

Developing the coronavirus vaccine supply chain

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The hunt for a COVID-19 vaccine is heating up. Scientists and pharmaceutical companies globally are researching and developing around 100 vaccine candidates, with at least 10 currently in early phases of human testing, according to the World Health Organization. The U.S. government has narrowed its vaccine candidate list to seven, NPR reported.

One or two vaccine doses are anticipated per person, immunizing 60% to 80% of the population to achieve herd immunity globally. At least 5.6 billion people need inoculations, meaning development of a lot of vaccine doses in a short amount of time.

Pharmaceutical companies and a host of other parties, including the federal government, nonprofit organizations and pharmaceutical suppliers, are busy readying the supply chain to handle that high number of vaccines. This is taking place while trying to maintain production of other inoculations — including the seasonal flu — and other medical products using some of the same materials and manufacturing capacity.

The vaccine supply chain involves not only manufacturing the vaccine contents, but storage and packaging components, cold-chain transit, domestic and global shipping, distribution strategies and storage.

Speeding the development timeline

COVID-19 vaccines could be ready for some frontline workers and at-risk populations later this year or early 2021. Unlike with traditional development timelines, interested parties are throwing money at this development process to speed up availability.

"We don't know which vaccines will be successful. This process is typically sequential," David Simchi-Levi, director of the MIT Data Science Lab and professor of engineering systems, told Supply Chain Dive. After lab testing, researchers move to animal testing and ultimately to humans. Then they build up manufacturing capability depending on the vaccine technology used. "We cannot afford a sequential process. We need to start the manufacturing capacity today, and the problem is it requires significant investment," he said.



[Watch Video At: https://youtu.be/JoSvutsCHrU](https://youtu.be/JoSvutsCHrU)

Vaccines are complicated to manufacture, even compared to other pharmaceutical products. Producing the antigen, which provokes the body's immune response, uses different techniques depending on the vaccine's design. The vaccine candidates use different technology types, like protein-based, non-replicating viral vectors or DNA vaccines. This means the equipment and processes to produce the vaccine differ.

The filling and packaging materials vary as well, whether in multi-dose vials or single syringes. All of this is done in a highly sterile environment with temperature controls and using skilled personnel. Equipment and processes must be tested and government-approved, along with testing the finished product.

By making the development steps parallel instead of sequential, some of that investment will be wasted as the manufacturing process may differ from the initial set-up. Facilities will not be built to spec for the specific vaccine candidate, but rather built and then modified later on.

Sourcing at scale presents shortage concerns

As a regulated product, vaccines manufacturers have limits on what they can use, making sourcing more complicated.

Glass and stoppers

There's a shortage of the sand used to make glass vials for vaccine storage. It would take two years to produce the volume of glass vials needed for the vaccine, according to Rick Bright, the former director of the Biomedical Advanced Research and Development Authority in his [whistleblower memo](#). Without an unlimited supply, the vials won't be available for other products as well, like hospital-administered sedatives. Government efforts to avert shortages have to begin soon if enlisting more manufacturers.

Stoppers are an issue as well, and they're typically approved by the FDA. The rubber or latex cap components can't interact with the chemicals inside. A few manufacturers dominate the stopper business, and some of them also make the vials.

Needles and syringes

Waiting for a vaccine to be developed is too late to ramp up syringe manufacturing, according to Troy Kirkpatrick, a spokesperson for Becton, Dickinson & Company, the largest U.S.-based needle and syringe manufacturer. "There is not capacity in the global industry to manufacture hundreds of millions or billions of syringes and needles in a month or two," he told [NBC News](#).

The Strategic National Stockpile (SNS), which already depleted its store of PPE, contains 2% of the required amount of anticipated needles and syringes needed for the coronavirus vaccine, according to Bright. Bright's memo also quotes Peter Navarro, White House director of trade and manufacturing policy, as anticipating needing 850 million syringes for COVID-19 vaccine delivery.

Chemicals and vaccine components

Vaccines can use thousands of ingredients, including adjuvants which strengthen the body's immune response to an inoculation. One such adjuvant comes from the bark of the *Quillaja saponaria* Molina tree in South America. It's harvested from November to January, making that ingredient in short supply until the next harvest, if needed for the COVID-19 vaccine.

Pharmaceutical company Inovio has concerns over its plasmid provider's ability to scale up manufacturing, which impacts Inovio's production goals.

Many of the chemicals used in pharmaceuticals come from China and India. "One challenge is how do you get this chemical," said Simchi-Levi. Relying on foreign sources proved concerning during the pandemic, as China's manufacturing shut down and India temporarily halted export of around 20 pharmaceutical ingredients and finished products. Moving that domestically isn't easy, and building domestic manufacturing capabilities for chemicals is highly polluting. "If you want to move it to North America or Europe, you need to develop a clean chemical manufacturing process," Simchi-Levi said.

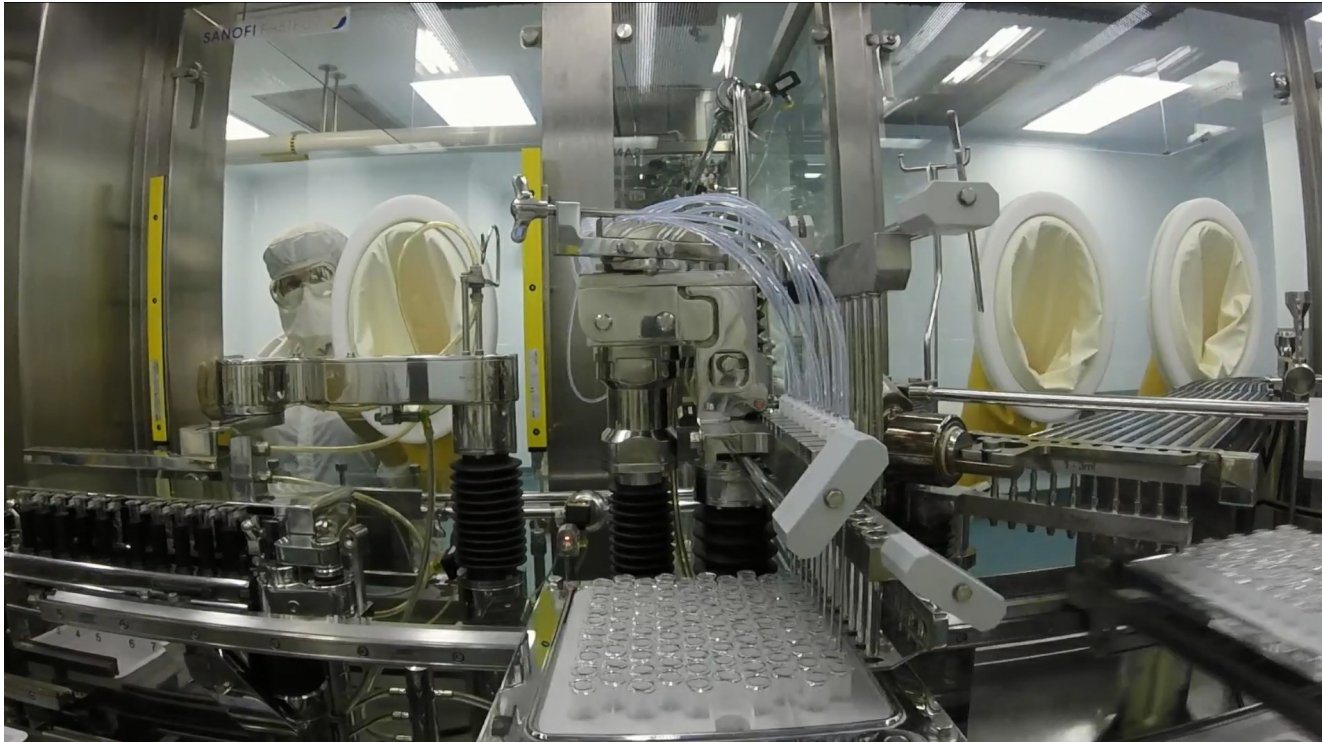
Nimble manufacturing capacity

Manufacturing billions of anything in a short time frame is a feat under normal circumstances. But there are not available manufacturing facilities just waiting for the coronavirus vaccines. Globally, manufacturers produce 5 billion vaccine doses annually, including 1.5 billion flu vaccines. And without excess capacity, production of a new coronavirus vaccine will cut into current vaccine production.

Alliances like the Coalition for Epidemic Preparedness Innovations (CEPI) and the federal government are investing in production capacity now, to have enough flexibility in the manufacturing process to shift once the best vaccine candidates are identified, said Simchi-Levi. The vaccine technology platform matters for packaging and delivery, and for manufacturing, as the vaccine candidates use different approaches. FDA-approved vaccines have never been produced using the mRNA platform, which Moderna's approach uses.

It costs \$50 million to \$700 million to build or prepare a manufacturing plant to produce a new vaccine. The most flexible manufacturing facilities can pivot to a different technology when operators know what the facility will produce, said Simchi-Levi.

Vaccine producer Johnson & Johnson said it was committing \$1 billion to expand manufacturing at its four facilities, and Sanofi also is scaling up.



Pharmaceutical manufacturers such as J&J and Sanofi Pasteur have committed to scale up vaccine manufacturing capacity.

Sanofi Pasteur

Agility is key to manufacturing vaccines and their components. "We're never going to have infinite capacity or resources for any supply chain, including the healthcare supply chain. We have to be mindful of how to think of creating a bit more nimbleness," Nicolette Louissaint, executive director of Healthcare Ready, told Supply Chain Dive. "It's often more about having capacity that can be adjusted and can be nimble, rather than focusing on a specific type of product."

Cooperation for speed and scale

Domestically, partnerships between the government and private industry can help advance vaccine production, said Simchi-Levi. That includes collaborating on research and development, as well as some public financing.

In the late 1980s and early 1990s, manufacturing partnerships between the government, academia and private sectors improved capacity in the semiconductor industry, he said. Cooperative research and infrastructure, as well as government funding helped move the U.S. semiconductor industry forward. This type of partnership bodes well for vaccine manufacturing, where the government has a vested interest in vaccine development success. "I'm confident that these partnerships will allow us to be successful to scale quickly," Simchi-Levi said

The Department of Health and Human Services set up a public-private partnership for high-speed, high-volume drug packaging solutions in March. The idea is to use it for vaccine delivery like COVID-19, for the Strategic National Stockpile or therapeutics. The private manufacturer in the partnership, ApiJect Systems America, is planning to build up to eight domestic facilities for surge capacity to produce prefilled syringes using a Blow-Fill-Seal process already used for nasal spray, eye drops and rotavirus oral vaccines. This use would eliminate the need for glass vials, using an interlocking needle hub.

The response to the pandemic "requires global cooperation," said Louissaint, to source ingredients and components for a COVID-19 vaccine, including for manufacturing and distribution. For pharmaceutical companies, the normal operating environment is the global environment, working with other governments, international vendors and an international workforce.

Part of that cooperation involves raw materials. "Twenty countries are investing heavily in vaccine manufacturing and scaling up the supply chain. If there is one raw material component everybody needs, then it will be a global competition," said Simchi-Levi. "The country where it's produced will have the ability to control capacity. It's exactly what we saw with drugs and PPE, and other essential healthcare components."

Transportation and the vaccine supply chain

Distributing and storing vaccines through the cold chain is easily done across the country, said Louissaint, provided logistics and transportation are moving continuously. UPS announced its involvement with pharmaceutical vaccine manufacturers to provide transport of drugs and ingredients for clinical trials and manufacturing. It will also distribute the vaccines, when they're ready, commercially via cold chain.

What's concerning is the reduction in passenger flights, used to move supplies economically across the country and the globe through belly cargo. "We're trying to determine how best to work with the aviation industry to find solutions to move product or to resume those flights because so much of our finished products move in that manner for multiple regions," she said. When the borders reopen, the supply chain will need increased passenger plane capacity, or that will negatively impact the flow of coronavirus vaccine components.



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UPS

The COVID-19 vaccines would not all be available at once, giving suppliers and manufacturers additional time to ramp up and continue production. Initial doses would likely go to front-line health workers and vulnerable populations, Anthony Fauci said at the recent Wall Street Journal's Tech Health Conference. The director of the National Institute of Allergy and Infectious Diseases said initially government entities like the CDC would help distribute vaccines, but likely companies would then take over that role.

While the COVID-19 vaccine process becomes parallel instead of sequential, it's only part of the larger preparedness equation. "We're not in the position to think about one system at a time," Louissaint said. "This is normally the time we'd be planning for the flu season."