Global Transport and Logistics

Pharmaceutical & Healthcare Policy

Group Compliance

Effective date: 01-02-2020

Contents

1 Introduction

The purpose of the Pharmaceutical & Healthcare Policy (Policy) is to set uniform requirements for the Pharmaceutical & Healthcare Network, where pharmaceutical and healthcare products are moving:

- **Forward in the logistics supply chain**
  including starting materials delivered to the manufacturer and from there to the entity responsible for dispensing or providing the products to the patient
- **Backward in the logistics supply chain**
  such as returns or recalls of products

DSV has an obligation to comply with legislation and mandatorily applicable industry standards related to the storage, handling and transportation of pharmaceutical and healthcare products. In all cases, the Client remains responsible for the quality of the products which they supply. Technical Agreements should be in place between the Client and DSV to safeguard patient safety and reduce the risk and liability assumed by DSV.

The Policy aligns with the World Health Organisation (WHO) and their applicable guidelines, hence setting up a comprehensive Quality Management System (*Illustration: structure of PharmaQMS*).

The Policy and the Global Pharmaceutical & Healthcare Quality Management System (PharmaQMS) are for internal use only. Documents such as Client Standard Operating Procedures (Client SOP) and Operational Manuals are for internal and Client specific use only.

The Policy may be supported by a regional and/or national policy, to further address regional and/or national regulations or requirements.

The first use of an abbreviation (initialism and acronym), should be written out with the short form placed in parentheses immediately after. Underlined (dotted) terms and abbreviations is available within the Pharmaceutical & Healthcare Glossary.

Illustration: Structure of PharmaQMS

2 Scope

The Policy will apply to the 3 (three) DSV divisions and all DSV entities within the DSV Panalpina Group, which are commercially obliged to adhere to requirements for the products and services supplied by DSV to any Client with products from the following categories:

- Human Medicinal products
- Veterinary Medicinal products
- Pharmaceutical starting materials
- Clinical trial material
- Medical devices
- Natural health products

The Policy covers activities described in the Divisional Pharmaceutical & Healthcare Services Catalogue (Services Catalogue), including wholesale activities and manufacturing services such as repacking of secondary packaging and relabelling.

Manufacturing Services such as mixing starting materials, combining products into a homogeneous batch and repackaging of products into a primary packaging are excluded from the Policy.

The Policy does not cover Privacy concerns. Privacy rules and legislation must be considered when handling pharmaceutical and healthcare products due to the potential processing of personal data. The Code of Conduct applicable for the DSV Panalpina Group must be observed and considered separately.

3 Responsibility

The *Group CFO* will on behalf of the *Group Executive Committee* (GEC) approve the Policy.

Group Compliance is accountable for the Policy and will ensure that a robust and effective PharmaQMS is in place, implemented and maintained at all levels of the DSV Panalpina Group and records retained.

In cooperation with the *Group Executive Committee*, *Group Compliance* will define the Policy Objectives to ensure a robust and effective PharmaQMS.

The *Divisional CEO* will appoint a *Divisional Pharmaceutical & Healthcare Product Owner (Product Owner)*, who will be responsible for:

- The Services Catalogue
- Maintaining a standard for qualifying and managing approved business partners
- Liaise with *Group Compliance* in respect of the divisional aspects of the PharmaQMS

The *Product Owners* and *Global Commercial Organisation (GCO)* will liaise with *Group Compliance* to maintain the necessary compliance level whilst supporting the ongoing business development. As the *primary stakeholders*, they work to ensure that DSV are at the forefront providing transport and logistics solutions to the pharmaceutical and healthcare industry.

The *Country Manager* is responsible for organisation charts with role, responsibilities and interrelationships clearly indicated. This expertise begins at the operational level with well trained material workers, operators and managers. Regulatory compliance may apply.

The *Branch Manager* is responsible:

- For the operational team and all products and services provided, subject to the PharmaQMS and applicable principles of Good Distribution Practices and Good Manufacturing Practices including relevant regulatory requirements
- For training of all employees involved
- For executing and maintaining relevant risk assessments
- To implement and maintain specific Client requirements which will also include applicable regulatory authorisations and ensuring proper internal communication
- To appoint a *Pharmaceutical & Healthcare Specialist* (*Specialist*) responsible for the commercial implementation, support and monitoring
- To appoint a *Pharmaceutical & Healthcare Quality Lead* (*Quality Lead*)

The *Quality Lead* will have a dotted-reporting-line to *Group Compliance*. Duties include, but are not limited to:

- Ensuring that the PharmaQMS is implemented and maintained
- Accuracy and quality of records
- Training programme for all employees involved
- Relevant nonconformities and change controls are evaluated and dealt with effectively
- Qualification and approval of business partners by a designated *Pharmaceutical & Healthcare Quality Auditor* (*PharmaQMS Auditor*)
- Self-inspections are performed by a designated *PharmaQMS Auditor* and necessary corrective actions are put in place
- Be engaged in external audits and inspections

The *Regional Manager* can designate a *Senior Pharmaceutical & Healthcare Quality Lead* to oversee a Divisional region, cluster or country, and as applicable assume the dotted-reporting-line to the local appointed *Quality Leads*. The *Senior Pharmaceutical & Healthcare Quality Lead* will liaise with and have a dotted-reporting-line to *Group Compliance* to ensure independence.

3.1 Governance

Within the area of responsibility, the *Country Manager* is authorised to approve any Branch to be admitted to the Pharmaceutical & Healthcare Network or changes to the Branch Network Capabilities.

Upon approval, *Group Compliance* will initiate a Compliance Audit with the purpose of certifying the Branch according to the PharmaQMS and Network Capabilities.

4 Pharmaceutical & Healthcare Network Capabilities

The PharmaQMS is aligned with specific WHO guidelines and monitored by *Group Compliance*. Four capability levels or categories define the Pharmaceutical & Healthcare Network.

Tier 4	
Transportation	This level has the fewest capabilities and sets the minimum standard for all Tier levels engaged in simple pharmaceutical and healthcare transportation without cross-dock capabilities. Pharmaceutical & Healthcare Products may not transfer to another vehicle after pick-up. An exception for cross-docking applies to airport cargo handling.
Tier 3 (addition to Tier 4)	
Transit	Dedicated cross-docking and handling area (in-transit storage) managed by DSV. Temperature monitored area must be frost-free (above +2°C and generally kept below +25°C) with a throughput time not exceeding 18 hours. Simple handling includes use of insulated thermal materials as well as autonomous data loggers and tracking data loggers.
Tier 2 (addition to Tier 3 and 4)	
Transit PLUS	At least 1 (one) dedicated temperature controlled area (required temperature range: +15°C to +25°C) with a minimum capacity of 10 standard pallets. Maximum throughput time for temperature-sensitive products is 72 hours (48 hours recommended). Handling includes shipping containers as well as active and passive shipping configurations and use of dry ice.
Tier 1 (stand alone or in addition to Tier 2, 3 and 4)	
Warehousing	Facility controlled by DSV and the holder of a regulatory good practice license (e.g. WDA). At least two (2) dedicated temperature controlled storage areas (+2°C to +8°C and +15°C to +25°C) with a minimum capacity of 20 standard pallets in each compartment. Handling includes pick-and-pack and batch inspection.

Table: Tier levels

Any Network Branch must be compliant with the PharmaQMS as applicable to the scope of the capabilities and must have an unambiguous understanding of the pharmaceutical and healthcare principles and guidelines, such as Good Distribution Practices (GDP) and, if relevant, Good Manufacturing Practices (GMP).

It is acceptable for a Network Branch to fulfil its defined requirements at two (or more) different addresses if relevant for the Branch Network Capabilities. The exact scope of activities at each address must be defined and reported to *Group Compliance*.

All Network Branches are subject to the Network Certification that will be issued by *Group Compliance* based on the criteria set in the PharmaQMS.

Group Compliance has the right to demand any Network Branch to implement corrective actions where needed, to fulfil the requirements defined in the PharmaQMS.

5 Quality Management

The PharmaQMS outlines the requirements defined in the Policy in documents such as Procedures, Manuals, Guidelines, Work Instructions as well as Client SOPs and Operational Manuals. These documents will ensure consistency throughout the Network of Certified Branches. The aim is to manage relevant documents electronically including the DSV Panalpina Group and divisional documents. All employees are obliged to refer to the latest version.

5.1 Competence, training and awareness

All employees involved in the storing, handling and transportation of pharmaceutical and healthcare products shall have a combination of training and experience to enable them to properly interact and understand the relevant elements of the PharmaQMS, the Network Capabilities and product requirements. The Network Branch will maintain an adequate level of employment to ensure product integrity and security. This is achieved through the recruitment process, as duties and responsibilities must be clearly defined and understood by the employee. Employees working in key positions (e.g. *Branch Manager*, *Specialist* and *Quality Lead*) will have a written job description defining their role and responsibilities.

Temporary and contracted labour are subject to the same screening process for personnel contracted to work on behalf of DSV.

5.2 Document and Record Control

Good documentation practises constitute an essential part of the PharmaQMS and are key to operating in compliance with good distribution and manufacturing guidelines. In accordance with the PharmaQMS, employees must follow the minimum requirements to establish control, monitor documents and records.

A method for proper communication and control of Client SOPs and Operational Manuals will be established by the Network Branch.

5.2.1 Retention of Documents & Records

The Policy, all related PharmaQMS documents and relevant records shall be retained in a consistent manner, for at least seven (7) years or subject to Client and regulatory requirements if longer retention period is required.

5.3 Nonconformity and Corrective Action

Nonconformity occurs when something affects product integrity and/or DSV liability. Requirements might be defined by the Client, a Regulatory Agency or in the PharmaQMS.

Nonconformity could be damage to and/or loss of product and is typically identified through complaints received from the Client, internal-/external audits and incoming product inspection or simply during normal testing and inspection activities. The Client should always be informed if the nonconformity is related to the product integrity.

Nonconformity must be documented in a Nonconformity Report (NCR) and records retained in a Nonconformity Register. The NCR will be used to recommend corrective actions.

The Network Branch shall evaluate the NCR and actions put forth for their effectiveness, and *Management* (appropriate level) must ensure that actions are approved, and the outcome conveyed to the relevant employees and Clients.

5.4 Change Control

The purpose of the change control process is to identify, document and assess changes that may have a significant impact on the PharmaQMS and may have the potential to affect traceability and/or product integrity.

Change Controls must be documented, and records retained in a Change Control register. Prior to implementation, the required actions must be approved by the *Management* (appropriate level) impacted by the change and by an employee responsible for Quality Assurance, such as the *Quality Lead*.

5.5 Audit and Inspection

To achieve and maintain a sustained state of audit and inspection readiness, a robust audit and inspection programme is essential. This ensures that the Network of Certified Branches are adequately prepared for the next inspection, be that a Client or Compliance Audit, or a Regulatory Inspection.

5.5.1 Self-Inspection

A key element in the audit and inspection programme is self-inspections. In accordance with the PharmaQMS, self-inspections must be conducted annually.

5.5.2 Compliance Audit

The Compliance Audit is executed on behalf of *Group Compliance*, by an accredited *PharmaQMS Auditor* in accordance with the PharmaQMS, prior to the issuance of a Network Branch Certificate.

The Network Branch Certification will be issued by *Group Compliance* and endorsed by the *Divisional CEO,* based on the result of the Compliance Audit.

Group Compliance may revoke a Network Branch Certificate in the event of non-compliance to the PharmaQMS.

5.5.3 Client Audit and Regulatory Inspection

The Network Branch will ensure a proper process for notification before, during and after Client Audits and Regulatory Inspections, including the correct documentation required if a visit is imminent.

5.6 Management Review

On an annual basis, all Network Branches shall as a minimum review their compliance level subject to the PharmaQMS. Mandatory participants should be the *Branch Manager*, *Specialist* and the *Quality Lead*.

Group Compliance will provide a summarised review for the DSV Panalpina Group subject to the agreed Policy Objectives.

5.7 Quality Risk Management

The Client has a fundamental obligation to maintain product quality throughout the logistics supply chain to ensure patient safety. DSV will support the Client by ensuring the minimum requirements defined within the PharmaQMS and Services Catalogue are met.

For storage and handling of pharmaceutical and healthcare products, a risk assessment will be conducted for activities such as facility and equipment qualification (all described in the PharmaQMS).

For transportation of pharmaceutical and healthcare products, the Network Branch will perform a lane risk assessment primarily for pharmaceutical products moving by regular transport modes (e.g. road, air and sea).

5.8 Business Partner Management

The selection and maintenance of business partners is a fundamental element of the PharmaQMS and are key to reduce the risk regarding product integrity and security.

All purchases of products and/or services must be made from an approved business partner that has passed the business partner evaluation process as defined in the PharmaQMS. Records of approved business partners will be retained in a register.

Each division will maintain a standard for qualifying and managing approved business partners. The criteria for evaluation depend on the complexity of the service provided (e.g. Air, Sea, Road, Cross-docking, Storage and Handling). This also includes business partners appointed by the Client.

5.9 Infrastructure and equipment

Facilities, installations and equipment must be suitable to ensure proper storage, handling and transportation of pharmaceutical and healthcare products.

5.9.1 Facility

Facilities used for storage and handling of pharmaceutical and healthcare products, are subject to qualification, prior to their use. The routine storage and handling activities are owned by and/or operated on behalf of DSV. The PharmaQMS defines the minimum requirements applicable. Regulatory compliance may apply.

Further qualification exercises must be conducted whenever significant modifications are made to the facility, layout, installation or to the way in which it is used.

Any facility used for storage and handling, must have an appropriate degree of security and sanitary accommodations. In addition, the facility must have dedicated areas for inbound and outbound as well as a segregated area for quarantine products.

Special attention should be given to the storage of products with specific handling instructions subject to regulatory compliance. Special storage conditions (and special authorisations) may be required for such products (e.g. narcotics and psychotropic substances).

5.9.2 Equipment

Equipment used for transporting temperature-sensitive pharmaceutical and healthcare products are subject to qualification, before the equipment can be used. The PharmaQMS has defined the minimum requirements applicable. Regulatory compliance may apply.

For temperature controlled vehicles and trailers, which are owned by and/or operated on behalf of DSV, the minimum requirements dictate an initial full mapping on each temperature control unit, combined with an installation qualification for each example when a new unit becomes operational.

Re-qualification of vehicles and trailers must be conducted whenever significant modifications are made. Attention must be given whenever temperature monitoring shows unexplained variability that is higher than normal.

The purchase of shipping containers, including passive and active shipping configurations, is subject to the section on "Business Partner Management". The Client is responsible for the qualification of such shipping containers. DSV will assist by providing relevant documents if available, such as pre-qualification reports.

5.9.3 Monitoring

Monitoring of temperature is applicable to facilities, vehicles and trailers owned by and/or operated on behalf of DSV. Monitoring may also refer to the monitoring of humidity and air pressure subject to Client specifications.

The PharmaQMS defines the minimum requirements for continuous temperature monitoring which is applicable for storage, handling and transportation of temperature-sensitive pharmaceutical and healthcare products. Monitoring records must be reviewed and approved regularly, to ensure compliance with the required conditions. Records must be retained.

Temperature excursions must be investigated and documented. The Client should be consulted to ascertain the effect of the temperature excursions.

5.9.4 Calibration

Measuring devices, such as sensors used for monitoring of temperature are subject to regular calibration. The Network Branch must ensure compliance subject to the PharmaQMS and any regulatory requirements.

All measuring devices must have a valid calibration certificate and be suitably tagged in order to be identified for traceability purposes. The calibration certificates must be reviewed to ensure the accuracy of each device is acceptable. Records must be retained.

When temperature measuring sensors used routinely are being recalibrated, measures must be implemented to ensure continuous temperature monitoring.

5.9.5 IT Systems

Group IT Compliance maintains the Global IT Security strategy including the "Information Security Policy" subject to the information assets and sets the minimum security level relevant for the DSV Panalpina Group.

The PharmaQMS stipulates the requirements for appropriate computerised system validation, relevant for those functions that will be used to confirm product integrity and traceability.

When computerised system validation has not been performed, the division or Network Branch must ensure the retention of hard-copy documents and records providing enough evidence to confirm product integrity and traceability.

5.9.6 Maintenance

The integrity of pharmaceutical and healthcare products can be affected if the maintenance of facilities, shipping containers, vehicles and trailers is not adequately controlled. The PharmaQMS requires the Network Branch to sustain the lifetime expansion and critical repairs, as well as implement effective and written maintenance and cleaning programs.

The minimum requirements for facilities, shipping containers, vehicles and trailers are to keep them clean and dry, free from rodents and accumulated waste.

5.10 Emergency Plans

The PharmaQMS describes the Emergency Plan necessary to enable a swift and effective recall from the marketplace of defective and/or potentially harmful products. Only the Client can initiate a recall and the Network Branch must assist. The Network Branch is expected to regularly challenge the effectiveness of the Emergency Plan to ensure that the process is effective and capable of tracing Clients and products. If requested by the Client, the Network Branch will ensure participation in a mock recall process.

5.11 Operational Management

DSV will provide guidance and support, which enables the Client to select the most appropriate solution in accordance with the PharmaQMS.

5.11.1 Warehousing

The Network Branch will ensure that the Client is authorised by a Regulatory Agency and that their products are intended for supply to the market and authorised for sale. The Client must confirm that they are responsible for the release of products to saleable stock, and that their customers are authorised to receive products.

Specific checks must be performed on temperature-sensitive products. If products are received under quarantine status, the Network Branch must ensure that these products are not released into saleable stock until released by the Client. An inventory list must be maintained of all products.

All products that are rejected by the Client are to be destroyed in accordance with the Client's instructions and/or relevant regulatory requirements. The decision to dispose products is the sole responsibility of the Client. Where the Client requests the return of products, this should be documented accordingly when dispatching the product.

A product should be considered a return, when it has left the facility and subsequently returned to that facility. The Network Branch must be vigilant in the handling of returned products and will await the Client's decision before the product is placed back into saleable stock.

It is imperative that the Network Branch display vigilance in the efforts to prevent falsified medicinal products from entering the market place. Any product suspected of falsification must be quarantined and the Client will be informed without undue delay. The Client will instruct the Network Branch of the actions that are to be performed.

5.11.2 Handling

The Network Branch will ensure that products are not kept in the facility longer than the requirements described in Section 4. The Network Branch must inform the Client of a planned change or without undue delay after a confirmed deviation, that could have an adverse effect on the product integrity.

When handling temperature-sensitive products, the Network Branch must follow the PharmaQMS as well as all applicable work instructions, Client SOPs and Operational Manuals.

5.11.3 Transportation

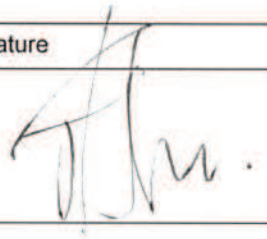
The Network Branch must be aware of the PharmaQMS and work instructions including Client SOPs and Operational Manuals. Special attention must be observed for the use of non-dedicated vehicles and trailers and any prolonged periods of storage during transportation. The risk assessment of the transportation methods and routes, including customs processes, must be conducted. The use of a seal control program or similar may apply.

6 Document Revision Summary

Version	Date	Modified by	Comment
01.00	11-09-2018	Peter Munch-Hansen	New Policy (DocNumber: PHG1.00.0G001)
02.00	13-09-2019	Peter Munch-Hansen	Scope to include GMP. Amendments to the Tier capabilities and an additional Tier level. Section 5.11.1 renamed from Storage to Warehousing

7 Authentication

Document owner	
Name	Title
Martin Andreasen	Executive Vice President, Group Compliance

Document validator		
Date	Name	Signature
23.10.2019	Peter Munch-Hansen Title Director, QHSE & Pharma Compliance	

Document Approver		
Date	Name	Signature
23/10 2019	Jens H. Lund Title Group CFO, Group Management