



Technology and Manufacturing

Keeping development moving during a global economic and health crisis.

Technology readiness and manufacturing were the greatest challenges to vaccine companies. Here's how development and production kept moving.

Technology readiness levels indicate that a vaccine has achieved higher levels of technical maturity. The final level is post-Food and Drug Administration (FDA) licensing. COVID-19 vaccine development under Operation Warp Speed (OWS) followed traditional practices, with some adaptations to follow the FDA's guidance for acceleration. In a report by the U.S. Government Accountability Office (GAO), some vaccine makers stated that they relied on data from other vaccines using the same platforms in order to meet OWS timelines.

The Pfizer/BioNTech and Moderna vaccines, for example, both use mRNA technology; Moderna has been a pioneer in its development since 2010 and acknowledges that other COVID-19 vaccines in development may use their patented technologies; moreover, during the pandemic, Moderna announced they will not enforce their patents against those vaccine companies and will even eliminate intellectual property barriers by licensing its technologies (upon request) to those combating COVID-19.

MANUFACTURING

Scaling up manufacturing under OWS proved to be challenging for vaccine companies, the GAO reported. Efforts by federal authorities to help ease the process include:

- Vaccine companies are working in partnership with OWS to expand production capacity and eliminate bottlenecks.
- Relieving a strained supply chain to expedite procurement and delivery of equipment and supplies identified as critical by OWS vaccine candidates.
- Closing workforce gaps. The U.S. Department of State is expediting visa approval for key personnel needed to run manufacturing processes.

Billions of federal dollars have already been spent as part of OWS. *Fortune* suggests that now may be the best opportunity for the U.S. to reshore medical manufacturing to not only potentially reduce spending during future public health crises, but to also help avoid reliance on a fragile global supply chain and revitalize America's industrial workforce. **IQ**

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