

Marine *Newslink*

September 2020



FEATURE ARTICLE

Vaccine

PHOTO(S) OF THE MONTH

Vaccine

BACK TO BASICS

Question of the month

VACCINE

The world has never waited for a vaccine like it does now. More than 300 different vaccines are being experimented and tested worldwide but only nine have reached phase 3 trials, the final stage before implementation. The bigger question is manufacturing, transportation and distribution of the approved vaccines at global level. The security breaches of trial vaccines have already been reported from across the world and most from developed nations. Airlines and Parcel Service providers like DHL, UPS, FedEx have already started planning & gearing up for mass transportation of vaccine or vaccines, whenever the right one is ready.

Vaccines must be handled very carefully from the time they are manufactured until they are administered. Proper maintenance of vaccines during transport is known as the cold chain. A proper cold chain is a temperature-controlled supply chain that includes all equipment and procedures used in the transport and storage and handling of vaccines, from the time of manufacturer to administration of the vaccine. Vaccines are fragile. They must be maintained at the temperatures recommended by vaccine manufacturers and protected from light at every link in the supply chain. Most live virus vaccines tolerate freezing temperatures but deteriorate rapidly after they are removed from storage. Inactivated vaccines can be damaged by exposure to temperature fluctuations (e.g., extreme heat or freezing temperatures). Potency can be adversely affected if vaccines are left out too long or exposed to multiple

temperature excursions (out-of-range temperatures) that can have a cumulative negative effect. It is a good idea to post a sign on the front of the storage unit(s) indicating which vaccines should be stored in the freezer and which should be stored in the refrigerator.

These highly sensitive and important vaccines are required to have their own defined procedures which can be laid down as SOP's (Standard-Of-Procedures) or Checklists so that no important step is missed in their packaging, handling, storage and transportation.

► *Storage and Handling SOP's*

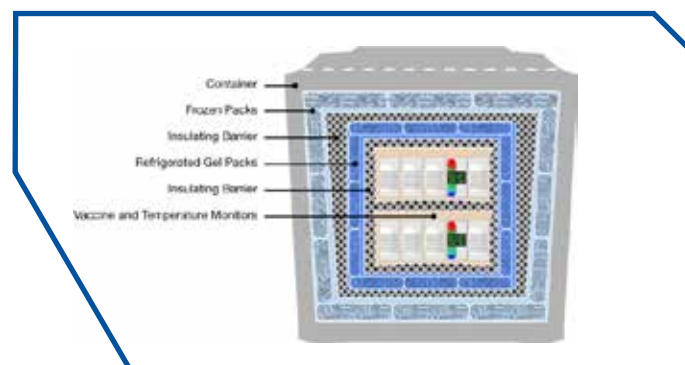
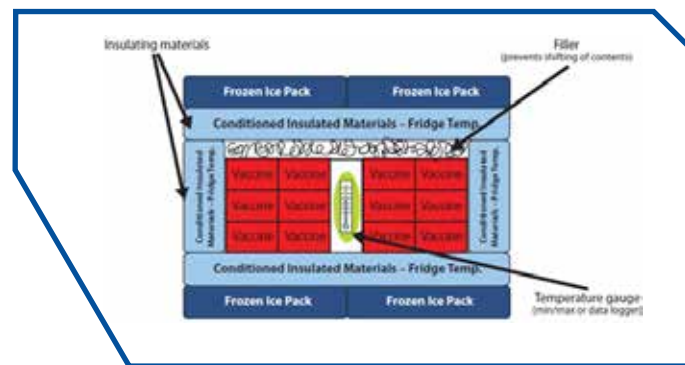


Standard-Of-Procedures should contain plans and information for three major areas:

- General information: include contact information-take it together for vaccine manufacturers, equipment service providers and important facility staff, as well as job descriptions, regularly used forms, and staff training requirements.
- Storage and handling SOPs: outline steps to be taken in the event of equipment malfunctions, power failures, natural disasters or other emergencies that might compromise vaccine storage conditions.

- Transport SOP: outlines step for types & modes of vehicles to be used. Vehicle inspection standards, requirement for accepting vehicles, loading, stowage & securing of cargo contents in trucks, seal management on trucks, stoppages & routes of trucks, Back-up power & repair arrangements on the route and emergency/incident reporting format.
- Each manufacturer, product & it's supply chain methods can have their own customized SOP's which should cover every aspect, from manufacturing to consumption.

this is the case, manufacturer's guidance should be strictly adhered for vaccine storage.



► Packaging



Vaccines must always be stored in their original packaging with lids closed until ready for administration. Vials and manufacturer-filled syringes should always be stored in their original packaging. Loose vials or syringes may be exposed to unnecessary light, potentially reducing potency and may be more difficult to track for expiration dates. They may also impact inventory management and increase the risk of administration errors because they may be confused with other vaccines. For certain purpose-built units, it is recommended that vaccine be stored outside of the packaging. If

-5 degree C to - 8 degree C: These vaccines are usually transported in appropriate size insulated box. These are insulated boxes, in which PCM (Phase Change Material) or commonly known as Gel-Packs placed at the bottom and vaccine boxes/packs are placed. Depending on requirement, gel packs are placed on all four or six sides of the vaccine or products. The gel packs are pre-frozen to maintain requisite temperatures in the insulated box and around the vaccine or product. The appropriate strength gel packs can maintain temperatures up to 190 hours. A Temperature Data Logger is placed on the top of the cargo and the insulated box is closed/sealed. This box is then usually placed in a cardboard box of good strength. The box carries the details of vaccine/product and other precautionary details required for handling the cargo. If shipments are in multiple boxes, then these may be palletized and one box on each pallet will contain Temperature Monitoring Devices (TMD).

pallet will contain Temperature Monitoring Devices. The pallets are covered with thermal covers and moved from reefer vehicles to cold storages in airports. The pallets or boxes are only brought out when the aircraft is ready for loading them.



Some airlines and airports offer cool-dolly services which are power-backed refrigerated ULD (Unit-Load-Device or air containers) that are used for storing such products at the tarmac, between removing from airport cold storage and loading on the aircraft.

15 degree C to 25 degree C: These vaccines/products can be packed in cardboard boxes. The vaccine/product in is first packed in a primary box with product and manufacturer's details or simply the brand box. These are placed in cardboard box of appropriate strength. Mostly such shipments are palletized & covered with thermal covers to avoid any serious temperature excursions during transit. Such covers can also provide some protection from rain or sudden showers.



Vaccine Storage and Temperature Monitoring Device

It is important that the facility has proper storage and monitoring equipment that is set up correctly, maintained appropriately, and repaired as needed.

Vaccine Storage Units: Refrigerator and Freezer Recommendations

There are several types of vaccine storage units available. Purpose-built units are specifically designed to store vaccines.

However, household refrigerator units are also an acceptable option for vaccine refrigeration under the right conditions.



- **COLD ROOMS:** Purpose-built or pharmaceutical-grade units designed to either refrigerate or freeze. These units can be compact or of large room size. These are sometimes also referred to as “pharmaceutical

grade” and are designed specifically for storage of biologics, including vaccines. These units are equipped with microprocessor-based temperature controllers with a digital temperature sensor (thermocouple, resistance temperature detector [RTD] or thermistor). These may also have fan-forced air circulation with powerful fans or multiple cool air vents promoting uniform temperature and fast temperature recovery from an out-of-range temperature.



- **REFRIGERATION:** Dedicated Refrigerators are also an acceptable alternative to pharmaceutical-grade vaccine storage units. The freezer compartment of this type of unit is not recommended to store vaccines and there may be other areas of the refrigerated compartment that should be avoided as well. If vaccine requires freezing, a dedicated freezer unit will be required.

Temperature Ranges for storage units:
Refrigerators should be able to maintain temperatures between 2° C and 8° C (36° F and 46° F). Freezers should be able to maintain temperatures between -50° C and -15° C (-58° F and +5° F).

▶ Data Loggers



Temperature Data Logger (TDL) or Temperature Monitoring Device (TMD): A TDL/TMD provides the most accurate storage and transport unit temperature information, including details on how long a unit has been operating outside the recommended temperature range (referred to as a “temperature excursion”). Unlike a simple minimum/maximum thermometer, which only shows the coldest and warmest temperatures reached in a unit, a TDL/TMD provides detailed information on all temperatures recorded at preset intervals.

Many TDLs use a buffered temperature probe, which is the most accurate way to measure actual vaccine temperatures. Temperatures measured by a buffered probe matches the vaccine temperature more closely than those measured by standard thermometers, which tend to reflect only air temperature. Temperature data from a TDL can either be downloaded to a computer using special software or retrieved through a website. The software or website may also allow you to set the frequency of temperature readings.

Use a TDL or other appropriate TMD (Temperature Monitoring Device) for:

- Each vaccine storage unit
- Each transport unit

Have at least one backup TDL/TMD, in case a primary device breaks or malfunctions.

Cold-Chain Transportation

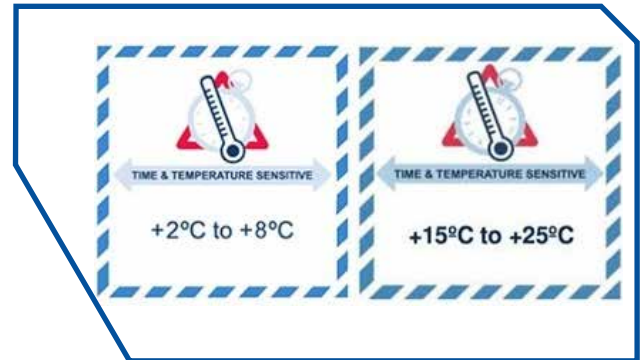
Transportation of critical products is always the weakest link in the entire supply chain of a product. The products are most vulnerable to damages during handling and transportation. Excessive jerks and jolts or vibrations may cause the product packing to disintegrate and if the product is liquid then the spilled contents will also cause damages to neighboring cargoes. In Pharma, such spillages may cause the details on adjacent packages to become illegible thus causing those Pharma items to be Incinerated/destroyed.



In domestic transports, vaccines can be transported in pharma-dedicated refrigerated/reefer vehicles. These trucks are equipped with active Temperature Monitoring Devices (TMD) and are also equipped with emergency backup generator, so that in case of vehicle failure the refrigerated machinery can be kept running. Many transport companies operate dedicated Pharma reefer fleet trucks which are equipped with GPS and emergency/panic button to send out SOS signal. However, each such vehicle should be thoroughly checked before accepting it for intended cargo and transit.

Airport Transportation

Air shipments are usually palletized and packed in cold-chain boxes depending on their temperature requirements:

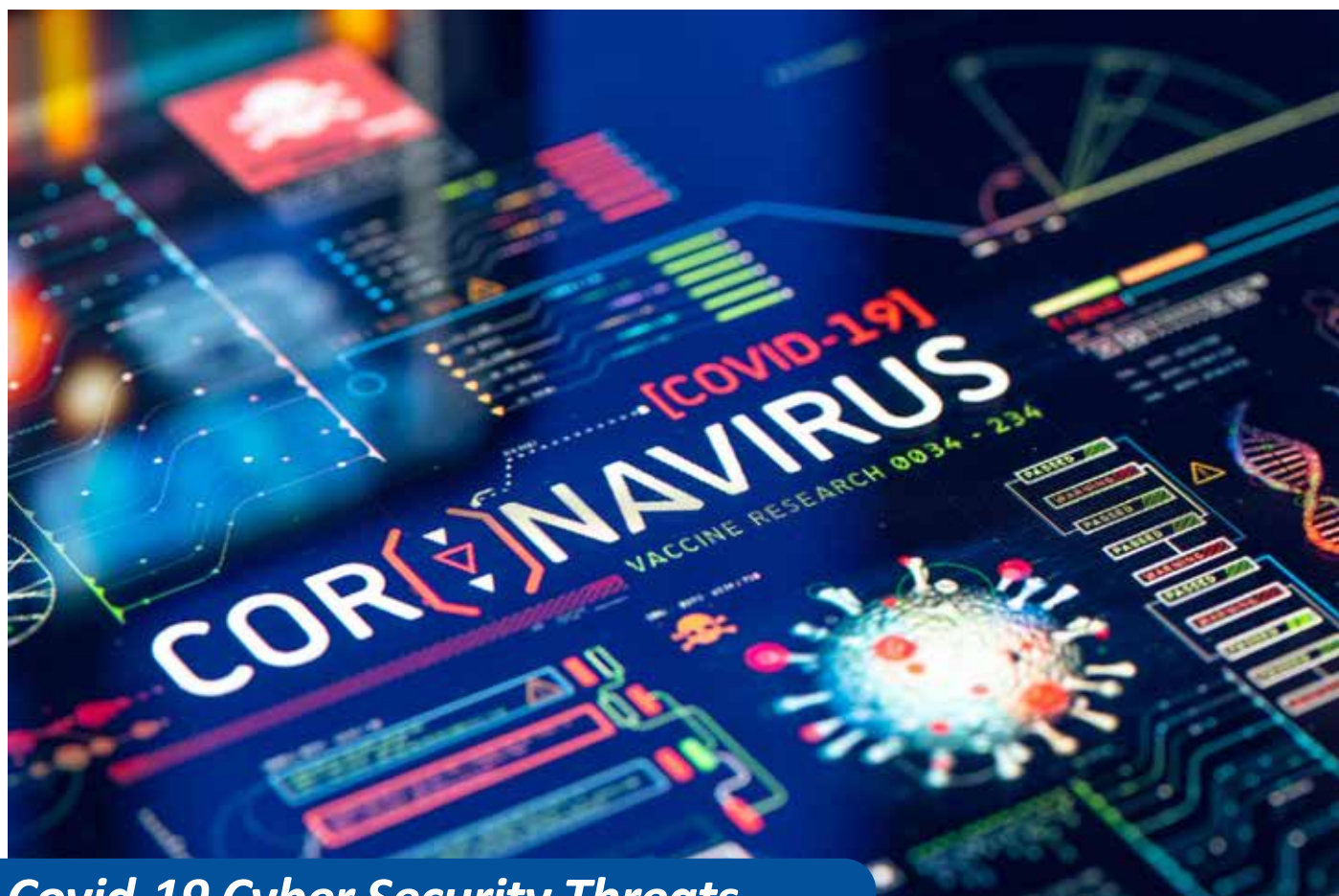


Shippers must ensure that there is complete transparency of air shipments: Cold-Chain and other facilities or vaccine handling and storage at loading airports. Airlines and their procedures for such cargoes. Uses of portable or ULD-based refrigeration units between airport warehouses and aircrafts. Trans-shipment airports and facilities at such airports, assessment of every possible risk at such airports and finally custom and other clearances at destination airports.

Security

Once the COVID vaccine is ready, the biggest threat will be security threats like thefts and hijacks. The shippers and governments will have to plan ahead to avoid any such untoward incidents. A single shipment loss may mean backlog and arrangement of substitute shipment. Not to mention, loss of life in absence of time-bound vaccines. Authorities, Shippers, logistics companies will have to invest in specialized or upgrade their vehicles & fleets, armed escorts, secure & defined stoppage locations for long distance transits, travel schedules to avoid high risk areas during dawn & dusk hours, contacts with police & authorities on the route and such. Whenever the vaccine is ready, the world will see unprecedented movement, unimaginable at present about its sheer volume and demand. Stay Safe.

PHOTOS OF THE MONTH



Covid-19 Cyber Security Threats



World-wide Coronavirus Vaccine

BACK-TO-BASICS

QUESTION OF THE MONTH

Vaccines from which three countries have been entered for human trials?

LAST MONTH'S QUESTION

Ethanol is primarily used in manufacturing of which product & what is its second most usage?

LAST MONTH'S ANSWER

Ethanol is primarily used in manufacturing of Fuel & Fuel Additives and second most usage is in Alcoholic Beverages followed by Industrial Solvents.

CORRECT ANSWERS SENT BY: (In order of replies received)

- PARESH SHAH - Madhuvan Insurance Broking Services Pvt. Ltd., Ahmedabad
- ROHAN DINESH LODAYA - Insurance World, Vadodara
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