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How vaccine manufacturers can prepare for the next pandemic

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mRNA technology enabled rapid SARS-CoV-2 vaccine development. How can the biopharmaceutical industry improve before the next pandemic?

Before the COVID-19 pandemic, the average time required to develop a vaccine was over a decade. But in 2020, the biopharmaceutical industry brought two SARS-CoV-2 vaccines to the market after less than a year of research and development. What changed?

First, the COVID-19 pandemic spurred an unparalleled level of collaboration among government, academia, and the biopharmaceutical industry to create safe SARS-CoV-2 vaccines as quickly as possible. To do their part, companies and industry organizations took financial risks, putting their pipelines and business goals aside and investing their time and capital in advanced therapies like mRNA platforms to facilitate vaccine development.

Although it was very niche and unproven at the start of the pandemic, mRNA became the platform of choice because of its potential to deliver vaccines more rapidly than traditional methods. And the gamble paid off: by the middle of March 2021, 14 months after COVID-19 first broke out, over 300 million doses of an mRNA-based SARS-CoV-2 vaccine have been administered.

With previous viral outbreaks, it was a challenge for vaccine manufacturers to pivot their facilities to begin producing novel vaccines. Even today, vaccine manufacturers are unable to repurpose their existing factories dedicated to traditional vaccines to meet the demands of the current pandemic. If all the world had to rely on was these older methods, there simply wouldn't be enough capacity within the industry to create the 14 billion vaccine doses needed to **vaccinate the world's population**. Rather, to prepare for the next pandemic, manufacturers need to invest in flexible platforms and other emerging technologies that will give them the flexibility to respond to new viruses.

Realizing the potential of mRNA

mRNA vaccines are not a novel concept. Scientists began **studying mRNA** as an alternative to killed or live attenuated viruses in 1990. But when the SARS-CoV-2 pandemic created an urgent demand for fast vaccine development, the industry decided to fully embrace mRNA technology; companies like Moderna, BioNtech and Curevac developed the idea into a tangible product. Unlike more traditional types of vaccines, where each vaccine must be built from scratch, mRNA technology is a true platform technology.

All mRNA vaccines are produced using the same process: manufacturers insert an mRNA sequence that encodes a protein antigen from the virus into a lipid nanoparticle. This antigen triggers an immune response that provides the recipient with immunity against the virus. To produce a vaccine for a novel virus, all manufacturers need to do is switch out the DNA template that is used to produce the mRNA sequence that will be placed in its delivery vehicles. Fortunately, making a large amount of mRNA in the lab is a relatively simple process.

mRNA makes it easy for a biopharmaceutical manufacturer to change over from one target to the next, giving them the flexibility to address new health threats quickly. This platform is also relatively easy to establish using fewer resources, making it possible for facilities around the world to manufacture these vaccines to serve their local populations.

Other ways to increase vaccine manufacturing flexibility

mRNA is not the only method to boost the speed of vaccine development in every scenario. As competition and increasing health threats continue to put pressure on the biopharmaceutical industry to innovate more efficiently, flexibility will become key to companies' survival in the marketplace and to the survival of the world's population.

One rate-limiting factor in vaccine production and manufacturing is dependence on stainless steel equipment. Older facilities that rely on this equipment cannot be repurposed. While this technology is needed to produce legacy vaccines, these same manufacturers should consider adopting more flexible, single-use technologies as a complement. Single-use technologies can be implemented and changed over much more quickly than stainless steel technologies. These technologies would enable legacy vaccine manufacturers to launch new vaccines, adjust their production capacity more easily, and prepare to confront future pandemics.

Before 2020, the biopharmaceutical industry did not have large-scale capacity to develop mRNA-based vaccines, but by adopting single-use technologies, existing CDMOs have been able to repurpose their facilities to manufacture mRNA-based vaccines.

Further optimization of mRNA vaccine platforms is needed

While mRNA vaccine development is a promising strategy, it is important to acknowledge that these production platforms are very new. The status of today's mRNA vaccines as the first-in-class means scientists are still seeking to improve studying existing processes, make vaccines stable at higher temperatures to simplify storage, tackle emerging virus variants, and optimize dosage. Companies, for example, are determining whether the vaccine can feasibly be made shelf-stable.

While the industry will benefit from adopting tools and techniques that increase flexibility, such as mRNA and single-use technologies, we're still learning what questions need to be answered.

Looking ahead

The COVID-19 pandemic is far from over, and the threat of future pandemics created by novel viruses is very real. But we now have a better understanding of how quickly a virus can spread across oceans to disrupt the entire world. We also know that traditional vaccine development workflows are not sufficient to respond to viral outbreaks quickly. Finally, we have seen that even with extremely rapid vaccine development, limitations in production capabilities can have real-world consequences.

To prevent another pandemic of this scale, biopharmaceutical companies need to continue investing in a larger vaccine pipeline, and the government and other entities need to increase their funding of research into virology, epidemiology, and biochemistry to enable the development of safer and more efficacious vaccines. In the meantime, as biopharmaceutical companies continue investing in flexibility, regulators must reexamine the rules around vaccine development to facilitate the approval of safe and effective vaccines as quickly as possible.

With enhanced knowledge and infrastructure, combined with the lessons learned in 2020 about the importance of collaboration, flexibility, and agility, we will hopefully be able to stop the next outbreak before it spreads too far.

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