

As the world continues to feel the impact of the COVID-19 pandemic, the biopharmaceutical industry is **working around the clock** to develop and manufacture safe and effective vaccines. To date, two vaccines have been granted Emergency Use Authorization (EUA) in the United States by the U.S. Food and Drug Administration (FDA). Another vaccine candidate has been submitted for an EUA and several others have made substantial progress in their clinical development programs. Meanwhile, Americans across the country have now started to be vaccinated. While this is a tremendous achievement, biopharmaceutical companies are not done fighting COVID-19.

Across the industry, companies are further continuing clinical research to assess whether modifications or boosters are warranted to existing vaccines to address emerging variants. Companies are also collaborating on **manufacturing** to increase the supply of **vaccines** and ensure continued protection against the virus.

Keeping pace as the pandemic evolves

Viruses are constantly changing, which can lead to genetic variations (commonly referred to as variants or mutations) that may have different characteristics both positive and negative. Importantly, not all variants are created equal. Some variants may spread easier or cause more severe disease. The human immune system also has the ability to adapt and respond to variants as well. Recently, the Centers for Disease Control and Prevention (CDC), identified **several COVID-19 virus variants** circulating among the general U.S. population.

Public health officials and biopharmaceutical companies closely track variants using **genomic surveillance** to identify and decode changes in the COVID-19 virus' genes and learn more about how these variants may affect public health and impact the efficacy of vaccines.

To enhance surveillance, the CDC has established the National SARS-CoV2-Strain Surveillance (NS3) system and partnered with commercial diagnostic laboratories, universities and local health departments. In addition, biopharmaceutical companies are investing in large-scale surveillance networks that help companies quickly test vaccine efficacy against identified variants.

Preliminary public data on the two currently authorized vaccines in the U.S. as of February 19, 2021, suggest some level of effectiveness against certain emerging variants, likely a direct result of careful target selection in the initial vaccine design. Developers utilized the sequencing of the virus to select a surface protein which the virus uses to infect cells, which scientists hypothesized would be conserved should the virus mutate. To address potential



surface protein mutations, researchers are working to develop new solutions for variants that could reduce the efficacy of or even elude current vaccines.

For vaccines that use an mRNA platform, companies are working to modify the basic building blocks of their vaccines by inserting the genetic code of variants. Meanwhile, other vaccine makers are developing modifications to their vaccines to take aim at the variants. Biopharmaceutical companies are also investigating both **booster** vaccines, which could be given following original vaccines, as well as new vaccines that target the common viral strain and new variants.

Collaborating to meet manufacturing demand

Across the industry, companies are working around the clock to meet the demands of manufacturing enough COVID-19 vaccines to get as many shots in arms as possible. Biopharmaceutical companies are continuously increasing their manufacturing capacity, such that as the U.S. capacity to administer the vaccines increases, the supply will also increase to keep ahead. Moreover, biopharmaceutical companies proactively enhanced

manufacturing capabilities and available capacity to ramp up production in parallel to clinical development to ensure they could meet demand if a vaccine candidate was authorized by the FDA.

Now, as two vaccines have received EUA in the U.S. and others reach the late stages of research, companies across the industry are partnering in new ways to deliver vaccines to patients as quickly as possible. In fact, several companies **have announced** that they will provide manufacturing capacity to mRNA vaccine production.

Recognizing vaccine manufacturing complexity

These recent announcements are remarkable given the complexity of vaccine manufacturing. Vaccine manufacturing is highly specialized work, and the technology behind vaccine production is not easily transferred from facility to facility. For example, mRNA vaccine manufacturing uses complicated bioprocessing techniques that utilize specialty bioreactors to first manufacture DNA that codes for the desired mRNA sequence, and then require a second bioprocess to create billions of identical mRNA segments. The mRNA segments are then wrapped in a nanolipid wrapper using yet another very specialized process. Providing capacity for the manufacture of these mRNA vaccines is no small feat.

As additional vaccines enter the market, it's important to note that different vaccines will require different approaches as each vaccine will have its own requirements for raw materials, equipment and technical specifications. In addition to the technical complexity of manufacturing vaccines, with the unprecedented volume of vaccine doses required to meet global demand, there are challenges in the end-to-end process that are also important to consider. For example, the filling and labelling of vials is an important final step but one that is highly in demand for many products, not just COVID-19 vaccines.

The biopharmaceutical industry is committed to developing and manufacturing safe and effective vaccines and to supporting our health care system as we work to vaccinate as many people as possible.

