

02.02.2021

Navigating the complex value chain: COVID-19 vaccine distribution – part 1: traceability

FDA Emergency Use Authorization approval for the first COVID-19 vaccines marks a major step towards ending the pandemic.



While it is a welcomed sign of the beginning of the end of the pandemic, it actually is the beginning of the next set of challenges: How can we get the vaccine distributed around the globe?

Diverse requirements

We have had to adapt with respect to COVID-19 related supply chain challenges since the pandemic began, such as coping with ‘surprise peak season’ conditions due to the sudden rise in online sales, while having fewer workers available due to COVID-19 protocols and required social distancing measures.

Looking at the distribution of the vaccine from a volume perspective does not seem particularly challenging, especially considering the e-commerce volume the U.S. has already been managing. However, we are facing a whole new set of requirements: transporting as fast as possible at a constant extreme temperature, while the vaccine is being kept safe and secure, to locations across the globe.

What distinguishes this operation is the complete value stream that has to be preserved throughout the supply chain: from the manufacturing process all the way to the point of distribution, and ultimately into the arms of millions of people. This contrasts with most supply chains, which are optimized for just one segment or industry. For example, some providers are experts in the cold chain, others in last-mile delivery, some for fulfillment, and others for track and trace. For example, Amazon doesn’t make products, they

Related solutions



Software Solutions

Software Solutions are designed to help manufacturing and distribution organizations to maximize

distributors for all of their products. And they cannot administer the vaccine to everyone at once. Therefore, they have to innovate their usual methods for receiving and disbursing vaccines.

As a result, there are new and complex requirements across the whole value chain, which makes the vaccine a massive logistics undertaking.

Distributing the vaccine during the pandemic

Usually, developing a supply chain solution involves many on-site visits to study processes and procedures, interview end users and employees, and test real-world scenarios. Working from home means businesses must work with limited information that is constantly changing and requirements that are evolving over time. As a result, development on the fly and designing on the back end become common, following an agile approach. While this works well in other industries, in the pharmaceutical environment, it adds another layer of complexity - the stringent testing requirements that go into validation and required documentation must be considered.

Traceability

Track and trace systems are already an important part of the pharmaceutical supply chain. This involves providing evidence of e.g., where a product comes from, where it was stored, at what temperature, and where it is going. Applying this to the vaccine becomes even more complex. As part of these track and trace procedures, serialization – assigning an individual product number to each saleable unit of a prescription product – plays a crucial role to ensure safety of pharmaceutical products.

The Drug Supply Chain Security Act (SCSA) will require serialization throughout the entire supply chain for pharmaceuticals beginning in November of 2023. While pharmaceutical companies are all working toward meeting those standards, they are not consistent across the entire supply chain yet. So, even if the vaccine were to be serialized right now, it could not be accurately tracked and traced through the entire chain. Therefore, for the vaccine, track and trace will have to be performed independently by each manufacturer and each part of the supply chain.

Just considering the above-mentioned aspects makes it clear that the vaccine distribution requires a concerted effort between supply chain partners to guarantee seamless operations without damage to the valuable goods. Knowing the requirements and operations of the distributor to develop a solution is crucial and track and trace is a must, but there are more challenges to consider. In the next part of this blog series, we address the cold chain. This provides another set of unique considerations at each step of the supply chain for distributing the vaccine. The cold chain is required to keep the vaccine safe and must consider security to shield the vaccines from interference during transport.



Matt Deep

[Read more →](#)



[Read more](#) →

Let's connect!

