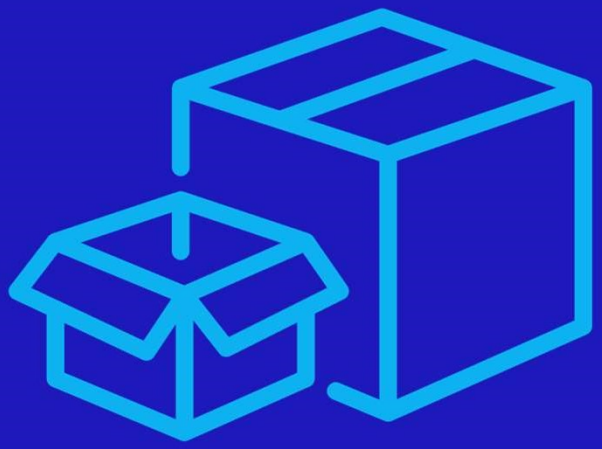
Assembling Packing & Redistribution Supplies



General Guidelines

- Only full trays (195 vials) should be redistributed at freezer temperatures
- Individual vials and trays must be redistributed at 2-8ºC, subject to the following recommended actions
- Trays or cartons that house the vials should be designed as small as possible so that vials are packaged securely and should protect the product from the distribution environment.
- Tray or carton materials should be capable of withstanding exposure to the product's required temperature setting.
- Consider robust materials for packaging, specifically to withstand dry ice transport and condensation.
- Tray should be able withstand the weight of the vials it is intended to transport.
- If intended to carry by hand, consider final weight of packaging for those who will be transporting the vaccines.
- It is recommended that protection and security devices (i.e. seals) be incorporated into all packaging to prevent tampering.
- If using Phase Change Material (PCM) coolant, fire testing/storage capacity constraints should be considered.
- Whenever possible, use packaging that has been tested to industry standards.

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Redistribution Container Considerations

- When selecting a thermal container for redistribution, ensure the packaging is fit for purpose and meets the Pfizer & BioNTech COVID-19 vaccine cold chain requirements.
- It's recommended that thermal containers have been tested against recognized standards (i.e. ISTA, ASTM). Make sure the containers and pack-outs are qualified to meet the required temperatures.

Considerations if Shipping Full Trays in Freezer (-90° to -60°C)

- Payload area needs to be capable of accommodating a thermal/insulated glove to remove the product.
- Coolant is typically dry ice for this type of container.
  - **Avoid liquid nitrogen as a coolant, which can damage the vials and stoppers**. Consider inner thermal packaging material that can withstand the condensation of dry ice.
- Provide dangerous goods training on handling dry ice.
- Vials should never be in direct contact with dry ice.

Considerations if Shipping Vials or Trays in Refrigerator (2° to 8° C)

- Consider freezer & refrigerator capabilities to condition coolant media (i.e. gel packs or PCM).
- If using PCM, conduct appropriate testing/storage related to fire concerns (EHS).

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Assembling Packing & Redistribution Supplies

Temperature Monitoring Devices

- Temperature monitoring devices are critical to ensure awareness of the vaccine temperature at all times.
- When selecting a temperature monitoring device for redistribution packaging, be sure to follow local board of health guidelines. See appendix for list of temperature monitoring device vendors.
- Do not use Pfizer's temperature monitoring device included in the Thermal Shipper for redistribution

Considerations for Temperature Monitoring Devices that Adhere to Good Practice (GxP) Requirements:

- ❑ High & low temperature alarms
- ❑ LCD Indicators (alarm or OK)
- ❑ Current temperature reading or method for accessing temperature requirements
- ❑ Integration to data analysis software (software compliant with 21 CFR Part 11 Systems)
- ❑ Recording interval with a minimum of every 15 minutes
- ❑ Start-up delay option
- ❑ Certified by the local governing body in charge of temperature monitoring and standards
- ❑ Probe or probeless
  - Some probeless temperature monitoring devices stop displaying temperature and require the display to acclimate to ambient temperatures before reading for dry ice shipments.
  - If re-icing is occurring, make sure if using probes, the temperature monitors are properly secured to ensure appropriate readings.
- ❑ If using a -90° to -60°C container, the temperature monitoring device should have a minimum -90°C temperature measurement range. Make sure when you are selecting a device that it's capable of monitoring a wider temperature range than the required storage conditions.

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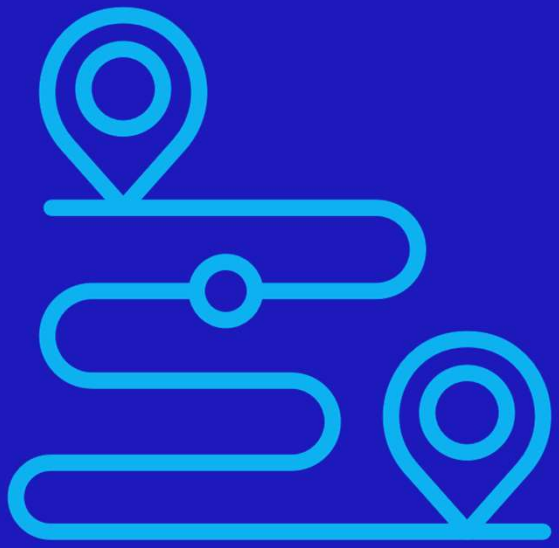
Preparing to Transport or Ship



General Guidelines

- Portable vaccine refrigerator and freezer units are considered the best option for vaccine transport. Portable vaccine refrigerator and freezer units that have built-in temperature regulation are optimal.
- Vials should be stored upright whenever possible. It is understood the vials may roll around in the trays when being moved in and out of storage.
- Thawed vials should be securely packed when transported.
- Caution should be taken while handling frozen vial trays to avoid damage to vials.
- Temperature tracking logs/alarms should be put in place for full trays and loose vials during transfer activities, pack-out, deconsolidation and redistribution.
- If transporting in a container with dry ice, avoid direct contact of paperboard materials with dry ice. Vials should never be in direct contact with dry ice.

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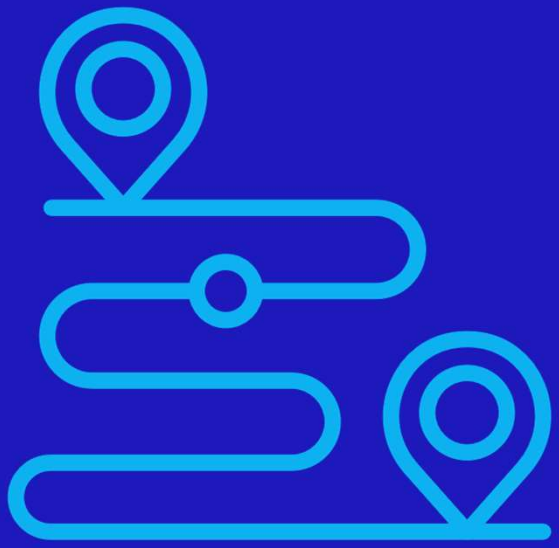

General Guidelines *(continued)*

- Do not submerse vials in cold water or ice water bath.
- Visible ice formation on outside of thermal container may be an indication of internal temperatures exceeding low range of –90°C.
- Point of Distribution (POD) should leverage their existing handling and packaging expertise and POD Standard Operating Procedures (SOPs) and protocols for transport preparation.
- Meeting cold storage requirements of product at distribution center is essential.
- Vials must be transported un-diluted. Do not transport vials after dilution.
- Select appropriate mode of transportation based on final weight of packaging.
- Avoid leaving containers in areas where they are exposed to direct sunlight.

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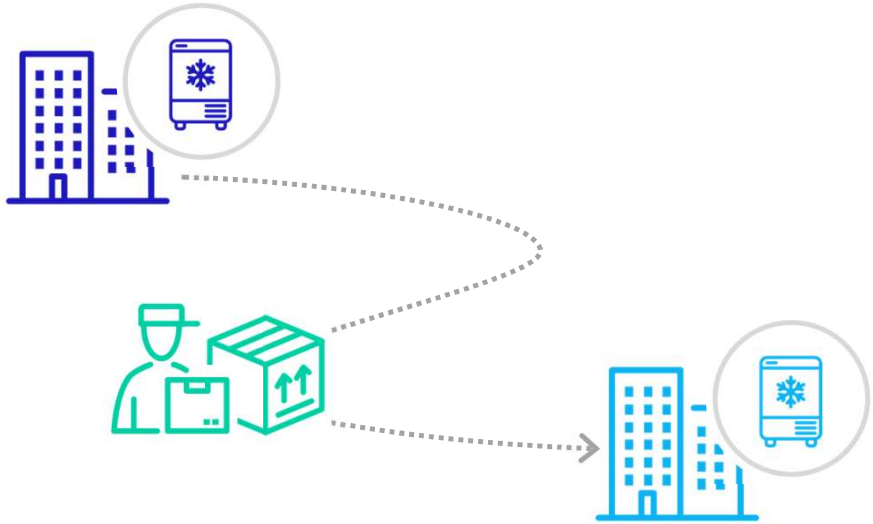
Preparing to Transport or Ship

Transferring full trays to an Ultra-Low Temperature (ULT) container (-90° to -60°C)

- Trays that arrive in frozen trays with 195 vials – which are kept closed – should not be at room temperature for longer than 5 minutes.
- Before repacking the vials into another thermal shipping container for transport, bring the vials back to -90° to -60°C (ULTF or Pfizer Thermal Shipper) before transferring to new container.
- Pfizer does not recommend the re-use of its Thermal Shipper for redistribution due to the potential for damage to the container and to ensure that it is returned no later than 30 days after receipt.

EXAMPLE

A centralized ultra low temperature freezer (ULTF) point of distribution (POD) receives vaccine shipment in a Pfizer Thermal Shipper then after a few days redistributes some quantity to another site with a ULTF.



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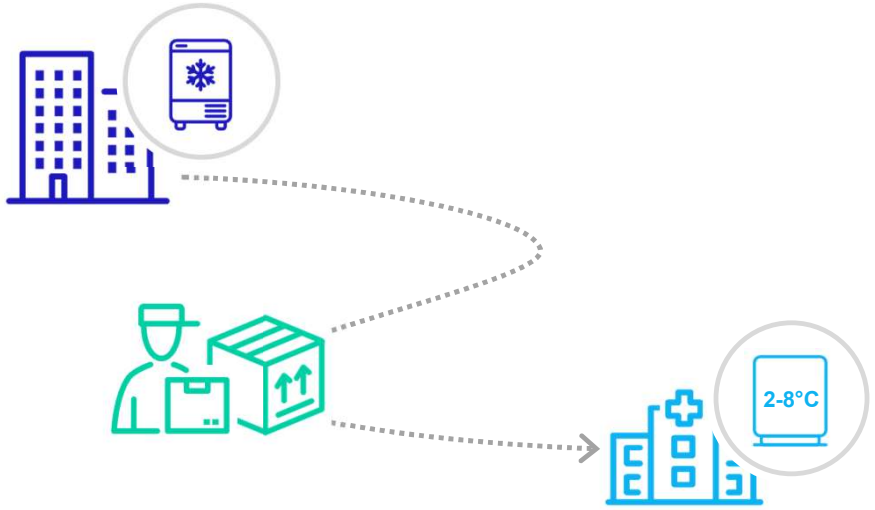
Preparing to Transport or Ship

Transferring vials or full trays to a refrigerated container (2° to 8°C)

- Based on current stability studies, a tray of 25 vials or 195 vials may take up to 2 or 3 hours to thaw in the refrigerator, respectively, whereas a fewer number of vials will thaw in less time. Vials may be stored in the refrigerator for up to 5 days (120 hours).
- If less than a full tray is repacked for redistribution, POD will need to provide smaller packaging unit that is transported via reputable courier or a temperature control vehicle (TCV).
- Repacking should be done in a 2° to 8°C environment whenever possible. Otherwise, time at room temp should be tracked and minimized to stay within the 2-hour allowance for room temperature.
- If using 2° to 8°C for transportation, POD needs to have a process to ensure that the 12 hours available for transportation at 2° to 8°C is not exceeded.
- The 12 hours available for transportation should be included as part of the total allowable 120 hours of product stability at 2° to 8°C.

EXAMPLE

A centralized ultra low temperature freezer (ULTF) point of distribution (POD) receives vaccine shipment in a Pfizer Thermal Shipper then after a few days redistributes to a rural area or point of use (POU) with a 2° to 8°C refrigerator.



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Transporting or Shipping

General Guidelines (CA doesn't allow shipping)

- Product packaging for transportation or shipping
  - An appropriate container should be used to minimize the potential for vials to be jostled. If vials are inadvertently bumped, they should be righted, however the risk to the product is minimal and vials which are temporarily knocked over may still be used.
  - If being transported outside of original trays, vials must be packaged securely to avoid breakage and to prevent vials from rolling during transport.
  - It is recommended that whenever possible that frozen vials are transported in unopened, full cartons.
  - Product should be stored in an insulated container filled with dry ice or gel packs. Vials should avoid direct contact with dry ice.
  - Packaging should include a temperature monitoring device in/on the insulated container as required by local health boards
- During transportation, frozen vials that are unsecured could become damaged.
- Thawed vials should be kept upright during refrigerated storage.

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Transporting or Shipping

General Guidelines *(continued)* (CA doesn't allow shipping)

- Rough handling of the thermal shipping container is linked to excessive sublimation of dry ice cooling below -90°C (if dry iced is used)
- Temperature should be controlled and monitored during transportation
- Action/review required in case of incident during transportation (e.g. temp deviation, off-road, unexpected box opening, delay, etc.)
- Ensure that commercial courier/transport provider is licensed to provide commercial transportation and has experience in handling pharmaceutical products/dry ice (if dry ice is used)
- In remote locations or where infrastructure is limited, drones could be a mode of transport for redistribution ensuring appropriate testing.

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Transporting or Shipping

Temperature Control Vehicle (TCV) Shipping
When Available

- TCV or refrigerated truck should maintain temperature at 15-25°C throughout transport
- 2-8°C container should be used in addition to the TCV maintaining temperature
- Ideally, same day service is used with an insulated container filled with dry ice or gel packs to ensure product is kept at the right temperature (max 12 hours transportation time at 2-8°C)
- TCV or refrigerated truck can be used for both larger shipments to direct points and milk runs (defined routes with drop-offs at specific points) and deliveries for large or small shipments to multiple points

Tracking Shipment tracked through TCV or device GPS tracking capabilities for real-time shipment status milestones and alerts

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