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		Effective date: 17-Sep-2025	

1. PURPOSE

To outline the responsibilities and expectations of the LSP as it relates to collection, transportation and delivery services for Sarepta Therapeutics. These are Cell & Gene Therapies for patients.

2. SCOPE

This Work Instruction is applicable to all the Logistic Service Partners handling Sarepta Commercial Program 9001 shipments.

3. DEFINITIONS AND ABBREVIATIONS

LSP - Logistics Service Provider
POC - Point of Contact
HAWB - House air waybill
MAWB - Master air waybill
HCPOD - Hard Copy Proof of Delivery
SOC – Site of care
L1 - Leg 1
L2 - Leg 2
L3 – Leg 3
SP – Specialty Pharmacy
POD – Proof of Delivery
PHS – Payload Holding System
HCPOD – Hard Copy Proof of Delivery

4. RESPONSIBILITIES

4.1 LSP Service Requirements:

- The service level for these shipments is White Glove. Drivers wear a proper uniform and carry the company's ID at all times.
- Where a dedicated or direct delivery service has been requested, the vehicle will proceed from the collection site to the delivery site without stopping for loading or unloading any additional shipments.
- Other vehicle stops will be limited to those required for driver safety/security and comfort or refuelling.
- The shipment is GPS-tracked and must move to designated delivery points only.



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4.2 LSP Vehicle / Driver requirements:

- LSP must provide picture of inside and outside of the vehicle including licence plate for approval before dispatching
- LSP must provide drivers name and phone number
- Required for each leg on every shipment.
- Identified preferred drivers that are always utilised
- Vehicle required at Catalent Philadelphia: 24 or 26 foot Dock high truck (must be able to be match a 48 inch high dock) or Cargo Van
- Vehicle required for remaining Pickup / deliveries: Cargo Van / Sprinter unless specified
- Vehicle must have straps and/or ratcheting load bars
- Vehicle must be clean
- Vehicle must have lock replaced after each milestone
- Driver must be able to lift up to 100 lbs without assistance.
- Driver must have a 4-wheel metal frame hand truck or 4-wheel dolly in vehicle
- Driver must have additional straps in vehicle
- Driver must have ID with them
- White glove delivery to naWhite Govlmed people only
- Driver cannot ask site personnel for assistance in loading or unloading the Elite Shipper from the vehicle
- Pictures of freight showing all four sides of the freight are required at each milestone
- Drivers to remain on site for processing time as requested
- Drivers to remain on site for unloading time as requested
- Liftgate requirements may be required based on site requirements and will be communicated

4.3 LSP 4-Wheel Hand truck / 4-Wheel Dolly requirements:

1. All will require a strap or mechanism to secure the 28L shipper down.
2. HARPER, 14 in x 7 1/2 in, 34 in x 13 in x 9 in, Convertible Hand Truck - 149CX2|JDC2223 - Grainger
3. DAYTON, 14 in x 8 in, 38 in x 13 5/8 in x 11 in, Convertible Hand Truck - 4W323|4W323 - Grainger
4. Milwaukee Hand Truck 2 in 1 Fold Up Convertible Hand Truck with Telescoping Handle 73333 from Milwaukee Hand Truck - Acme Tools
5. 2-in-1 Convertible Hand Truck - 800 Lb. / 600 Lb. Capacity - Harbor Freight



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5. CROSS REFERENCE

BD-SOW-02 Sarepta Commercial Program
BD-SOW-08 Sarepta 9001 Escalation Path
BD-TPL-01 Collection from Catalent PHL
BD-TPL-02 Specialty Pharmacy (SP) Collection
BD-TPL-03 Collection from Site of Care
BD-TPL-04 Specialty Pharmacy (SP) Delivery
BD-TPL-05 Site of Care (SOC) Delivery

6. PROCEDURE

6.1 Pick up/Collection:

- Driver to thoroughly complete checklists as per instructions 6.1.1, 6.1.2, 6.1.3 and 6.1.4
- LSP must provide picture of inside and outside of the vehicle including license plate for approval before dispatching
- LSP has to read and sign off on the Sarepta checklists, confirming he understands all requirements
- LSP must provide drivers name and phone number
- LSP arrives promptly at designated pick up time (but not earlier than 15 min)
- Vehicle must be locked after collection and before proceeding to next step
- LSP to provide HCPD as soon as possible on the provided CRYOPDP HAWB for the collection
- Pick up from **Catalent PHL** for all commercial flights: the LSP will attach a Temperature Controlled label on the shipper and write down ambient +15 - +25 Celsius and attach to the shipper, before tendering (labels are provided from CRYOPDP)
- Tender to airline per the information provided in dispatch email from CRYOPDP
- Provide pictures of the shipper prior to tender, all 4 sides (it has to show the seal of the shipper including the seal number)
- Provide constant updates if delays at airport at time of recovery / tender

6.1.1 Pick up/Collection at Catalent PHL

- Driver to thoroughly complete checklist **BD-TPL-01**
- LSP Driver arrives with 2 Air Waybills (AWB) for collection
- Catalent Personnel signs both AWBs
- Catalent Personnel places one copy in the outer pouch of the shipper
- This AWB remains in the pouch until delivery to Leg 2 (L2) location
- LSP Driver keeps one copy for LSP Files



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6.1.2 Pick up/Collection CCSF cargo at Catalent PHL- complete checklist BD-TPL-01

- CCSF Van and equipment requirements:
 - Driver arrives with min 5 serial zip ties (including back up) to cover all out and inside doors of the cargo van and additionally a Long Schakel PAD-LOCK for all outside doors
- LSP Driver documentation requirements:
 - The driver needs 2 copies of HAWB, 1 copy MAWB and CRYOPDP IAC Authorization to Handle CCSF Screened Cargo Written Certification for collection at Catalent PHL
- Check-in with Catalent personnel at the time of collection:
 - Driver arrives to the scheduled time at Catalent PHL
 - Driver must show his company ID including a picture and STA#
 - Driver must hand over the HAWB, Master AWB copies and CRYOPDP IAC Authorization to Handle CCSF Screened Cargo Written Certification
 - Driver provides the serial # of the zip ties (used for this transport)
- Catalent process the CCSF shipment:
 - Catalent will complete and sign the MAWB, HAWB and CRYOPDP IAC Authorization to Handle CCSF Screened Cargo Written Certification will be returned to the driver
 - Catalent Personnel places one copy of CRYOPDP HAWB in the outer pouch of the shipper
 - This CRYOPDP HAWB remains in the pouch until delivery
 - Catalent will fill out the CRYOPDP IAC Authorization to Handle CCSF Screened Cargo Written Certification and a CCSF Chain of Custody form including Master AWB #, all the seal #, and hand it over to the driver (the original document is required to be provided to the airline)
 - Driver will secure the shipper and lock all door of the cargo van with a serialized zip tie and Long Schakel PAD-LOCK
 - Driver has to check seal # on the form, everything has to match, driver will sign off on the CCSF Chain of Custody for, he is confirming the shipper is stored and locked in the van
- Tendering process at the Airline:
 - Arriving at the airline the driver needs to check in with the desk agent and advise them he has a prescreened cargo in the van
 - The driver has to present the Master Air Waybill, statement screened Cargo, the CCSF Chain of Custody and CRYOPDP IAC Authorization to Handle CCSF Screened Cargo Written Certification



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- Driver CANNOT open the van at the airline, he needs to present the CCSF documents and follow the orders of the airline personnel
 - Airline agent should break the seals and confirm the shipper has the CCSF seal or follow airline agent instructions
- Emergency situation / Van breakdown:
 - Inform CRYOPDP immediately about the breakdown
 - Arrange a replacement van submit pictures to CRYOPDP and wait for approval
 - Break the original van seals, and safely transfer the shipper to the new van
 - Secure the shipper and take picture and send it to CRYOPDP, transport the shipper to the airport
 - Tender the shipper under standard TSA screening procedures

In this scenario, the cargo would no longer be pre-screened.

6.1.3 Pick up/Collection at Specialty Pharmacy (SP) if applicable

- Driver to thoroughly complete checklist **BD-TPL-02**
- LSP Driver arrives with 2 Air Waybills (AWB) printed for the Leg 3 (L3) Shipment
-
- SP Personnel signs both AWBs
- SP Personnel places one copy in the outer pouch of the shipper
- This AWB remains in the pouch until delivery to (L3) location
- LSP Driver keeps one copy for LSP Files (LSP has to provide a copy to CRYOPDP)

6.1.4 Pick up/Collection from the hospital/ Site of care (SOC)

- Driver to thoroughly complete checklist **BD-TPL-03**
- LSP Driver arrives with 2 Air Waybills (AWB) for the Return Shipment to Cryoport Morris Plains
- SOC Personnel signs both AWBs
- SOC Personnel places one copy in the outer pouch of the shipper (this AWB remains in the pouch until delivery to (L3) location)
- LSP Driver keeps one copy for LSP Files (LSP has to provide a copy to CRYOPDP)

6.2 Specialty Pharmacy stop-over:

- LSP is taking pictures of the shipper after collection from Airline and shows the seal including seal number and sends it over to CRYOPDP, in case of missing or broken seal on the shipper please contact CRYOPDP immediately and standby for further instructions



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- LSP collects shipment from airport deliver immediately to Pharmacy for processing
- Delivery to the Pharmacy address must be completed in a cargo van (commercial vehicle required)
- Delivery **CANNOT** be made earlier than the scheduled time. Drivers can check in with POC 15 minutes before the scheduled time.
- LSP will deliver to the specific named person on the documentation only
- If Sarepta updates the POC, CRYOPDP will provide a new POC. LSP driver must cross out the previous POC and clearly note the new POC name.
- LSP cannot release the shipper to any other person
- LSP will wait up to 2 hours for inspection and processing
- LSP to provide HCPD as soon as possible on the provided HAWB for this portion
- Pharmacy will turn shipper back over to LSP for tender to airline for next leg of journey
- Pharmacy POC should sign the correlating HAWB for the re-collection
- Vehicle must be locked after re-collection and before proceeding to next step
- Provide constant updates if delays at airport at time of recovery / tender

6.3 Delivery:

- Driver to thoroughly complete checklists as per instructions on 6.3.1 and 6.3.2
- LSP must provide picture of the inside and outside of the vehicle including license plate for approval before dispatching
- LSP had to read and sign off on the Sarepta checklist, confirming he understands all requirements
- LSP must provide drivers name and phone number
- LSP to recover from airline
 - **LSP is to take pictures of the shipper at time of recovery from the Airline to show that the seal is still in place and send it over to CRYOPDP, in case of a missing seal please contact CRYOPDP immediately and standby for further instructions**
- LSP to remove all airline tape (Lifeguard or PPS Critical tape)
- Delivery to the Hospital address must be completed in a cargo van.
- LSP only can use their own equipment to complete the delivery
- **Delivery CANNOT be made earlier than scheduled time.** Drivers can check in with POC 15 minutes before the scheduled time.
- LSP to ensure delivery to the specific named person (POC) on the documentation
- LSP **cannot** release shipper to any other person, call CRYOPDP Escalation path to be followed



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- If Sarepta updates the POC, CRYOPDP will provide a new POC. LSP driver is to cross out the previous POC and clearly note the new POC name.
- LSP to wait on-site for unloading of shipper, up to 2 hours wait time
- LSP let sign the HCPOD's for the delivery part and the collection part from POC (2 different HAWB)
- LSP to provide a clear HCPOD of the delivery part after completing the delivery leg to CRYOPDP, the HCPOD for the collection has to be placed on top of the shipper's clear documentation holder
- LSP to recover the shipper with the remaining dry ice and all other internal components
- When the internal payload holding system (PHS) cannot be placed back into the shipper
 - The site personnel have been instructed to leave the PHS portion on the outside of the shipper
 - The LSP will ensure to take the PHS portion and replace it inside when they dispose of the dry ice.
- Vehicle must be locked after collection and before proceeding to the next step
- LSP to ensure to follow the dry ice greenlight process

6.3.1 Delivery Specialty Pharmacy (SP) if applicable

- Driver to thoroughly complete checklist **BD-TPL-04**
- SP Personnel sign the AWB from within the outer pouch and hand over to the LSP
- Driver for POD file. (LSP has to provide a copy to CRYOPDP)
- SP may make copies if needed for SP files

6.3.2 Delivery to Hospital / Site of care (SOC)

- Driver to thoroughly complete checklist **BD-TPL-05**
- SOC Personnel sign the AWB from within the outer pouch and hand over to the LSP
- Driver for POD file. (LSP has to provide a copy to CRYOPDP)
- SOC may make copies if needed for SP file

6.4 Return portion

- When the internal payload holding system (PHS) cannot be placed back into the shipper at the collection site
- The site personnel have been instructed to leave the PHS portion on the outside
- The LSP will ensure to take the PHS portion (metal frame) and replace it inside when they dispose of the dry ice.



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- LSP has to read and sign off on the Sarepta checklist, confirming he understands all requirements
- LSP to ensure to follow the Greenlight dry ice disposal
- The driver collects the shipper from SOC (site of care/ hospital).
- The driver returns to the LSP Depot/warehouse
- The driver alters LSP dispatch upon arrival
- LSP dispatch contacts CRYOPDP to request approval to open the shipper and dispose of the dry ice.
- CRYOPDP confirms the shipment is a return, approves the opening and disposal of the dry ice, and requests pictures of the empty shipper
- LSP disposes of the dry ice, removes the UN1845 dry ice label, affixes a new label with the word "Empty" to the outside of the shipper and provides pictures to CRYOPDP
- CRYOPDP approves the tender for the return shipment

6.5 POD

6.5.1 POD Requirements

- Name, Role, Date and Time, must be clear and fully legible.
- At the time of collection or delivery the specific portion must be completed by the driver prior to POD signing.
- Driver should ensure the title/role, date and time is clearly marked
- Any special notes, circumstances, critiques of collection or delivery must be noted legibly.
- Final copies of PODs must be SCANNED to sarepta@cryopdp.com, in order for payment approval.
- The scanned copies of POD must be clear quality and legible. Please ensure the signatures, date and time are legible
- Photo proof of POD is acceptable only for milestone updates not for final payment approval
- Drivers who download the CamScanner app (<https://www.camscanner.com/download>) can send PODs this way - the POD should be clear, no fingers, hands or clipboards in the picture.

6.5.2 Refusal of signature on CRYOPDP HAWB

- If a site refuses to sign a CRYOPDP HAWB at any of the legs, please contact CRYOPDP immediately.
- The LSP driver must note "REFUSE TO SIGN" and note the name of the person refusing to sign as well as the date & time on the appropriate section on the CRYOPDP HAWB.
- If the site gives a reason, please also note on the HAWB
- If the refusal is not noted properly, the payment approval process may be delayed or denied.

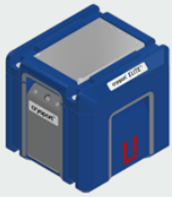


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6.6 Equipment Information

- The **Elite shipper 28L** has external dimensions of 20.5 x 21.1 x 20.3 inches
- Weighs 55 lbs empty and 100 lbs loaded with commodity and dry ice.

28 LITER



Temp Range
Internal: -60 to -80°C
Operational: -20 to +60°C
Storage: -20 to +25°C

Static Hold Time
5+ days | 140+ hours

Exterior
20.50" L x 21.15" W x 20.34" H

Interior
11.75" L x 11.75" W x 11.75" H

Payload
8" L x 8" W x 5.25" H

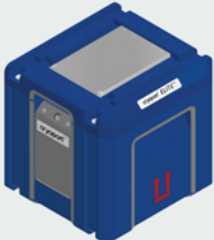
Weight
90-100 lb (fully loaded with dry ice);
55-60 lb (empty with payload holding system)

Pallet
2x2 in 2 levels (8 total)
48" x 48" pallet

Recommended Capacity
Patient materials, source materials, etc

- This Elite Shipper will take an initial total weight of dry ice of 16 kgs (35.2 lbs) and that weight must be declared on the Dry ice sticker UN1845.
- The **Elite shipper 56L** has external dimensions of 24.5 x 23.8 x 23.9 inches
- Weighs 75 lbs empty and 155 lbs loaded with commodity and dry ice.
- This Elite Shipper will take an initial total weight of dry ice of 32 kgs (70.5 lbs) and that weight must be declared on the Dry ice sticker UN1845.
- Due to the weight, the Elite shipper 56L will always be transported in a pallet. Once palletized, the final dimensions will be 30x42x30.5 inches.

56 LITER



Temp Range
Internal: -60 to -80°C
Operational: -20 to +60°C
Storage: -20 to +25°C

Static Hold Time
7+ days | 185+ hours

Exterior
24.55" L x 23.85" W x 23.93" H

Interior
15" L x 15" W x 15" H

Payload
12.75" L x 7.625" W x 8.25" H (This can be customized to fit packaging needs)

Weight
145-155 lb (fully loaded with dry ice);
75-85 lb (empty with payload holding system)

Pallet
2x1 in 2 layers (4 total)
48" x 48" pallet

Recommended Capacity
Large bulk quantities of vaccines, vials, cryovial boxes, etc

6.6.1 Dry Ice Replenishment

- LSP to replenish the dry ice when requested and complete the CRYOPDP Shipment verification Sheet - CC-TPL-57. Training will be provided on how to perform the replenishment procedure. See below the Re-icing escalation path:
- Cryoport Ultra Cold shippers have a temperature threshold warning exception trigger at -70C. Once this temperature is reached, the Ultra Cold shipper has approximately 24 hours of holding time remaining and should be assessed for potential re-icing.
- Once the -70C exception is received, the Logistics Management will perform the following steps.



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- Logistics Management will verify the pending delivery status of the shipment to see if the delivery window is within the 24-hour limit.
- If the delivery window is within the 24-hour time limit, continue monitoring of shipment
- If the delivery window is outside the 24-hour time limit, Initiate re-icing procedure

Any deviation from this work instruction, at any point during transport, stops or out of norm circumstances, LSP must contact CRYOPDP immediately.

6.6.2 Escalation point of contacts below (24/7)

Escalation level 1	Escalation level 2	Escalation level 3	Escalation level 4
Jenny Reinoso 347-804-5589	Anne Coughlan 908-335-6296	Moe Mir 347-804-7982	Carter Buck 610-809-9657

7. DOCUMENT REVISION HISTORY AND APPROVAL

Version	Date	Description of Change
01	30/08/2023	New document
02	06/09/2023	Add more details about the POD process
03	22/08/2024	New updated format and review. Change the name of the Document from Sarepta Guidelines to Sarepta LSP Work Instruction
04	24/09/2024	Added new requirement for Collections and Deliveries to complete checklists Added the Cross reference name and numbers of the checklists Change version number and effective date
05	26/02/20205	Added in 4-wheel hand truck/dolly requirement
06	02/05/2025	Added a 6.1.2 Pick up/Collection CCSF cargo at Catalent PHL- complete checklist BD-TPL-01.
07	17/09/2025	Added to 6.1.2 Pick up/Collection CCSF cargo at Catalent PHL- Emergency situation / van breakdown



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Prepared by	Jenny Reinoso	 Signature
Job Title	Sr. Implementation Manager	
Date	2025-09-17	

Reviewed by	Moe Mir	 Signature
Job Title	Director of Operations	
Date	2025-09-17	

Approved by	Jazmin Reyes	 Signature
Job Title	Quality Manager	
Date	2025-09-17	

Audit trail

Details

FILE NAME	BD-WI-04 Sarepta LSP guidelines V07 - 17/09/2025, 15:10
STATUS	● Signed
STATUS TIMESTAMP	2025/09/17 19:29:05 UTC

Activity

 SENT	jazmin.reyes@cryopdp.com sent a signature request to: • Moe Mir (moe.mir@cryopdp.com) • Jenny Reinoso (jenny.reinoso@cryopdp.com) • Jazmin Cruz Reyes (jazmin.reyes@cryopdp.com)	2025/09/17 19:10:28 UTC
 SIGNED	Signed by Jenny Reinoso (jenny.reinoso@cryopdp.com)	2025/09/17 19:11:21 UTC
 SIGNED	Signed by Jazmin Cruz Reyes (jazmin.reyes@cryopdp.com)	2025/09/17 19:11:08 UTC
 SIGNED	Signed by Moe Mir (moe.mir@cryopdp.com)	2025/09/17 19:29:05 UTC
 COMPLETED	This document has been signed by all signers and is complete	2025/09/17 19:29:05 UTC

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