



## LESSONS AND OPPORTUNITIES FOR THE PHARMACEUTICAL INDUSTRY

One of the few silver linings emerging from the coronavirus pandemic has been the remarkable speed with which vaccines have been developed. A lesser-known part of the narrative is that this success story was built on a robust knowledge-sharing infrastructure that was developed based on lessons learnt from past pandemics. In this article, we look at how smart use of available technology and approach to knowledge management has and could help the Pharmaceutical industry in battling this pandemic and rise to similar challenges in the future.



**Learning from the Past:** Lessons learnt from the epidemics of the past two decades have spurred the scientific community to work with global organizations to create knowledge sharing initiatives. The life-saving Ebola vaccine was a story of a missed opportunity and led to alliances such as GLOPID-R. The world realized that thousands of lives could have been saved if there had been coordinated efforts to complete clinical trials of the Ebola vaccine and take it to the market quickly. The vaccine was 100%

effective in priming the body's immune system to fight off the Ebola virus.

GLOPID-R is the only alliance of its kind in the world, that brings together global research funding organizations to facilitate rapid development of essential diagnostics, vaccines, and therapeutics at the outset of an outbreak with epidemic or pandemic potential. Another scientific initiative, GISAID launched after the 2006 H1N1 epidemic, has been instrumental in promoting rapid sharing of influenza

virus data as and when new strains emerge. Such initiatives facilitated rapid exchange of information at the start of this pandemic, paving the way for accelerated development of vaccines to fight COVID-19.

**Looking to the Future- Opportunities and Way Forward:**

While vaccine development occurred at a fast pace, the COVID-19 pandemic threw quite a few challenges that the Pharmaceutical industry was unable to effectively address (refer to Infographic)

	Challenges	Factors to consider	Consequences for Pharma Industry
Primary challenges from COVID-19	<b>Challenge with newer variants</b>	<ul style="list-style-type: none"> <li>WHO is tracking spread of four variants of concern (alpha, beta, gamma, delta). Delta+ and lambda (emerging variants) being studied for their propensity to escape immune response</li> <li>Pharmaceutical companies are studying the need for booster doses to maintain body's immune response against COVID-19. Combination of vaccines are also being studied</li> </ul>	<ul style="list-style-type: none"> <li><b>Manufacturing Capacity-</b> Regular booster doses for all vaccines represent a 100% increase in vaccine demand from pre-COVID levels of 3.5-5.5 B doses/yr</li> <li>26% of world population under-18. Manufacturing vaccines for this age group would further add to the strain on capacity</li> <li><b>Advanced cold-chain capabilities-</b> Need for refrigerated vehicles for transportation, monitoring and tracking vaccines temps. in transit, adequately refrigerated warehouses and last mile delivery to remote and rural areas</li> <li><b>Developmental Needs:</b> Need to invest in local talent development and pharmaceutical infrastructure in underserved regions of world (beyond article scope)</li> </ul>
	<b>Developing effective vaccines for the younger population (below-18 age group)</b>	<ul style="list-style-type: none"> <li>Strong case for vaccinating children before in-person teaching begins to protect them against potential threat from new variants</li> <li>In addition to planning vaccinations for under-18 age group, parents of infants below 4 yrs might need vaccinations on priority in the rare event of a need for isolation of infants</li> </ul>	
Structural deficiencies exposed by COVID-19	<b>Infrastructure for storing and dispensing vaccines</b>	<ul style="list-style-type: none"> <li>WHO estimates that more than 50% of all vaccines are wasted due to equipment failure or poor planning</li> <li>Losses from temperature excursions, including lost product cost, replacement cost and wasted logistics outlay are estimated at \$34.1 billion annually</li> </ul>	
	<b>Inequity in vaccine availability</b>	<ul style="list-style-type: none"> <li>WHO estimates that countries representing 53 % of the world population have received 83 % of the world's vaccine so far</li> <li>As of July 7th, 24.7% of the world population had received at least one dose of a Covid-19 vaccine. However, only 1% of people in low-income countries had received</li> </ul>	



- **GLOPID-R-** Global Research Collaboration for Infectious Disease Preparedness

**GISAID** is a global science initiative and primary source established in 2008 that provides open-access to genomic data of influenza viruses[3], the coronavirus responsible for the COVID-19 pandemic

**Operation Warp Speed (OWS)** is a public-private partnership initiated by the United States government to facilitate and accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics

The pharmaceutical industry could use lessons learnt from this pandemic as an opportunity to reset, analyze existing processes and build better systems. We explore ways in which technology can be and, in some cases, is already being effectively used to build

- Manufacturing systems that enable collaborative use of existing capacity and provide flexibility to add capacity
- Distribution systems with good cold chain capabilities and reliable tracking mechanisms

### How can pharmaceutical companies deal with manufacturing capacity constraint?

The task of manufacturing ~15 Billion vaccines within a short period of time is daunting. Building and maintaining unique manufacturing facilities required to produce new vaccines at scale could cost \$500 million to \$1.5 billion (Plotkin and others 2017). Validating newly built sites could take anywhere between 12 to 24 months or even longer depending on the geography, degree to which documentation is streamlined etc. Given the cost and time taken to expand manufacturing capacities, creative solutions and workarounds are the need of the hour.

Manufacturing of vaccines for polio (1.5 billion doses/yr), diphtheria and tetanus (0.7 billion doses/yr), meningococcal meningitis (0.7 billion doses/year) and seasonal influenza virus (0.5 billion doses/yr) have been impacted due to COVID vaccine production



### Sub-contracting and Technology

**Transfers** - The vaccine manufacturing landscape has changed dramatically, with three-fourths of the pharma & biotech companies having entered into agreements with contract manufacturers to develop COVID-19 vaccines. Innovator companies have formed alliances with manufacturing companies & ramped up manufacturing of vaccine via Technology transfer. Outsourcing/ sub-contracting/ tech-transfer has gained high significance as it offers significant advantages such as

end-to-end manufacturing solutions and expertise in vaccine manufacturing

In an increasingly digital world, life science companies will have to embrace solutions for content management and data sharing, that integrate seamlessly with other systems and business functions, both inside and outside the organization. There is also a pressing need to secure data and protect proprietary technology by building a cyber resilient IT infrastructure, with Biotech companies increasingly coming under Cyber Attack.

The Global "Vaccine Contract Manufacturing Market" Research Report (2021-2026), estimates that the vaccine contract manufacturing market size would reach US\$ 1785 million by 2026 at a CAGR of 5.3%



**Smart use of technology to drive efficiency across the manufacturing eco-system** Vaccine manufacturing requires specific raw materials, primary and secondary packaging materials. Shortage of these could be a roadblock in speedy manufacture of vaccines. Any effort to enhance visibility while not being a sufficient solution, could be a critical enabler that makes the manufacturing process more efficient. Traceability software solutions, next-

generation supply chain control towers that use digital twin technology to model constraints in transportation, warehousing and production are solutions that could increase visibility across the pharmaceutical supply chain.

Automation of repetitive manual tasks could be another way to reduce burden on skilled resources and build efficiency into the system (Refer to Infosys' proposed solution)

Infosys is bringing innovation in the form of AI & RPA to cut the time of getting paper recipes in digital format with a system called iRME.

- iRME automates preparation of reagents and buffers to improve efficiency and reduce wasteful use of workers' time
- It captures data electronically in the system, makes recommendations on ingredient quantities, handling and equipment to use to manufacture the product

**Building flexible manufacturing facilities:** The COVID-19 pandemic has highlighted the need for flexible or modular manufacturing capacity that can be easily deployed. Validation and qualification requirements for every single piece of equipment used in manufacturing makes capacity expansion a time-consuming and expensive process. To mitigate this challenge, manufacturers are moving towards the concept of disposable manufacturing equipment- bioreactors, chromatography columns, hold bags for storage. These

are part of a larger concept called 'factory in a box' or 'disposable factory' that was introduced more than a decade ago and is seeing gradual acceptance by the industry. Companies like GE Healthcare have developed a modular end-to-end biomanufacturing platform that allows manufacturers to add modules necessary to increase capacity. With the rise in flexible factories, there is increasing demand for adaptable and flexible 'Plug and play' automation platforms, that can enable centralized control of activities in a modular set-up.

## How Technology is helping address issues with cold chain distribution and problem of vaccine inequity:

Digital technology helps manage distribution once the products leave the factory. Tracking with IoT sensors can help identify weak links along the supply chain, like if there's a trend where temperatures change at a specific point in the route. The infographic provides examples of three companies using next-generation technology to address issues related to cold chain distribution

### Digital twin

*Cloud leaf, a supply chain company uses a digital twin that maps the product's transit history in real time. Sensors read light, temperature and humidity, along with manufacturing details like serial or lot numbers, enabling continuous monitoring of vaccine integrity.*

### Block-chain

*Vaccine Ledger, a block-chain based technology developed by StaTwig enables real-time monitoring of vaccine distribution, temperature excursions and other vital parameters. Vials are tracked globally using a unique serialization code. It has been deployed at Hyderabad Air Cargo facilities.*

### IoT

*Controlant Global, is helping track Pfizer's vaccines using IoT devices that route real-time data to it's proprietary cloud-enabled software and analytics platform. This helps prevent irreversible damage to vaccines due to temperature excursions.*

Creative use of technology is also helping reduce vaccine inequity by tackling the issue of last-mile delivery in underdeveloped regions of the world.

A French start-up, Kool Boks, has developed a solar-powered freezer to cater to the cold-chain requirements of Vaccines. Kool Boks provides IoT-fitted freezers whose temperature can be monitored from anywhere around the world. The company also has off-the-grid solutions for regions that do not have consistent power or internet. With 24/7 maintenance assured and a pay-as-you-go model, Kool Boks aims to revolutionize last mile delivery of vaccines in underdeveloped countries.

"Project Last Mile" is an initiative that taps into the deep supply-chain expertise built by Coca-Cola in Africa, Latin America, and Pacific nations. In Africa, 50% of the population does not have assured access to life-saving medicines, yet one can find a Coca-Cola product nearly everywhere on the continent. Coca-Cola, in partnership with the Bill and Melinda Gates foundation works with public

health centers and governments of various countries to redesign last-mile distribution of medicines, improve uptime of cold chain

equipment, and improve availability of chronic life-saving medicines by creating more pick-up points.



## Closing Thoughts

The COVID-19 pandemic has highlighted underlying challenges in health systems and equitable delivery of therapeutics and vaccines, that need to be addressed if we are to minimize the negative health and economic consequences. The time is ripe for the pharmaceutical industry to embrace the latest advancements in technology and position itself for the future.

## References

- India's vaccine distribution challenge, explained in five charts (livemint.com)
- StaTwig: Improving food and vaccines distribution systems more efficiently through blockchain | UNICEF Office of Innovation
- What we do – PLM – Project Last Mile
- Koolboks: Using Geospatial Technology and Solar Power to Provide Sustainable Refrigeration in Africa | Sun-Connect-News (sun-connect-news.org)
- Statista - The Statistics Portal for Market Data, Market Research and Market Studies
- Launch and Scale Speedometer, Duke Global Health Innovation Center
- About us – GloPID-R (glopid-r.org)
- Do COVID-19 variants mean that we need a booster shot for our booster? | Gavi, the Vaccine Alliance
- Pfizer CEO says third Covid vaccine dose likely needed within 12 months (cnbc.com)
- COVID vaccine: some waste is normal – but here's how it is being kept to a minimum (theconversation.com)
- Blockchain, IoT to Streamline Global COVID-19 Vaccine Distribution (counterpointresearch.com)
- Population Clock (census.gov)
- <https://www.cdc.gov/coronavirus/2019-ncov/variants/variant.html>
- <https://www.who.int/en/activities/tracking-SARS-CoV-2-variants/>
- [https://www.who.int/immunization/programmes\\_systems/procurement/mi4a/platform/module2/2019\\_Global\\_Vaccine\\_Market\\_Report.pdf?ua=1#:~:text=Global%20market%20volumes%20increased%20approximately,large-scale%20campaigns%20in%20India.](https://www.who.int/immunization/programmes_systems/procurement/mi4a/platform/module2/2019_Global_Vaccine_Market_Report.pdf?ua=1#:~:text=Global%20market%20volumes%20increased%20approximately,large-scale%20campaigns%20in%20India.)
- Bavdekar SB. Pediatric clinical trials. Perspectives in Clinical Research. 2013;4(1):89-99. doi:10.4103/2229-3485.106403
- <https://science.thewire.in/the-sciences/combining-astrazeneca-and-pfizer-covid-vaccines-may-boost-immunity-new-study/>
- Coronavirus (COVID-19) Vaccinations - Statistics and Research - Our World in Data

## About the Authors



**Ankita Mehta**

Consultant – Infosys Consulting

Ankita works within Life Sciences Consulting, supporting various Digital Transformation Projects for Regulatory. She has over 12 years of experience focused on Regulatory Affairs in both Pharmaceutical Industry and Clinical Research Organizations. Ankita has a Master's in Analytical Chemistry & DDRA. She is a PMP certified professional and is currently pursuing an Executive MBA degree from SP Jain School of Global Management.



**Anuja Chandrasekar**

Senior Consultant – Infosys Consulting

Anuja is a part of the Life Sciences Practice, where she has worked on M&A projects for global Pharmaceutical companies. She has ~ 7 years of industry experience in Pre-clinical research and LifeSciences consulting. Anuja holds an MBA in Strategy and Operations from the Indian School of Business and a Master's degree in Computational Neuroscience and Biophysics from University of Texas Health.

For more information, contact [askus@infosys.com](mailto:askus@infosys.com)



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