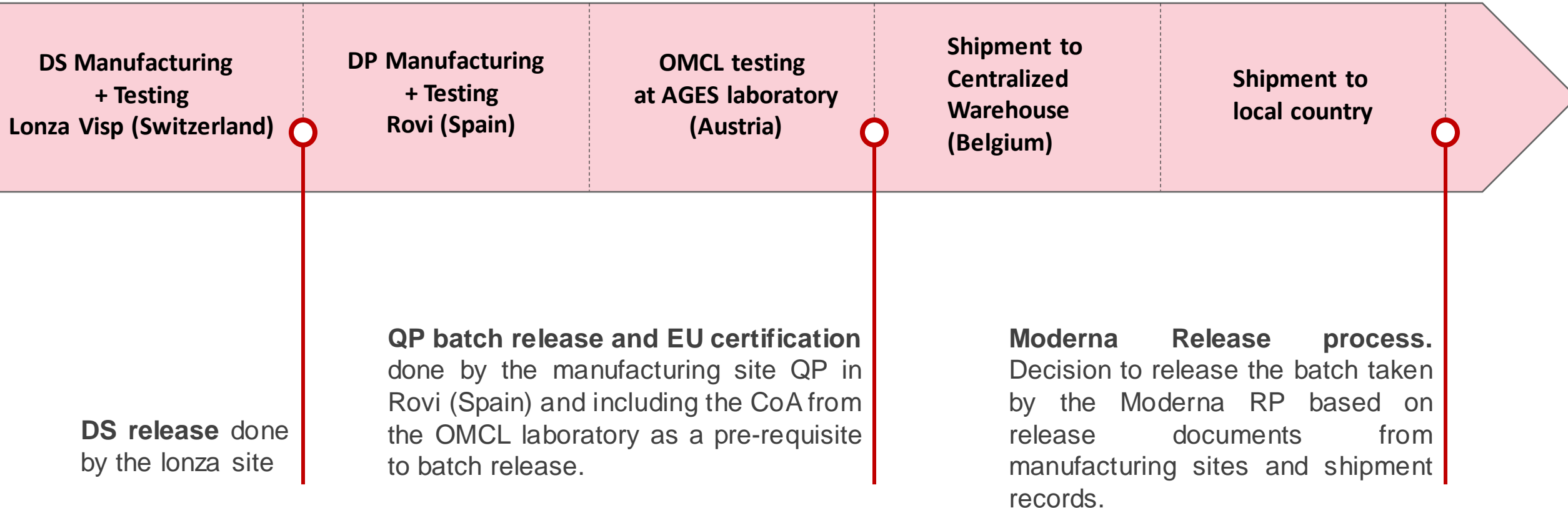


Product Release to EU Countries

Previously distributed to EC on December 29, 2020

December 24, 2020

Overall Manufacturing and release process



General Process overview

- The product will have a **technical release and EU batch certification** from the manufacturing site QP and must be in released/approved status in the European distribution center before shipment to the destination country.
- Product is shipped to a distribution warehouse defined by the customer in the destination country under the following arrangement:

DAP/DDP - Moderna is responsible for shipment to a designated storage and distribution center or transit point in the destination country. In such cases, Moderna is part of the final in-country release process together with the customer or their agent.

- Status control on receipt at the in-country distribution warehouse will be the responsibility of the customer or their agent.

The **Moderna release process** is based on review of the relevant documentation for the batch. This includes, but is not limited to:

- Release documentation from the manufacturing sites, including Certificate of Analysis and Certificate of Conformance (also termed Certificate of Manufacturing in some jurisdictions) for Drug Substance and Drug Product.
- Shipping documentation: packing lists, security seal records, etc.
- Shipping controls, e.g., temperature records, including datalogger placement and readouts.
- Receiving record at the destination warehouse.

The Moderna RP carries out a review of the documentation listed above, following arrival at the destination warehouse.

The Moderna RP will decide on the release or withholding of the product. The decision on the status of the product will be communicated to the destination warehouse.

Shipment, in-country receipt, and release of product

Shipment to in-country distribution centers

- Moderna Supply Chain will advise the customer or their agent that the material is available for delivery.
- The European distribution warehouse will arrange the transport of the material, including:
 - preparation of packing lists,
 - truck/container preconditioning,
 - datalogger placement, truck/container seals, etc.
 - The records of these actions will be sent to Moderna QA
- Moderna Supply Chain will advise the customer or their agent of the intended delivery date and time. The European distribution center will execute the shipment as directed by Moderna Supply Chain.
- The European distribution center will send confirmation of shipment to the RP at Moderna Switzerland. This will include copies of packing lists and shipping documents as outlined above.

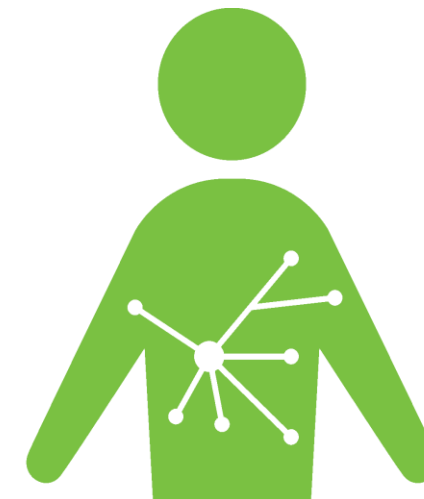
Receipt of product at the in-country distributor

- The in-country distributor will carry out incoming checks for the labeled identity (product name, batch number, quantity) of the material as well as seal checks.
- The distributor will also retrieve dataloggers or other temperature recording devices from the shipment. The analysis of the temperature data will typically be done by the distributor and the results sent to Moderna QA in Basel.
- The distributor should also confirm that the goods have been received in good physical condition. Any discrepancy in the incoming checks at the distributor should be notified to Moderna QA in Basel within 24 hours of goods receipt.
- The distributor will collect and store the retention samples for each batch in accordance with European and/or local national requirements.

Release of product by Moderna¹

- The RP at Moderna QA will review the documentation provided by the manufacturing site, the European distribution warehouse, and the in-country distributor.
- If the RP is satisfied that the product is of suitable quality, and that the manufacturing, transportation and warehousing records confirm compliance with GMP/GDP, they may release the product.
- This release will be recorded and batch status changed in SAP accordingly.
- The confirmation of release will be sent to the distributor.
- Further controls within distribution operations will be managed by the distributor.

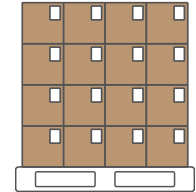
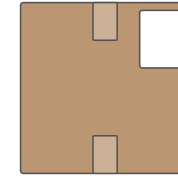
1. DAP/DDP where Moderna is responsible for shipments



International Logistics Information

January 4, 2021

Packaging Configuration



| | Vial | Pack | Shipping Case | Pallet |
|---------------------------------|--|--|--|---|
| Viols/Doses | 1 Vial 10 doses | 1 Pack 10 Viols 100 Doses | 1 Shipping Case 12 Packs 120 Viols 1,200 Doses | 1 Pallet 96 Shipping Cases 1,152 Packs 11,520 Viols 115,200 Doses |
| Dimensions & weights | H: 50mm D: 24mm | H: 60mm L: 51mm W: 126mm 217g | H: 135mm L: 267mm W: 169mm 2.7kg | H: 960mm L: 1,200mm W: 800mm 290kg |
| Packaging features | Tamper evident Vial cap | Tamper evident label on Pack | | |
| GTIN | 00380777700687 | 30380777700688 | 50380777700682 | N/A |
| Label | LOT & EXP - Printed Only (No Barcode) QR Code encoded with: https://www.ModernaCovid19Global.com | Product Code, EXP & LOT - Printed & 2D Data Matrix (Not serialized) QR Code encoded with: https://www.ModernaCovid19Global.com | Product Code, EXP & LOT - Printed & 1D GS1-128 (Not serialized) | Serial Shipping Container Code (SSCC) Label |

Transport, Handling and Storage

- All vaccines shipped out of Central Warehouse at Kuehne & Nagel in Belgium
- -20°C (-25°C to -15°C) for storage and transport
 - No dry ice allowed
- **Maximum handling time in 2°C to 8°C**
 - 30min for loading and unloading
- **Sensitech loggers added to the product for temperature control**
 - Low Temp / High Temp: -25°C to -15°C
 - Interval: Every 5 minutes
 - Start-up delay: 0 minutes
- **Transport Equipment**
 - Transport in -25°C to -15°C pharma trucks / trailers (Qualified Active System)
 - Transport in va-Q-Tec containers (Qualified Passive System)
- **No X-Ray allowed**



Transport Concept

Road

- **Truck / Trailer with active temperature control -25°C to -15°C**
- **Van with passive va-Q-Tec system in 2°C to 8°C**
 - Quantities up to 2 pallets
 - Containers to be unloaded and returned with delivery van
- **GPS tracked (temperature and position)**
- **Security concept - escort service door-to-door**

Air

- **Passive va-Q-Tainer system shipping in 2°C to 8°C**
 - Containers to be unloaded and returned (to va-Q-Tec depot)
- **GPS tracked**
- **Security concept - escort service for pre- and onward carriage**

Transport Equipment Trailers

Qualified Active System for road transports

- Qualified according to the GDP standards
- FRC certified and qualified
- Equipped with Bi-temperature and Double-deck equipment + ADR
- Equipped with Idem Telematic system with Full visibility and Alarm setting
- TAPA compliant trailers, equipped with high security locks
- -25°C to -15°C



Transport Equipment va-Q-Tec

Qualified Passive System for Air transport and Road / Van solution

- **va-Q-one**
 - Qualified, dry-ice free single-use thermal packaging solution
 - >96h according to ISTA 7D (summer & winter profile)
- **va-Q-proof**
 - Qualified, dry-ice free reusable thermal packaging solution
 - from >96h to >168h according to ISTA 7D (summer & winter profile)
 - box portfolio from 4 to 264 L payload volume
- **va-Q-pal**
 - Qualified, dry-ice free pallet shipper
 - >95h according to ISTA 7D (summer & winter profile)
 - re-qualification with va-Q-check® possible for re-use
- **va-Q-tainer**
 - deviation-free, advanced passive container ≥ 102 hrs
 - 4 different sizes (EUROx, TWINx, Usx, XLx)
 - Global shipments and pay-per-use-rental



Vaccines Transport Warehouse to customer

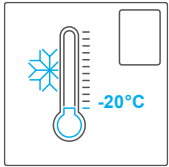
| Requirement | Description |
|---------------------------------|--|
| Shipping temperature | -20°C (-25°C to -15°C) / No dry ice allowed |
| Packaging configuration | Shipping Cases Pallets |
| Shipping System | Qualified Active System (Vehicle) Qualified Passive System (PCM) |
| Load | Depends on customer order (shipping cases, picked pallets, full pallets) |
| Transport Mode | Road / Air |
| Temperature Monitoring Strategy | 100% monitoring of shipment |
| Routes / Duration | K+N, Liege/Brussels BE – Worldwide Distribution |
| Chain of Custody | Tamper resistant seal Dedicated fleet of trucks Door to Door / Nonstop Temperature monitoring & recording and GPS technology while in transport |



Air Freight solutions 

Road Freight / Overland solutions 

Pre-conditioned
-20°C shipper



-20°C Temp
controlled vehicle for
full loads

