



Supplier Management

Logistics & Quality

Global Distribution Quality Assurance Manager
Global Healthcare Operations | Healthcare Quality



MERCK

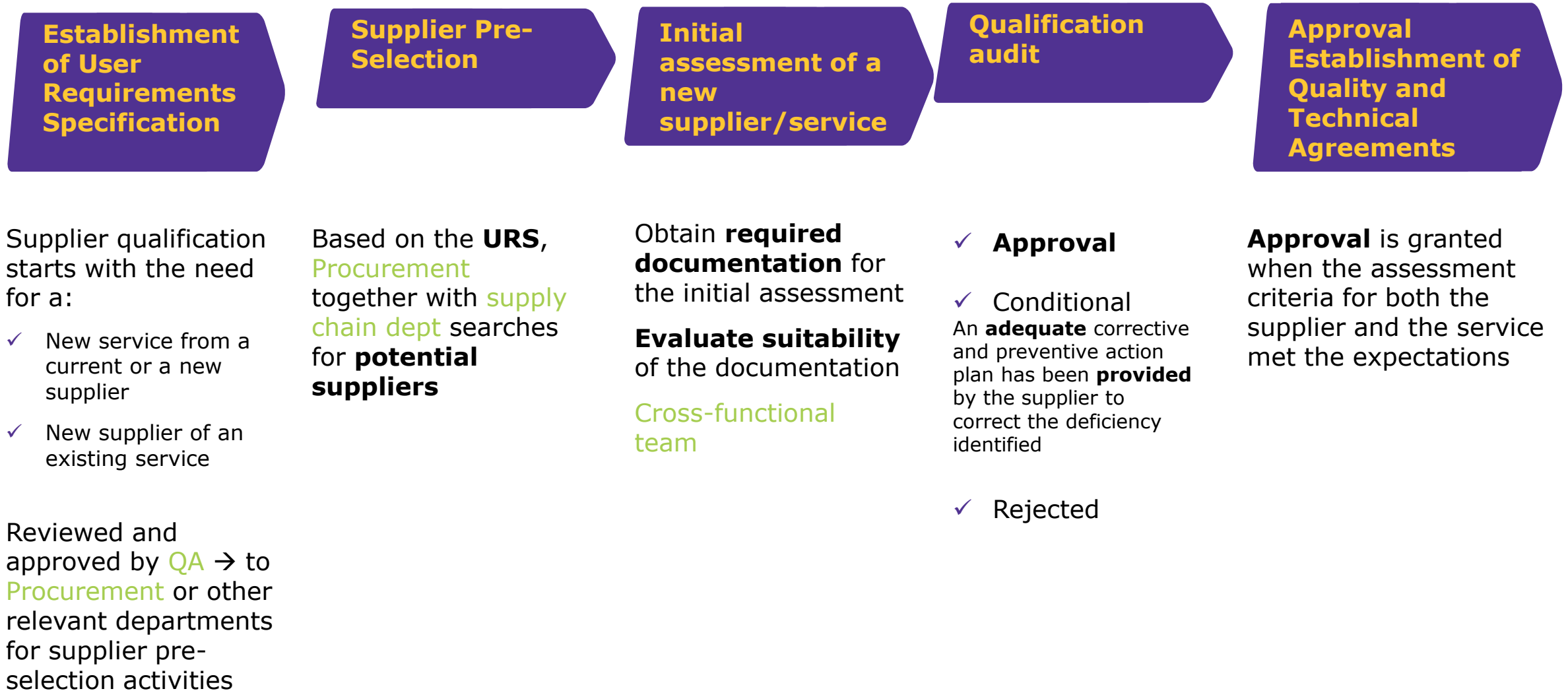


We want **quality** to be maintained during **all the distribution process**

We want **GDP requirements** to be **followed by all providers** and for **each operation**. That's why we:

- **Qualify** global Third Party Logistic providers
- Write and actualize global **technical agreement** to describe operational processes
- Conduct **audits** of global Third Party Logistic providers
- Check the conformity of global Third Party Logistic providers with GDP requirements in performing **regular reviews**

Supplier Quality Management: Qualification



Supplier Quality Management: Lifecycle

Monitoring of suppliers service

Periodic review and reporting from monitoring

- ✓ **KPI**
- ✓ **Audit program**
- ✓ **QBR**

Disqualification and Supplier Phase

Suppliers disqualification

- ✓ **Unacceptable outcomes** from an Merck Audit or Health Authority audit
- ✓ **Repetitive or critical quality issues** identified in the Supplier Quality Risk Assessment
- ✓ **No implementation of corrective actions** by the supplier to resolve problems
- ✓ **Regulatory noncompliance** (warning letter, importation ban...)
- ✓ **Unsatisfactory supplier monitoring** (e.g. responsiveness and collaboration inadequate with Merck cross-functional team expectations, **unsatisfactory performance** identified through the Supplier Quality Risk Assessment.

Suppliers Phase Out

A decision taken to stop supply of service due to business and not quality reasons

BACK UP SLIDES

Merck solutions for +15+25°C Product

Loose cargo with thermal blankets

Trucks

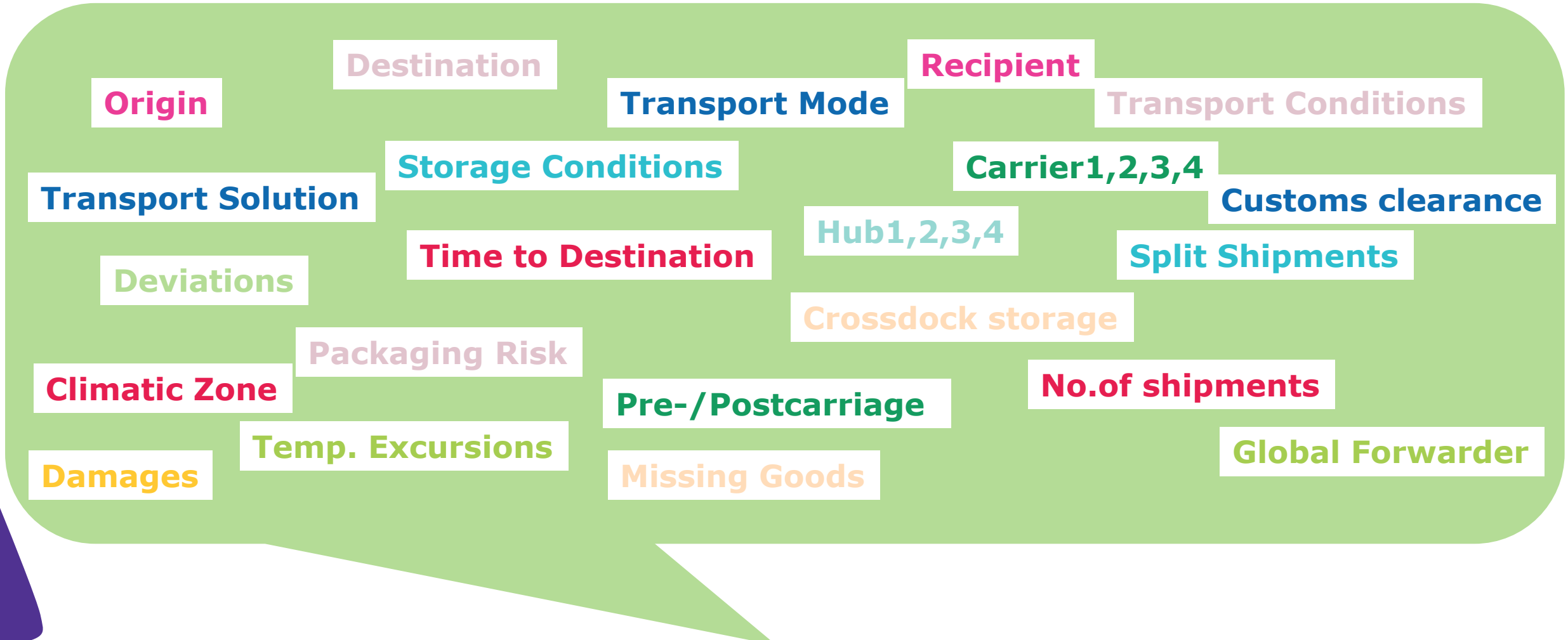
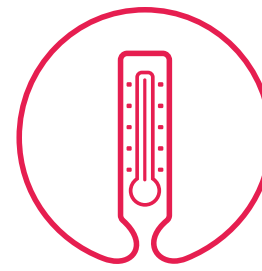
Active cooling/heating containers by air and sea

Passive containers

Train to come...

During Primary transportation, each and every shipment is temperature monitored

Some points to consider



Origin

Destination

Transport Mode

Recipient

Transport Conditions

Transport Solution

Storage Conditions

Carrier 1,2,3,4

Customs clearance

Deviations

Time to Destination

Hub 1,2,3,4

Split Shipments

Crossdock storage

Climatic Zone

Packaging Risk

Pre-/Postcarriage

No. of shipments

Damages

Temp. Excursions

Missing Goods

Global Forwarder

What is difficult with +15+25°C shipments ?

- Limited Infrastructure for 15°-25°C versus +2+8°C
- Special Services for 2°-8°C while for 15°-25°C products only standard packaging and standard logistics processes were available.
- Ambient from one country to the other
- Higher volumes for 15°-25°C and lower value to +2+8°C increase shipping costs
- Lack of awareness/training leads to handling issues with +15+25°C products



Merck Prerequisites for Airfreight

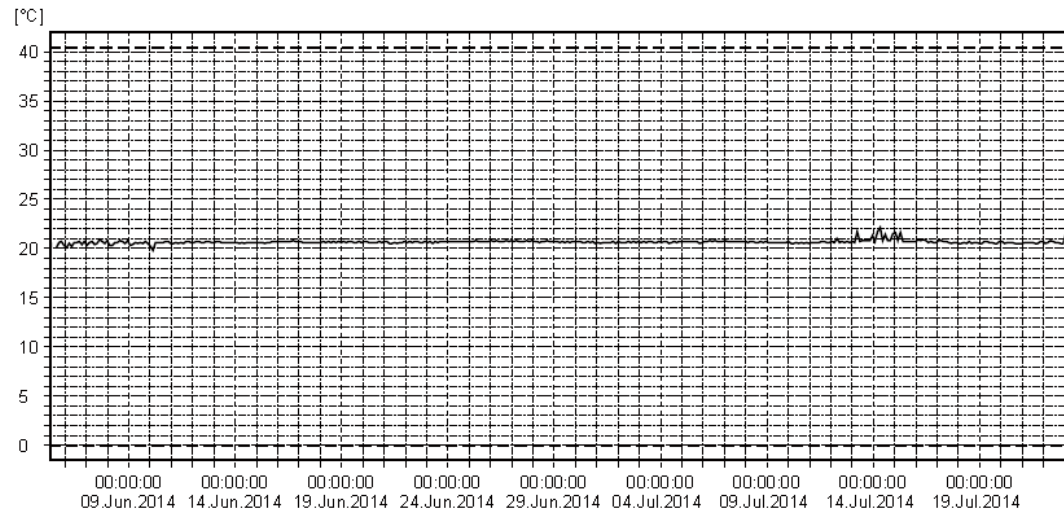


- Prefer direct flights to minimize transfer hub/transit airports
- Select night time arrival and handling for hot weather countries (climatic zone III and IV)
- Select night time or early morning departure for hot weather countries (climatic zone III and IV)
- Avoid hubs in areas where temperatures are high and no protection equipment is available
- Prefer cargo planes to avoid shipment to be split
- Avoid big shipments (huge amount of pallets) to minimize the risk of splitting
- Avoid weekend or holidays arrivals at destination country
- Use airlines with experience in T° controlled shipments, with dedicated pharma services or pharma hub access at destination airport
- Prefer responsive partners in the investigation of issues and T° deviations

Merck Prerequisites for Sea Freight



- Prefer direct connections to minimize transfer hub/transit ports.
- Use sea lines with experience in T° controlled shipments and/or experienced with Pharma business.
- Ask for a copy of the PTI (Pre Trip Inspection)



- Provide all necessary information to the consignee so that he can follow-up the importation process

Merck Prerequisites for Road Freight for +15+25°C Product

- For all shipping modes (air, sea, train) road freight is part of the chain
- Use an approved transportation company experienced with Pharma business
- Use temperature controlled hard cover trucks only
- Use direct routes to destination

In case these above mentioned criteria cannot be fulfilled due to lack of infrastructure mitigation actions like additional passive or active containers must be used.

