# Repligen

## Customer Case Study

FORECAST 3D

# Solutions to Speed COVID-19 Vaccine Production

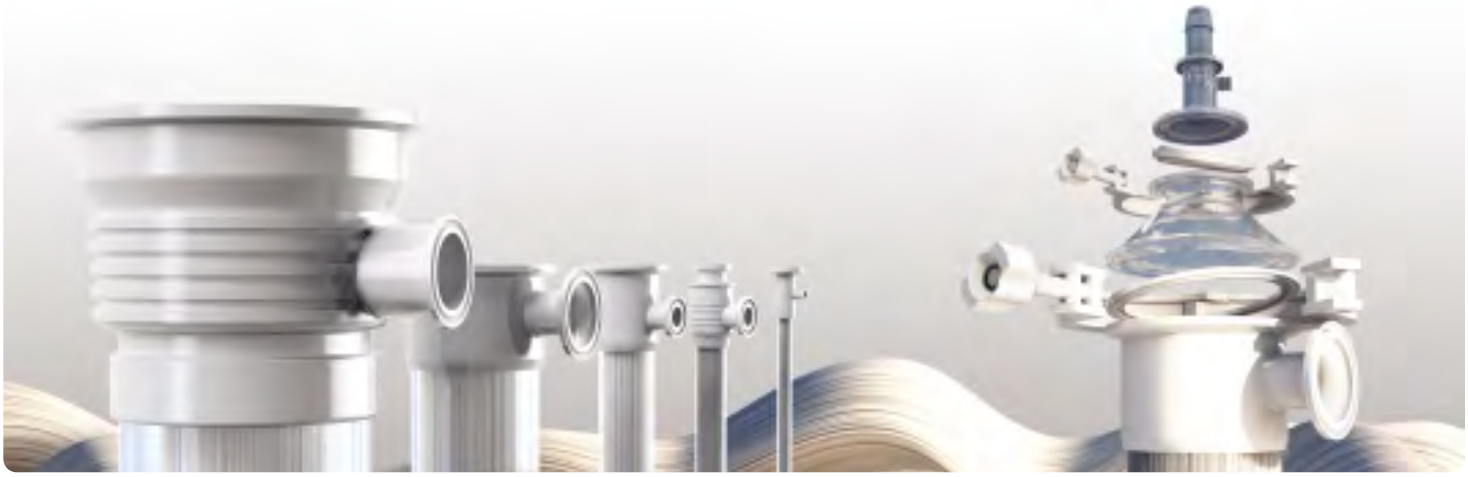
**Repligen**, a global life-sciences company renowned for inspiring advances in modern bioprocessing, is supporting the development of safe, viable COVID-19 vaccines by supplying specialized filtration equipment to its major biopharmaceutical clients. As a critical link in the bioprocessing supply chain, Repligen has opted for additive manufacturing solutions provided by GKN Forecast 3D to address the massive challenge of rapidly re-engineering and scaling up its Spectrum® Hollow Fiber Filter and ProConnex® Flow Paths product lines.


Since 1981, Repligen has been delivering innovative technologies and solutions in bioprocessing.

# Pandemic Chokes Medical Supply Chain

When the COVID-19 pandemic hit, the biopharmaceutical industry raced to expedite the production of vaccines that would help protect against the SARS-CoV-2 infection. However, vaccine manufacturing is an inherently challenging and time-intensive process. It typically takes anywhere from six months to several years to produce a vaccine that is safe, effective, and consistent over its life cycle while ensuring compliance with local and international regulations, among other requirements.

Filtration technologies, such as tangential flow filtration (TFF) and tangential flow depth filtration (TFDF), are vital to vaccine development, helping to separate and purify drug ingredients while minimizing cross-contamination risk and bioburden issues. Unfortunately, pandemic-induced supply chain disruptions severly impacted access to these specialized filters, as the escalating competition for raw materials, consumables, and supplies triggered significant bottlenecks. This, in turn, stymied the initial deployment of COVID-19 vaccines, forcing biopharma companies, manufacturers, and suppliers to reevaluate and adapt their processes to overcome such hurdles.



Repligen hollow fiber filters deliver high flux rates, excellent separation, and low protein binding for higher product yields.

One company that stepped up to meet this critical demand is Repligen, which develops and commercializes advanced bioprocessing technologies and systems to support the creation of biologic drugs, primarily monoclonal antibodies. Founded in 1981 by scientists Alexander Rich and Paul Schimmel, Repligen is one of the fastest-growing businesses in America today, with U.S.-based administration and manufacturing operations in California, Massachusetts, New Jersey, and New York, as well as multiple facilities overseas.

Even with a wealth of in-house resources at its disposal, Repligen was challenged to find a quick, efficient way to expand and optimize its production of the advanced filtration systems needed to engineer COVID-19 vaccine solutions. This is when the team turned to GKN Forecast 3D, one of North America's largest additive manufacturing service providers, for assistance.

## Scaling Up to Stay Ahead

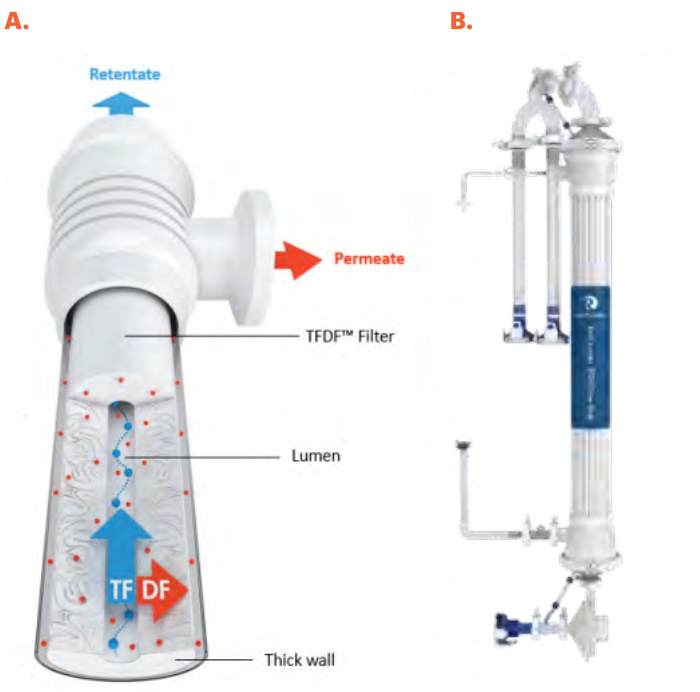
Repligen is a longtime customer of GKN Forecast 3D, which offers a full spectrum of 3D printing solutions as well as rapid machining and quick-turn tooling services to clients across a range of industries. Uniquely qualified in prototype, production, and bespoke manufacturing, GKN Forecast 3D has access to more than 50 pieces of additive manufacturing equipment and boasts a state-of-the-art, 49,000-square-foot production facility at its base of operations in Carlsbad, Calif.

"We have done business with GKN Forecast 3D since the mid-2000s," says Bao Le, vice president of engineering at Repligen. "We usually prototype with GKN Forecast 3D and then get the final production tooling made by one of our injection molding partners. But when we're trying to expedite things for launching a product on time or — in this case — putting out a fire, I think of them first because I know what I'm going to get."

Repligen's team at the Rancho Dominguez California Center of Excellence partnered with GKN Forecast 3D's additive manufacturing experts to fabricate certain parts for its TFF and TFDF fluid-management products, including proprietary fixtures used in hollow fiber filter production.

Due to the pandemic, there was an exponential increase in demand for hollow fiber filters from vaccine manufacturers. Repligen had to ramp up production 30 times compared to pre pandemic levels. "We had to reengineer our existing production processes to make the large-scale filters used in the production of COVID-19 vaccines," Le explains.

"In partnering with GKN Forecast 3D, we were able to innovate and iterate new production processes and the necessary tooling in a matter of weeks. GKN Forecast 3D also helped us meet production levels very quickly by leveraging their ProCAST Production Tooling solution: a process that combines the precision and accuracy of a CNC (computer numerical control) machined master pattern with the repeateability of the urethane casting process."




**A.** Tubular Depth Filter Operated In Tangential Flow Mode
**B.** ProConnex® TFDF® Flow Path


ProCAST Production Tooling machines a master pattern

# AM Accelerates Product Delivery

GKN Forecast 3D hit the ground running, simultaneously deploying two additive manufacturing strategies to help Repligen meet the fast turnaround time. “They needed parts fast, and we delivered using the ProCAST Prototype and ProCAST Production Tooling methods,” says Caleb Christenson, GKN Forecast 3D business development manager. “Their part quantity needs aligned perfectly with what our systems provide: hundreds to thousands of pieces, as opposed to 15,000 to 100,000-plus pieces, which likely would have required a conventional manufacturing approach.”

In a nutshell, the prototyping method additively manufactures the master pattern into a tool shape, while the production method machines a net (aka “final”) shape of a permanent master pattern. With both approaches, parts can be cast in any color or texture to achieve the desired aesthetic, but the latter technique requires minimal finishing steps. Cost-effectiveness, speed to market, and reduced labor are other prime advantages of GKN Forecast 3D’s batch production process, as it bypasses expensive tooling costs and lengthy lead times compared to injection molding.

GKN Forecast 3D’s all-hands-on-deck approach allowed the team to deliver the first batch of 300 hollow fiber filter potting caps in just three weeks.

“With traditional manufacturing, you usually have to wait one to three months before you see even one part,” Le explains. “To go from handing GKN Forecast 3D a CAD design file to getting 300 functional parts in less than three weeks — it’s phenomenal and displays a level of consistency that is truly invaluable.”

Repligen also improved the design of the cap to make it more robust and durable. Le notes the simplicity and speed of proofing design iterations through GKN Forecast 3D, which he says made the process even more seamless. The new-and-improved part is now made of a rigid urethane material classified as UABS 83. Together, the design enhancement and new production method have significantly increased product yield, resulting in an estimated annual cost savings of more than $10 million, according to Le.


Filling the mold made from the CNC-machined master pattern


The GKN Forecast 3D office in sunny Carlsbad, Calif.

## Partnering With the 'Best Game in Town'

Le further asserts that GKN Forecast 3D's proven track record for consistency and quality has been key in keeping up with client orders and delivering quality product solutions for the Repligen brand.

"What's most impressive about working with GKN Forecast 3D is the level of customer service and consistency they provide, and the overall ease of working with their team," Le says. "When it comes to getting something precise and functional enough for production, GKN Forecast 3D is, in my mind, the best game in town."

Supporting the delivery of safe, effective COVID-19 vaccines has far-reaching socioeconomic impacts, which are near-impossible to measure, yet tremendous nonetheless.

"Repligen is proud of its efforts to help end the pandemic," Le says. "We are also grateful for the opportunity to partner with GKN Forecast 3D to meet the needs of our vaccine manufacturing clients. Our company is growing, which drives a lot of opportunities to innovate. GKN Forecast 3D is going to continue to be our preferred additive manufacturing partner when it comes to product development and rapid prototyping."

## About GKN Forecast 3D

GKN Forecast 3D is a digital manufacturer of advanced and metal additive manufacturing (AM) parts, backed by GKN Powder Metallurgy's 260+ years of engineering and production expertise. Equipped with one of the world's largest global networks of industrial 3D printers, GKN Forecast 3D supports projects from one part to more than 1 million, offering innovative digital solutions for aerospace, automotive, industrial, healthcare, defense, electronics, consumer products, and more. Leading in prototyping to production with international manufacturing, advanced technologies, and raw materials, GKN Forecast 3D gets products to market faster.

## Start Your Project Today

Contact us at **hello@forecast3d.com** or **(877) 835-6170** to learn more about our world-class additive manufacturing options.



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