to employ the best tools and equipment for continuous process improvement.

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