



GET GDP INTO MOTION

GDP-compliant transportation of pharmaceuticals — Continuous documentation, qualified vehicles, staff training: the EU guidelines on “Good Distribution Practice” (GDP), amended in 2013, impose significantly greater obligations on manufacturers and freight forwarding companies dealing with pharmaceutical products. They transfer the already familiar principles of the Good Manufacturing Practices (GMP) from pharmaceutical manufacturing onto the streets.

THOMAS SCHLEIFE*

The current version of the long awaited amendment to the EU-GDP dated 7th March 2013 has been in force since 24th November 2013. The amendment to the EU guidelines replaced the European regulations for the transport of medicines from 1994. The guidelines are divided up into the following ten chapters: Quality Management, Personnel, Premises and Equipment, Documentation, Operations, Complaints, Outsourced Activities, Self-inspections, Transportation and Specific Provisions for Brokers. Along with the GMP, the amendment to the GDP now sets higher legal standards for the storage and distribution of medicines. Implementation

is also regulated by Article 7 of the Arzneimittel- und Wirkstoffherstellungsverordnung (AMWHV, Regulations on the production of pharmaceuticals and active substances) and Article 1a of the Verordnung über den Großhandel und die Arzneimittelvermittlung (AM-HandelsV, Regulations on the retailing and procurement of medicinal products). Both regulations were derived from the already well-established and internationally applicable WHO GDP guidelines.

What does GDP 2013 entail?

Stricter regulation, in particular for the transportation of pharmaceuticals, was long overdue, as the

theft and counterfeiting of medicines are rapidly becoming more widespread in Europe and worldwide. Added to this is the fact that an increasing number of highly sensitive hi-tech medicines such as bio-pharmaceuticals are being developed, which are particularly sensitive to temperature and correspondingly demanding with regard to storage and transportation. Since 2013 the GDP guidelines have imposed significantly stricter obligations on the manufacturer as the consignor and on its logistics

* The author is Managing Director Transco Berlin Brandenburg, Contact: Phone +49-3378-51930-0

service provider. These are the most important criteria and requirements from the GDP guidelines:

- The storage and transportation of medicinal products must comply with the temperature requirements listed on the packaging.
- Deviations during conveyance must be reported to the contract giver.
- The driver and all those involved in the process must have received GDP training.
- Standard Operating Procedures (SOP), that is to say procedures for dealing with vehicles and equipment, must be drawn up.
- The recipient is entitled to request the temperature printout during transportation.
- Temperature-controlled vehicles: the temperature must be mapped and maintenance and calibration of the temperature mapping equipment must be undertaken annually.

How do you go about successfully implementing GDP-compliant transportation of pharmaceuticals? The road to achieving the safest possible transportation of pharmaceuticals starts with acquiring experience, knowing about the risks involved and regular analyses of all eventualities in order to protect the goods, the staff and the vehicles.

The first thing is to know and analyse the manufacturers requirements as the basis for the logistics process. What exactly is to be conveyed and under what temperature conditions? How is the secure handover of the goods to be organised and how will the temperature be monitored during transportation? What is to be done in the event of deviations?

If these and other questions have been answered and the basic processes are in place, then SOPs can be formulated, staff given GDP training and, finally, equipment can be purchased or modified in order to ensure GDP-compliance. The main purpose of the training is to make staff aware of the sensitive nature of the cargo and to practise measures to be implemented in the event of deviations and emergencies.

How all of this works in practice can be illustrated using the example of the specialist pharmaceutical logistics company Transco Berlin Brandenburg. The company from Ludwigsfelde in the greater Berlin area has been organising the conveyance of pharmaceuticals for over 24 years—in some cases for particularly demanding routes such as Berlin-Moscow.

GDP live

Maintaining the temperature is the biggest technical challenge, whilst quality control, customs regulations and tackling organised crime are the main organisational issues. This starting position was a crucial factor in revising its supply chain processes in advance of the GDP amendment being brought in.

As part of its “secure cold chain” project, from 2011 on the company devised a holistic pharmaceutical logistics concept—in close collaboration with external partners and with scientific support from the Technical University of Applied Sciences Wildau. The company had its refrigerated trailers qualified, organised GDP training and documented its internal processes. Transco also carried out a comprehensive risk analysis and devised worst case scenarios and intervention plans for particular routes based on this. Implementation of the project was broken down into two sub-areas. One team dealt with the technical equipment, concerning itself with the definition and selection of equipment and ensuring that the essential trailer components such as refrigeration units, the ventilation system and the refrigerated trailer itself work together perfectly. A second team designed the supply chain processes, built in the necessary IT systems and carried out the vehicle qualification. Staff training was provided by trainers from an external service provider. At the end of 2012 a practical test was undertaken successfully. After successfully passing the audit, Transco was awarded a GDP certificate by TÜV Rheinland—demonstrably becoming the first pharmaceutical logistics company in Germany to do so.



Essential element of the training is to sensitize the staff for their damageable cargo and practicing actions to be taken in case of emergencies or abnormalities.

Pictures: Transco

Exactly one year after the initial certification, the company successfully passed the testing institutes re-audit in August 2015 with flying colours.

As part of its quality management system Transco is gradually incorporating its subcontractors into its GDP qualification. These measures are being driven by the management and the Quality Management Officer (QMB) and are supported by an external Qualified Person (QP).

In the first stage potential transport service providers are selected based on years of experience and on-site visits, including a tour of the company and talks. If they pass this pre-selection phase, potential candidates, who could work as subcontractors, complete a comprehensive self-evaluation questionnaire on GDP compliance. The results of this “self-audit” are taken into account in the subsequent evaluation by Transco, which also includes drawing up a blacklist of unsuitable companies which receive a negative evaluation. The final stage is the on-site subcontractor audit, including a point-scoring system and the final conclusion: “Is the service provider GDP-compliant—yes or no?”. If they are found to be compliant, the relevant subcontractor is incorporated into the GDP training system and, following completion of staff training, is “approved” to undertake the transportation of pharmaceuticals on behalf of Transco. The long-term re-audit process includes an annual supplier evaluation in which the German company evaluates the performance and quality of the subcontractor.