

moderna

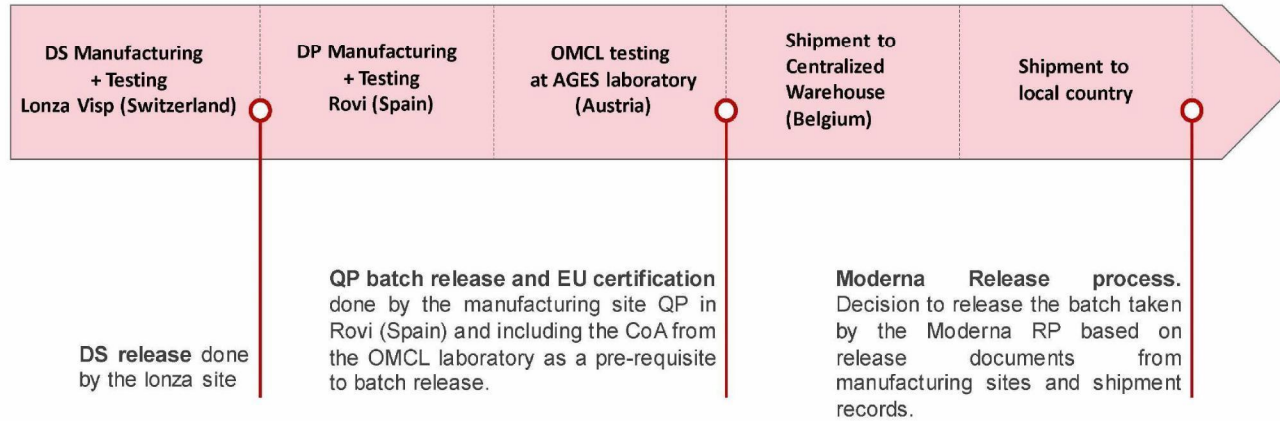


Product Release to EU Countries

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.

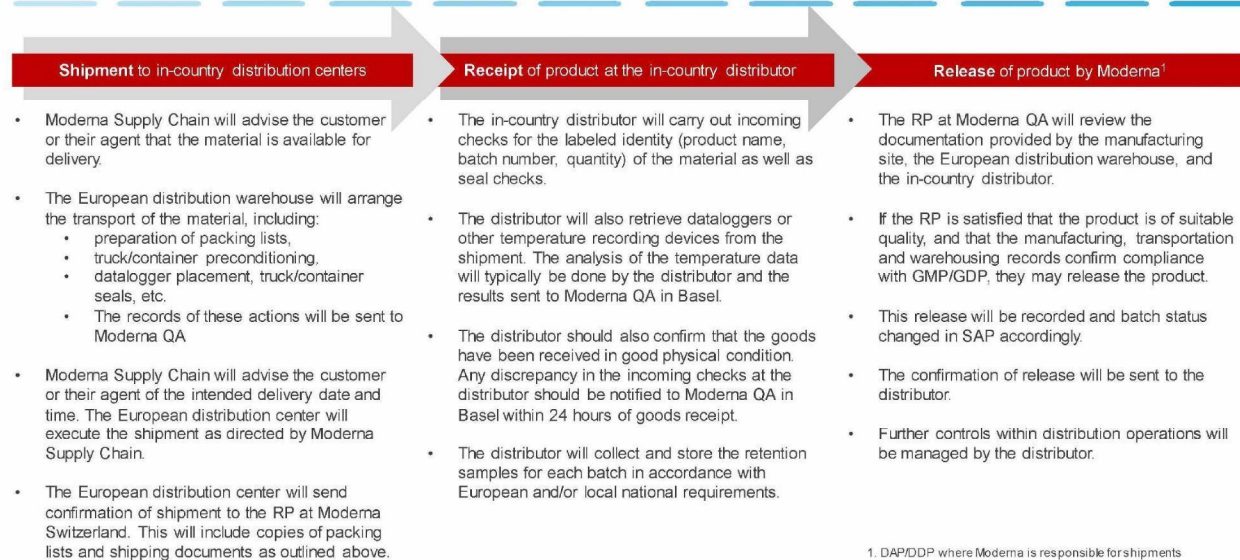
The **Moderna release process** is based on review of the relevant documentation for the batch. This includes, but is not limited to:

- 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





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 v-a-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

