





Checklist for SRP-9001 Bulk Shipments For the Logistics Service Provider Marken

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1. Equipment /Supplies


All shipment solution items are sourced by Logistics Service Provider to the CDMO.

Item	Manufacturer	Description	Image
Va-Q-proof 57	Va-Q-Tec	Dry Ice Shipper	
2 x SAGA -P	Controlant	Smart Sensor Device	
Serialized Security Seal	Uline	Serialized Security Seal	
Outer carton with special height and three flaps at the front for va-Q-proof 57	N/A		

2. Shipment and documentation preparation

Shipment Scheduling, Controlant Shipment, and Documentation Preparation		
1	Ensure shipment is booked and received in the LSP portal	<input type="checkbox"/>
2	Ensure the proforma invoice from Sarepta, USA is received. If not, contact the Rochel Logistics team.	<input type="checkbox"/>
3	<p>Create the Shipment in the Controlant SCM website</p> <ul style="list-style-type: none"> ● Navigate to the Shipments View. ● Press the “Create a Shipment” button at the bottom of the screen. ● Choose between a template-based shipment and a custom shipment. ● Use the live shipment AWB number to name the Controlant shipment <p>3.1 Check if the created shipment appears in the Preparation tab under the section "Ready to ship".</p>	<input type="checkbox"/>

Additional Setup		
1	Placement of required boxes are booked and will be delivered to Catalent Philadelphia on the date indicated in the booking accordingly	<input type="checkbox"/>
2	Live shipment AWB copies are attached to the shipment pouch to be delivered to Catalent Philadelphia.	<input type="checkbox"/>
3	Confirm the Shipment in Controlant is created indicating the live AWB No as reference	<input type="checkbox"/>
4	Seal numbers are indicated in the AWB	<input type="checkbox"/>
5	Book the shipment with the airline and communicate Roche Logistics team about the booking details (Flight, ETD and ETA)	<input type="checkbox"/>

Shipping Solution Preparation		
1	Va-Q-Proof 57 Shipper Solution:	
	<ul style="list-style-type: none"> • Ensure the right quantity of Va-Q-Proof 57 shippers & outer boxes 	<input type="checkbox"/>
	<ul style="list-style-type: none"> • Use PPE, including gloves and safety glasses, while handling the shipping solution. 	<input type="checkbox"/>
	<ul style="list-style-type: none"> • Ensure the shippers are fully conditioned 	<input type="checkbox"/>
	<ul style="list-style-type: none"> • Inspect the shipping solution for any leaks or damages. 	<input type="checkbox"/>
	<ul style="list-style-type: none"> • Ensure the Controlant Saga-P Logger placement sheet is included. 	<input type="checkbox"/>
	<ul style="list-style-type: none"> • Ensure you added two plastic sleeves at the outside of each box 	<input type="checkbox"/>
		
	<ul style="list-style-type: none"> • Assemble and load with dry ice. 	<input type="checkbox"/>
2	Controlant SAGA-P Smart Sensor Devices:	
	<ul style="list-style-type: none"> • Ensure the right quantity of Controlant SAGA-P smart sensor devices (2 devices per Va-Q-Proof 57 shipper). 	<input type="checkbox"/>
	<ul style="list-style-type: none"> • Ensure there are no physical damages on the devices. 	<input type="checkbox"/>
	<ul style="list-style-type: none"> • Verify the devices are powered up. 	<input type="checkbox"/>
	<ul style="list-style-type: none"> • Confirm each device has batteries and is charged to at least 98%. 	<input type="checkbox"/>
	<ul style="list-style-type: none"> • Check that each device is blinking every 5 seconds. 	<input type="checkbox"/>
	<ul style="list-style-type: none"> • Verify that the logger ID number on the label matches the logger ID number indicated on the AWB. 	<input type="checkbox"/>
	<ul style="list-style-type: none"> • Ensure Logger probe placement and cable management 	<input type="checkbox"/>

	<ul style="list-style-type: none"> Place Loggermount and logger, ensure proper function. 	<input type="checkbox"/>
	<ul style="list-style-type: none"> Ensure the logger calibration date meets the requirement: logger calibration date + 1 year - 1 month \geq current date. 	<input type="checkbox"/>
3	Serialized Security Seals:	
	<ul style="list-style-type: none"> Ensure serialized security seal per Va-Q-Proof 57 shipper 	<input type="checkbox"/>
	<ul style="list-style-type: none"> Ensure that serialized security seals numbers are added to the live AWB 	<input type="checkbox"/>

3. On the Day of Collection

	Placement at Catalent Site within agreed timeline	
	Drive to the Catalent site within the agreed timeline to pick up the shipper solution.	<input type="checkbox"/>

	Handover from CDMO to LSP after Pack Out	
1	During the handover, ensure that the correct quantity of Va-Q-Proof 57 shippers is sealed.	<input type="checkbox"/>
2	Use PPE, including gloves and safety glasses, while handling the shipping solution.	<input type="checkbox"/>
3	Ensure there are no physical damages.	<input type="checkbox"/>
4	Ensure that Catalent has secured the shipping boxes to pallets.	<input type="checkbox"/>
5	Ensure that serialized seals are applied to outer box by Catalent	<input type="checkbox"/>
6	Ensure to have the PoC signed by the CDMO	<input type="checkbox"/>
7	Provide a copy of the signed PoC via email to the Roche Logistics Team.	<input type="checkbox"/>

Shipment from Catalent Site to departure airport in the US		
1	Confirm the collection was completed and the flight schedule to the Roche Logistics Team.	<input type="checkbox"/>
2	Confirm the shipment was loaded to the aircraft and communicate the departure at the origin airport to the Roche Logistics Team.	<input type="checkbox"/>

Arrival in Germany, Customs Clearance and Final Delivery		
1	Communicate the arrival at the destination airport to the Roche Logistics Team.	<input type="checkbox"/>
2	At the airport, replaces the Sarepta invoice by the FHLR invoice in the packing slip	<input type="checkbox"/>
3	After customs clearance, re-ice the shipping boxes (if required)	<input type="checkbox"/>
4	If re-icing is needed, ensure to write down in the AWB the new security seals numbers used to secure the box	<input type="checkbox"/>

At Roche Mannheim warehouse		
1	Communicate the arrival at the Roche Mannheim warehouse to the Roche Logistics Team.	<input type="checkbox"/>
2	Receive the signed Proof of Delivery (PoD) upon receipt at the Roche Mannheim warehouse.	<input type="checkbox"/>
3	Provide a copy of the signed PoD via email to the Roche Logistics Team.	<input type="checkbox"/>

Version History Control

Version	Date	Author	Changes	Reviewed by	Approved by