

Across the industry, biopharmaceutical companies are working around the clock to meet the demands of COVID-19 vaccine manufacturing. Companies are working to source needed raw materials and other supplies and increasing manufacturing capacity to get COVID-19 vaccine shots in as many arms as possible. Even prior to knowing the efficacy of particular vaccine candidates, companies have proactively been increasing their own manufacturing capabilities as well as partnering with other manufacturers who are sharing available capacity to support production. These partnerships have been key to manufacturing ramp-up following vaccine authorization.

MANUFACTURING PROCESS

Manufacturing vaccines on a global scale is a highly specialized and intensive bioprocess given that COVID-19 vaccines are complex biologic products. At a high level, the manufacturing process falls into six critical phases and biopharmaceutical companies are lending a hand at every step:



RECENT EXAMPLES OF PhRMA MEMBER COMPANY VACCINE MANUFACTURING COLLABORATIONS INCLUDE:

AstraZeneca

AstraZeneca is partnering with [Catalent](#) and [Emergent BioSolutions](#) to assist in bulk drug substance production for the COVID-19 vaccine.

[Oxford BioMedica](#) has reserved capacity for AstraZeneca in up to three manufacturing suites to support large-scale commercial manufacturing of the vaccine.

To support broad and equitable global access, AstraZeneca has [partnered](#) with the Coalition for Epidemic Preparedness Innovations (CEPI), GAVI, the Vaccine Alliance and Serum Institute of India who will [support](#) the manufacturing, procurement and distribution to bring the COVID-19 vaccine to low- and middle-income countries.

AstraZeneca has partnered with SK Bioscience to boost COVID-19 vaccine production in South Korea. SK Bioscience plans to invest \$132 million into expanding its vaccine production space which produces the AstraZeneca vaccine.

Bayer

[Bayer](#) and [CureVac](#) are partnering to manufacture CureVac's mRNA-based COVID-19 vaccine. Bayer will contribute its expertise and established infrastructure in areas such as clinical operations, regulatory affairs, pharmacovigilance, medical information and supply chain performance as well as support in selected countries. In February 2021, Bayer [announced it will contribute even further](#) by making more vaccines available to help fight the pandemic.

CSL

[CSL](#) is manufacturing the AZ-Oxford COVID-19 vaccine in Melbourne for the Australian government and is providing MF59[®] adjuvant to multiple COVID-19 vaccine development programs.

CSL's manufacturing of AstraZeneca's COVID-19 vaccine will be distributed to the Pacific Islands (including New Zealand, Papua New Guinea, Tuvalu, Fiji, Samoa, Vanuatu) and SE Asian Nations (including Indonesia and Vietnam) – in addition to Australia.

GlaxoSmithKline

GlaxoSmithKline is collaborating with CureVac and leveraging their established manufacturing network in Belgium to support the manufacturing of up to 100 million doses of CureVac's first-generation COVID-19 vaccine, CVnCOV, in 2021.

GSK has reached an agreement in principle with Novavax and the UK Government Vaccines Taskforce to support manufacturing of up to 60 million doses of Novavax's COVID-19 vaccine candidate for use in the United Kingdom. GSK will provide 'fill and finish' manufacturing capacity at its facility in England.

Johnson & Johnson

Johnson & Johnson has established a global manufacturing and supply network for its COVID-19 vaccine, collaborating with nine manufacturing partners across four continents.

The company is partnering with Merck and Co. to expand manufacturing capacity for the second half of this year and help ensure a stable supply of the Johnson & Johnson vaccine.

Beyond Janssen's manufacturing facility in the Netherlands, other partners who are central to Johnson & Johnson's manufacturing and supply network include: Emergent BioSolutions (U.S.), Catalent (U.S., Italy), Biological E (India), Reig Jofre (Spain), Aspen Pharmacare (South Africa) and Grand River Aseptic Manufacturing (U.S.).

Merck

Merck has announced the signing of a voluntary licensing agreement with the Medicines Patent Pool (MPP) to facilitate affordable global access for molnupiravir, an investigational oral COVID-19 antiviral medicine for the treatment of mild-to-moderate COVID-19 in adults who are at risk for progressing to severe COVID-19 and/or hospitalization.

Novartis

Novartis announced an initial agreement to leverage its manufacturing capacity and capabilities to support the production of the Pfizer-BioNTech COVID-19 Vaccine. Novartis plans to take bulk mRNA active ingredient from BioNTech and fill this into vials under aseptic conditions for shipment back to BioNTech for their distribution to health care system customers around the world.

Novartis also signed an initial agreement to manufacture the mRNA and bulk drug product for the COVID-19 vaccine candidate CVnCoV from CureVac. Novartis plans to produce up to 50 million doses in 2021 and up to a further 200 million doses in 2022.

Pfizer

Pfizer and the Medicines Patent Pool, a United Nations-backed public health organization working to increase access to life-saving medicines for low- and middle-income countries, announced the signing of a voluntary license agreement for Pfizer's COVID-19 oral antiviral treatment candidate PF-07321332, which is administered in combination with low dose ritonavir (PF-07321332; ritonavir). The agreement will enable MPP to facilitate additional production and distribution of the investigational antiviral, pending regulatory authorization or approval, by granting sub-licenses to qualified generic medicine manufacturers, with the goal of facilitating greater access to the global population.

EMD Serono sped up its production of lipids to Pfizer/BioNTech, custom lipid nanoparticles that are crucial to producing their vaccine which leverages messenger-RNA technology.

Teva Pharmaceuticals serves as the sole distributor of the Pfizer vaccine in Israel through partnership with Pfizer and the government. Israel has a unique health care system, with a strong interconnected system of only four HMOs and Teva's state-of-the-art storage and distribution capabilities provided a strong public-private partnership.

Pfizer and BioNTech announced a collaboration with Biovac to distribute their COVID-19 vaccine within the African Union. At full operational capacity the annual production will exceed 100 million doses annually.

Another collaboration was established with Brazil's Eurofarma Laboratórios SA, with expected annual production to exceed 100 million finished vaccine doses exclusively distributed within Latin America. Eurofarma will perform manufacturing activities within Pfizer's and BioNTech's global COVID-19 vaccine supply chain and manufacturing network, which will now span four continents and include more than 20 manufacturing facilities.

Sanofi

Sanofi and BioNTech have entered into an agreement under which the company will support manufacturing and supply of BioNTech's COVID-19 vaccine which is being co-developed with Pfizer. Sanofi will provide BioNTech access to its established infrastructure and expertise to produce over 125 million doses of COVID-19 vaccine in Europe. Initial supplies will originate from Sanofi's production facilities in Frankfurt from summer of 2021.

Sanofi will provide access to the established infrastructure and expertise of its vaccine manufacturing plant in Marcy l'Étoile, France, to formulate and fill vials of Johnson & Johnson's COVID-19 vaccine candidate in 2021, at a rate of approximately 12 million doses per month.

Sanofi has entered into an agreement with Moderna, under which Sanofi will help manufacture Moderna's COVID-19 vaccine, supporting the COVID-19 pandemic and vaccine supply needs. Sanofi plans to manufacture up to 200 million doses of Moderna's vaccine in the U.S. starting in September 2021.

Takeda

Takeda announced it will use its Hikari facility in Japan to manufacture more than 250 million doses of Novavax's COVID-19 vaccine candidate. They also plan to import and distribute 50 million doses of Moderna's COVID-19 vaccine candidate, mRNA-1273, in Japan.

Takeda will make manufacturing capacity available at IDT Biologika's facilities in Germany to manufacture Johnson & Johnson's COVID-19 vaccine.

The biopharmaceutical industry has embraced its leadership role in responding to COVID-19 and continues to establish effective partnerships to boost manufacturing capacity to keep pace with global demand so that vaccines make it to those in need as quickly as possible.

“You know, what’s clear is this is a historic, nearly unprecedented collaboration. During World War II, one of the country’s slogans was ‘We are all in this together.’ And companies took that slogan to heart.”

– President Joe Biden