



## **Transportation of Drugs, Modern Approach**

**Keywords:** transportation conditions, temperature management program, temperature-sensitive drugs, proof of delivery.

Drugs storage and transportation requirements are set out in the Food and Drug Regulations Section C.02.015 which states as follows: «The Quality Control Department is responsible for ensuring that guidelines and procedures are in place and implemented for storage and transportation conditions, such as: temperature, humidity, lighting controls, stock rotation, sanitation, and any other precautions necessary to maintain the quality and safe distribution of the drugs». The responsibility of a pharmaceutical company is to ensure that the required storage and transportation conditions are met through their respective GMP activities. Modern transportation technologies of drugs, especially temperature-sensitive pharmaceutical products, require availability of computer systems with possibility of transmitting data to a central monitoring station.

Temperature management program includes technologies, systems and procedures which ensure controlled ambient conditions for each piece of shipment. Common shipment procedures start at pharmaceutical manufacturing facility at packaging section and drugs storage facility. Proof of temperature from point of shipment to the final distribution point is required for all freight transport, buffer storage facilities, company's warehouse, and drug-store premises. In the event of several buffer storage facilities, a scanning technology is applied that is necessary for tracking each package per each transportation stage. Storage and transportation temperatures must be pre-set in a proper way, and transportation from shipper to final distribution point must be performed on high level of confidence.

Any temperature management program must be developed and designed by a transportation company in compliance with goals of pharmaceutical industry and in cooperation with a pharmaceutical manufacturer. In order to fully integrate existing distribution processes with temperature requirements, a respective scanned information for premises and route must be sent through the network. This ensures correct selection of product transportation route and constant monitoring of ambient environment by means of entering information from one spot to each next. All personnel must be trained in respect of new procedures and technologies. Respective system for identification and scanning of cargos with temperature-sensitive products must be installed and recognized. A scanner is usually used that reads bar code information and enters it into computer database connected to data tracking system. All procedures and technologies must be fully verified and qualified in compliance with GMP requirements for preparation and constant monitoring of temperature managed facilities. Regulated requirements and standards for refrigerators and heating equipment must be taken into consideration. However, it can be technically difficult to install temperature management software or implement technologies of data and route transfer. In this case all information on temperature and cargo forwarding is to be entered at the cargo forwarding location by using local computer for monitoring purposes.

To determine temperature with rigid standards the special sensors are installed in storage premises and on transportation vehicles. To set up precise temperature and temperature deviations, annual temperature fluctuations and fluctuation between full and minimal trailer load are taken into consideration. Such data show the best location of calibrated sensors and cargo placement to prevent temperature deviation from allowed standards. All procedures, equipment and systems must be authorized by a company that is a holder of valid licence from respective authorities. Necessary precaution measures must be taken during loading and unloading of cargo in a trailer or on storage shelves. Personnel must be trained on how to handle cargos and pallets and to be aware about stowage procedures, air flow charts and refrigerating equipment. Air pump with required temperature should be installed between a trailer and loading premise so it can prevent change of ambient temperature in the event of opening main gates in a storage facility. In addition, a telescopic lock is used between a trailer and unloading premise in order to prevent air leakage. Prior to departure a driver must make sure that a vehicle, refrigerating equipment and cargo are in accordance with established procedures checklists.

In the event of modern monitoring system implementation, temperature-sensitive drugs must be scanned into an IT label tracking system at each point of shipment delivery and in premises with managed temperature. Temperature managed trucks of Canadian company ATS are equipped with four temperature sensors, plus a fifth sensor that indicates when the rear door is open. Two sensors read the temperature of the air in the truck, while two others are filled with glycol, to simulate the temperature of the freight. Readings are monitored every six minutes. Alarms are preset at 2°C from threshold, ambient = 17°C - 23°C, cold chain = 4°C - 6°C, to prevent an excursion before it can occur. Readings from all sensors are shown at the left of this screen. The speed and location of each vehicle are included. The technology allows for the playback feature to reconstruct any event. In case of deviation from pre-set route, procedures are taken to prevent failure to comply with scheduled conditions of storage.

Availability of centralized computer that conducts monitoring of transported cargos allows accumulating information for further analyzing and formatting in required documents and reports that confirm quality of transported drugs. Confirmation of drugs quality by means of monitoring system such as GPS (Global Positioning System) is in full compliance with GMP regulations. Such system allows seeing a route in real time mode and at forwarding location. Every driver must report to centralized workstation in case of deviation from trip schedule. A driver must be aware about procedures and necessary actions in the event of malfunction of refrigerating equipment. Emergency procedures for personnel must be introduced, for instance procedures in case of vehicle breakage or vehicle replacement deadline. Each trailer must be replaced within 4 hours at any location.

All drivers must be trained on how to manage documentation and they must fill out transportation temperature management report upon arrival. All necessary documents are to be entered into Proof of Delivery file. If required, a driver enters proof of transportation along the route and makes notes in trip schedule. All drugs transportation documents are stored at least for one year. All documents of transportation department must be in compliance with GMP regulations including Standard Operation Procedures, trip schedules, cargo transfer documents, temperature management reports etc. In the event of deviations or incidents an investigation procedure will be turned on and conclusion on the impact on product quality with quality evaluation will be included in the file. Contracts between pharmaceutical company and transportation company in respect of temperature-sensitive drugs transportation must be also included into the files. This allows showing the inspectors that liabilities and responsibilities of shipper and consignee was clearly determined. All actions in respect of transportation of pharmaceutical products are targeted to quality procurement and patient's satisfaction.

