



COVID-19 Therapies and the Fast-Approaching Race For Cold Chain Logistics

As the focus on COVID-19 shifts from virus spread to resurgence prevention, a new story is emerging. The media now is reporting on the supply chain constraints a COVID-19 therapy is likely to bring. The mission to prevent the virus's spread among more than seven billion people worldwide will create a run on global cold chain capabilities. Vaccination development speeds are moving historically faster than ever. While scientists and medical professionals are creating viable treatments, it will be the logistics industry who puts the life-saving therapies into the hands of people who need it most.



THE CONNECTION BETWEEN COVID-19 AND COLD CHAIN CAPABILITIES

For background, it is important to understand how Severe Acute Respiratory Syndrome (SARS), such as SARS-CoV-2, is treated.

People often compare coronavirus and influenza. The CDC classifies each as a “contagious respiratory illness.” However, SARS is a coronavirus for which no medication recommended for treatment or cure exist¹. Whereas, the CDC recommends four FDA-approved antiviral drugs² and numerous vaccines for the treatment of the three to four viruses causing influenza each year³, there are no FDA-approved therapies for COVID-19.

Absent an approved treatment for coronavirus, research is focusing on existing therapeutic efforts for influenza as a platform for prophylactic success. This includes messenger RNA (mRNA), cell-based, and traditional egg-based vaccines. Inherent to the vaccine manufacturing process, regardless of methodology, is the need to preserve treatment efficacy through storage at temperatures typically below 8°C (46°F).

Recent reports⁴ focus on mRNA vaccines as a “cell-free” and easily scalable process offering clinical batches of material just weeks after encoding the disease⁵. However, temperature profiles for mRNA therapies present a broader handling challenge. In August 2020, executives from Moderna and Pfizer reported their mRNA candidates (mRNA-1273 and BN1162b2) for coronavirus require storage at -20°C (-4°F) and -70°C (-94°F) respectively⁶. The combination of a need for frozen storage and the scale to which mRNA manufacturing efforts can quickly produce vaccination doses has created a pressing concern for available storage capacity among third-party logistics providers worldwide.

THE HISTORICAL CONTEXT OF DRUG DEVELOPMENT AND DEPLOYMENT

The drug development journey is a proven and tested one. Most drug candidates (including vaccines) are subject to rigorous “end points” across a landscape of sequential and regulated clinical trial phases (I, II, IIa, III and IV) before ever achieving commercial availability.

Traditionally, vaccine development is measured in years. Dr. Jonas Salk invested three full years in developing the polio vaccine before even announcing he had discovered a cure.⁷ The record for the fastest commercialization of a vaccine dates back to 1967 when Dr. Maurice Hilleman’s vaccination for mumps was licensed by Merck & Co., Inc.—four years after the first cultivation for the vaccine was developed.⁸ With a treatment expectation for COVID set at just months⁹, the typical drug development processes most vaccine manufacturers rely on are being challenged at every phase. The pressure to produce a viable prophylactic



product has shortened the capacity planning window of drug development woven throughout standard discovery models. With so much riding on treatment and prevention by 2021, proportionally less has gone toward preparing for manufacturing, warehouse storage, distribution, or delivery. The challenge becomes even more complex with viable vaccine candidates likely needing to remain frozen or near frozen for their entire lifecycle from manufacturing to patient inoculation.

PREPARING FOR COVID-19 VACCINE DEMANDS ON LOGISTICS

As of this writing, 46 vaccine candidates are under trial consideration. Approval of even one of these will strain the global supply chain. Professionals across academia, public sectors, private industry, and NGOs are hyper-focused on solving the rising concern for proper and ample storage of a COVID-19 treatment. Typical lead-times for infrastructure development needed to support a new drug launch have been compressed well below what most experts consider feasible. The lack of time for building validated storage facilities has created both opportunity and anguish for an industry skilled at serving the distribution of pharmaceutical and life sciences clients.

To solve this challenge, specialty third-party logistics providers are shifting focus from allocating existing space for historic seasonal vaccination inventory storage demands (such as influenza, with defined temperature requirements of 5°C for storage and distribution¹⁰), to planning entirely new spaces focused on quick-to-market therapies. Using CDC recommendations on handling vaccine distribution and storage¹¹, both the public and private sector are sprinting to create a network that ensures stability, efficacy, and reliable delivery. After all, this is arguably the most anticipated life-saving therapy of our generation.

THE LOGISTICS EXPERTISE NEEDED TO SAVE LIVES

The CDC's recommendation that state public health officials "consider partnering with the private sector"¹² for distribution of a vaccine to prioritized populations is clear. Given the timetable, wholesale distributors, hospital systems, public health officials, and third-party logistics providers have incentive for fast-paced collaboration. Managing a frozen vaccine requires a focused effort for procuring the proper storage equipment and validating that equipment for reliable use. Also essential is a team of experts with a deep understanding of time-out-of-refrigeration, qualified packaging systems, and logistics solutions capable of delivering on-time, in-full orders when needed most.

As the public and private sectors navigate the crossroads of product launch and vaccination policy, traditional methodologies and available vaccine storage space will provide a viable



platform. The skillset necessary for successfully bringing a commercially available COVID-19 vaccine to the point of patient intake includes: 1) collaboration on efficient execution of a supply chain model; 2) nimbleness around storage and distribution resource deployment; 3) innovative solutioning in response to evolving patient needs; and 4) capacity planning to maintain efficacy of a novel discovery, like the ones in the coronavirus treatment pipeline.

Langham Logistics, with our well-known reputation within the pharmaceutical industry, sits at the forefront of COVID-19 treatment distribution. When the vaccine is ready, we will be too. Find out more about our cold storage expertise or contact us at 855-214-2844 (Nick Hoagland, Sales).

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