

Meeting the Challenges of Rapid COVID-19 Vaccine Cold Chain Deployment on an Unprecedented Scale

For months, pharmaceutical organizations and researchers worldwide have been focused on developing a vaccine for COVID-19. “Operation Warp Speed” (OWS), a collaboration among several U.S. governmental departments and 18 biopharmaceutical companies, was created to accelerate the development of a COVID-19 vaccine.

Upon vaccine approval, OWS will aim to deliver 300 million doses by January 2021. This is an unprecedented and complicated challenge, given the speed of deployment, global scale of distribution, and because some vaccine candidates must be stored at ultra-low temperatures (ULT), which are beyond the normal cold storage range for vaccines (-40 to -4 C).

Although OWS accelerated vaccine development/testing, meeting the cold chain storage requirements of a vaccine could prove the project’s most daunting challenge.

Today, few vaccine manufacturers, third-party logistics (3PL) providers, health care facilities or pharmacies are set up to

continuously store and transport vaccines in temperatures as low as -80 C. Therefore, to meet this monumental task, these organizations must rapidly ramp up ULT cold chain capacity — from end to end — to safely store and deliver vaccines to hundreds of millions of people.

There is a lot at stake. The World Health Organization estimates that more than 50% of vaccines may be wasted globally every year because of temperature control, logistics and shipment-related issues. Given the urgent global need for a COVID-19 vaccine, this is not an option. By proactively addressing key challenges, manufacturers, regional 3PLs and local points of patient care can rapidly deploy the ULT freezers needed to maintain vaccine efficacy while mitigating potentially negative financial and infrastructural impacts to their organizations.

Challenge:

Be prepared for the range of temperatures at which multiple COVID-19 vaccine candidates may have to be stored.

There are currently more than 30 vaccines in the testing pipeline worldwide, so it's not yet possible to tell at which temperatures an approved vaccine will need to be stored. It already appears that certain candidates will require -80 C storage, while others may only require -50 to -40 C and warmer storage. Not being able to meet the storage requirements of any one of the viable vaccine candidates could put all cold chain stakeholders at a disadvantage. The smart play is to cover all the bases now, so that they will be ready the moment vaccine approval arrives.

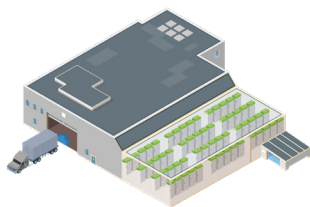
Solution:

Choose ULT freezers with the widest temperature range to optimize cold storage setpoints for most/all vaccine candidates.

Look for ULTs that can maintain the broadest range of temperature setpoints (from -86 to -20 C), not a limited range starting below -50 C. By opting for a ULT freezer that supports a wider range of temperatures, facilities can accommodate the storage efficacy requirements of more vaccine candidates, regardless of which are ultimately approved.

Challenge:

Overcome facility infrastructure obstacles when quickly ramping up ULT freezer capacity.



Few distribution center facilities are designed to house high-volume biobanking operations. As 3PLs and pharma distributors find themselves rapidly adding ULT freezer capacity, they can expect to encounter infrastructure challenges, including heat generation, limited floor space, power demands and high energy costs.

Significant heat output and HVAC load

Standard compressor-powered ULTs produce a lot of heat; the more ULTs in a facility, the more heat they produce. Rising ambient temperatures can have significant impacts on ULT performance, reliability and efficiency.

Once ambient temperatures exceed 26.7 C, compressor-based systems must work more, compromising efficiency, reliability and even shortening compressor lifespans. As compressors work harder, they produce even more heat. And as temperatures in these facilities rise, the HVAC systems will also have to work harder, leading to increased strain on the HVAC systems, higher energy costs and resulting freezer failure. Once ambient temperatures exceed 32.2 C, system reliability is compromised when using compressor-based ULTs, placing vaccines at risk.

For this reason, biobanking facilities generally require oversized HVAC systems and chillers to maintain optimal interior temperatures, particularly in warmer months of the year. Since distribution centers are typically not equipped for such significant HVAC loads, this could involve unforeseen building modifications, which potentially can threaten the planned ULT deployment budgets and schedules managed by 3PL organizations.

Floor space limitations

Distribution centers will have to ensure they have enough room to accommodate a multitude of ULT freezers; this goes beyond just having enough space for the physical cabinet of a freezer. They must account for freezer size, storage volume, door swings and ventilation clearances to make efficient use of floor space when setting up freezer farms.

Storage density should also be considered; it is measured by the number of vaccine doses that can be stored per freezer and within an available floor space. Inefficient use of ULT storage density will not only drive up valuable floor space cost, but can also increase the capital costs needed for purchasing more ULT units, with further ongoing energy, maintenance and infrastructure costs needed to operate additional freezers to accommodate a given storage capacity.

Electric power distribution, quality and cost issues

Aside from the physical space challenges, there also may be obstacles faced when powering these ULT units. Ultra-low temperature freezers typically plug into high-voltage power outlets with a range of outlets and power supply requirements when deploying units in various regions of the world. Depending on the ULT freezer models chosen, facilities may have to modify their building power and/or carefully plan ULT freezer options to accommodate a range of voltages and standards that are encountered globally.

A related concern is the availability of quality power. While not quite an issue in many regions, facilities have to contend with low-grade power in certain parts of the world, which presents abnormalities such as frequent brownouts, voltage/frequency variations and surges. Given that COVID-19 vaccine distribution will happen globally, power availability could be a significant challenge for those companies managing distribution centers in foreign countries.

Finally, distribution centers can expect a spike in costs to pay for the extra energy ULT freezers consume. ULT freezers can demand large amounts of power; standard compressor-based units consume as much electricity as an average U.S. household. Thus, distribution centers could see their energy costs skyrocket.

Solution:

Choose ULT freezers with more storage capacity that require less space, energy and infrastructure to operate over a wider range of ambient conditions and voltages.

When evaluating ULT freezers, pay close attention to exterior cabinet dimensions relative to how many samples they hold. Larger freezers don't necessarily store more vaccines. Choosing ULTs that offer a larger storage volume in the

cabinet and a smaller exterior footprint enables facilities to maximize vaccine storage capacity while minimizing floor space. By maximizing ULT freezer capacity, facilities may be able to reduce the number of units they need on-site, lowering capital purchasing and operating costs.

To reduce the burden on HVAC systems and lower energy costs, opt for ENERGY STAR®-certified units. By choosing high-efficiency ULTs, companies can significantly reduce energy use and costs, as well as the associated heat output and operating carbon footprint.

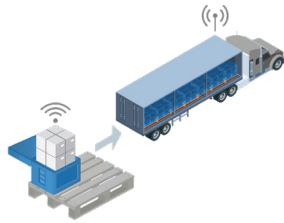
Stirling engine-based ULT freezers do not use compressors, which not only reject much less heat than standard compressor-based models, but operate safely at up to 35 C ambient room temperatures, thus maintaining vaccine integrity in warmer interior spaces and throughout a much wider range of ambient conditions.

Since Stirling engine-powered, ultra-low temperature freezers produce less heat and operate reliably in warmer conditions, COVID-19 vaccine storage facilities won't have to run their HVAC systems as hard and potentially can avoid expensive and time-consuming facility modifications when building new dedicated spaces or repurposing existing spaces for ULT freezer storage.

Some ULT freezers are designed to plug in anywhere. By merely changing power cords, these models can automatically switch across a wide voltage range, including standard outlets from 110 to 240 volts, to operate anywhere in the world without electrical modifications. Such units are ideal for distribution centers that are rapidly installing large ULT freezer farms and hope to avoid laborious building electrical system modifications. Some newer ULT technologies are even brownout-tolerant, making them perfect for deployment in developing countries where this is a concern.

Challenge:

Maintain the ULT cold chain as vaccines are transported from manufacturing facilities and regional distribution centers.

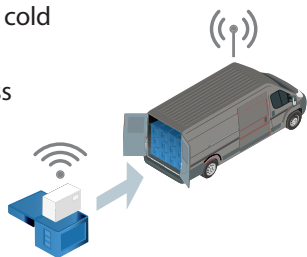


Vaccines undergo two critical transportation legs in their cold chain journey: one from manufacturing facilities to regional distribution centers, and another from those distribution centers to the many thousands of health care providers and pharmacies where doses will be administered to patients.

Manufacturers will need to temporarily warehouse most COVID-19 vaccines at optimal freeze-down temperatures, as staging areas for outgoing bulk shipments. Seamless cold chain temperature control must be maintained throughout the on-site storage, bulk loading and transport processes.

During bulk shipment to regional warehouses and parcel transport to local points of care, hold temperatures must be maintained with chain of custody and temperature tracking that is audited to ensure vaccine efficacy at final delivery. Maintaining cold chain during transport will also involve the use of dry ice, active refrigeration, passive cooling containers or a combination of these methods.

Established active and passive cold chain technologies may have limited range and effectiveness for COVID-19 vaccines that are stored at -80 to -50 C. For example, dry ice sublimates over time, potentially



causing unregulated temperature excursions that can risk vaccine efficacy, resulting in rejection and loss of product.

Solution:

Combine active and passive cooling with mobile temperature monitoring to eliminate cold chain gaps in transit.

Vaccine manufacturers and distribution centers can use a combination of active and passive cooling technologies to ensure vaccine efficacy while in transit. Active cooling technologies include stationary ULT freezers and shipping containers with built-in refrigeration powered by plug-in and/or battery backups to maintain cold chain cooling during transport.

Passive cooling options include vacuum-insulated panels (VIPs) and containers using phase-change materials (PCMs) that must be “charged” via active cooling prior to transport. When smartly used together, these cooling solutions can maintain storage temperatures throughout the cold chain at a lower weight and cost than active cooling solutions alone. While passive technologies can only maintain temperatures for a limited time, when periodically recharged using active cooling devices at manufacturing, distribution and vaccination sites, cold storage hold times can be maximized.

To assure the efficacy of vaccine doses in transit, temperature logging or monitoring must be integrated into shipping containers to establish a cold chain audit trail. Temperature-tale USB trackers or real-time wireless monitoring devices can be used, with cloud-based monitoring platforms enabling continuous cold chain of custody through all stages of the vaccine distribution process.

Challenge:

Maintain vaccine efficacy/cold chain at thousands of clinical and pharmacy sites around the world.



One of the most significant challenges of COVID-19 vaccine deployment will be maintaining safe and effective doses over extended periods of time in the hundreds of thousands of clinical sites and pharmacies where vaccines are administered. Built to deliver care, these facilities rarely are equipped with ultra-low temperature freezers. ULTs tend to be too expensive, bulky and noisy for clinical environments, and often require special power and infrastructure to operate. Passive and consumable cooling options, such as dry ice, will not provide the long-term temperature stability and control needed to safely store COVID-19 vaccines at ultra-low temperatures close to patient care.

Solution:

Use portable, benchtop and undercounter ULT freezers specifically designed for remote and compact spaces.

To maintain vaccine efficacy, point-of-care facilities and pharmacies have the option of deploying ULT freezers designed for remote and portable use in limited spaces. Units like Stirling Ultracold's ULT25NEU portable freezer and

SU105UE undercounter model are ideal for health care and retail pharmacy locations that will suddenly find themselves needing on-site, ultra-low storage for COVID-19 vaccines.

The ULT25NEU is built for portability and provides safe, long-term storage of vaccine vials at -86 to -20 C. The compact SU105UE undercounter model is ideal for use at clinical sites where a larger volume of vaccine doses must be stored in tight spaces. These compact, lightweight units deliver the same performance and reliability of full-size ULTs and can be easily moved throughout clinical sites and plugged into any outlet worldwide, avoiding the need for building rewiring or HVAC modifications. Lastly, these unique models provide point-of-care facilities with accurate temperature setpoint control and the abilities to monitor and log vaccine temperatures for maintaining a reliable audit trail on-site.



The ULT25NEU freezer is portable and plugs into any standard outlet, worldwide.

Keeping Vaccines Safe and Effective

Vaccine manufacturers, 3PLs and point-of-care providers face a range of complex challenges as they quickly ramp up ULT freezer capacity to meet COVID-19 distribution demands. Using facilities typically not built to house the number of ULT freezers required for global vaccine distribution, these organizations must start preparing for operational challenges now to scale up ULT storage capacity — even before a vaccine is approved — and do it in a way that doesn't risk vaccine efficacy, while limiting the infrastructural and financial impacts of rapid, large-scale cold chain deployment.



Learn more about our unique advantages for supporting vaccine cold chain at stirlingultracold.com/covid-19-products.

