

PHARMASOLUTIONS

— vital expertise for pharmaceutical transport —



Manage risk during pharmaceutical transportation with PharmaSolutions

Maintaining the quality and integrity of medical and biological products during transport is critical for pharmaceutical manufacturers and logistics providers for public health and patient safety.

As most medical and biological products require a temperature controlled environment at all stages of manufacturing and distribution, the control of storage and transportation temperatures is vital in maintaining the quality and effectiveness of medicines.

At Thermo King we understand that if the quality of pharmaceutical product shipments is compromised, the risk is more than loss of cargo - it can compromise the health and well-being of patients. PharmaSolutions, a comprehensive and dedicated expertise platform from Thermo King, addresses the precise needs of the pharmaceutical industry by delivering applications know-how and a broad spectrum of services.

What is Good Distribution Practice (GDP) for pharmaceutical products?

The objective of Good Distribution Practice (GDP) guidelines is to ensure that the high level of product quality, determined by good manufacturing practices, is maintained throughout the distribution chain. This extends beyond the transport vehicles used to take pharmaceuticals (such as APIs) and medical components from the manufacturing facility to distributors and wholesalers. It must also ensure compliant delivery to hospitals and pharmacies.

It is mandatory for distributors to comply with the European Union guidelines on good distribution practice of medicinal products for human use.

Industry statistics indicate that:

- 25% of vaccines reach their destination in a degraded state because of incorrect shipping.
- Almost 30% of scrapped sales at pharmaceutical companies can be attributed to logistics issues.
- Almost 20% of temperature-sensitive health care products are damaged during transport due to a broken cold chain.
- Approximately 0.5% of transported goods are damaged during transport through non-compliance to temperature guidelines.

Source: World Health Organisation (WHO), Parenteral Drug Association (PDA) and other industry estimates.

Common non-compliance issues include failure to:

- Monitor and/or record storage temperatures
- Temperature-map warehouses to find hot and cold spots
- Calibrate temperature monitoring devices
- Take appropriate action when temperature excursions are noted

Source: Recent review of regulatory inspection findings for UK wholesale distributors.



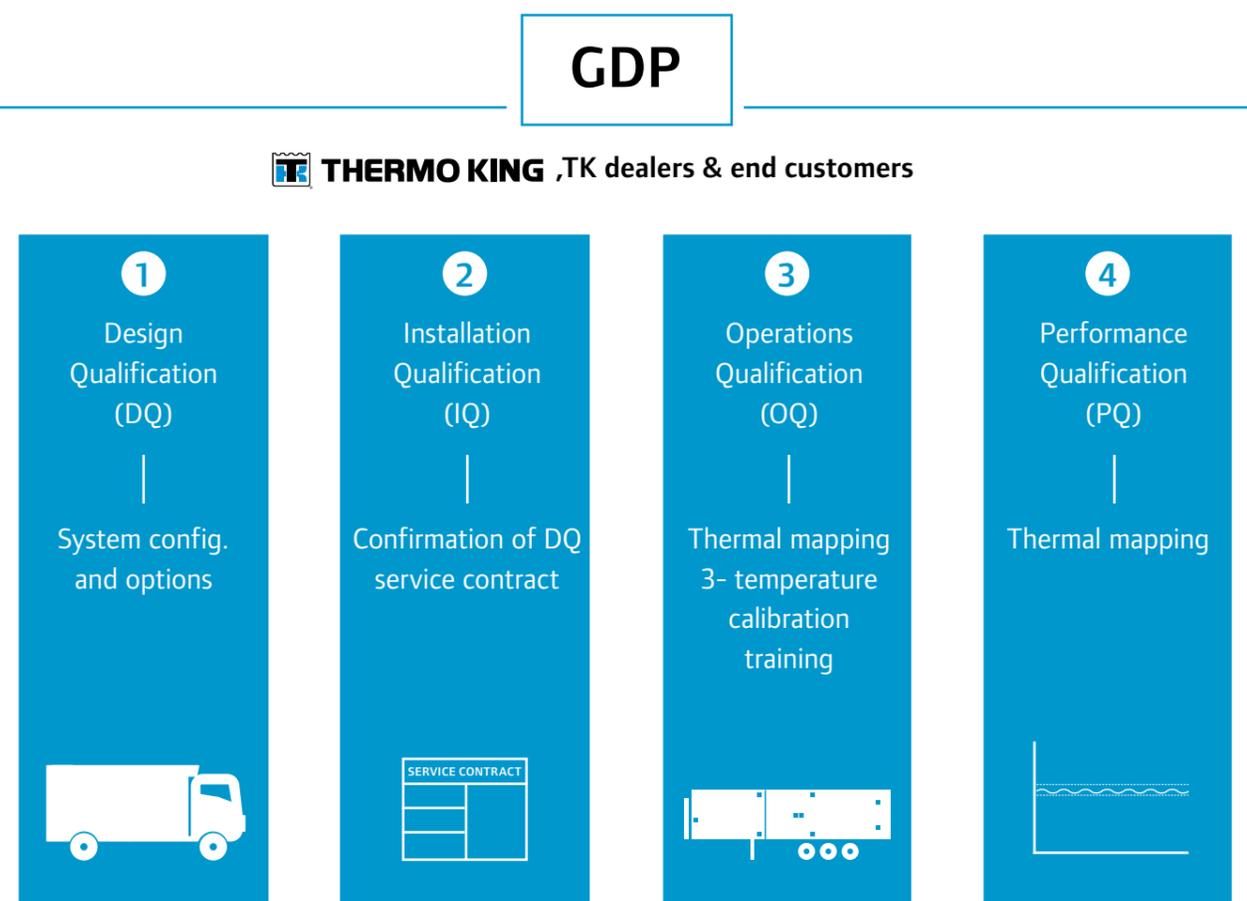
PharmaSolutions: Thermo King GDP protocol

PharmaSolutions, a comprehensive and dedicated expertise platform from Thermo King, addresses the precise needs of the pharmaceutical industry by delivering applications, advice and a broad spectrum of services.

Thermo King developed a GDP protocol covering the four stages outlined in the European Commission's Good Distributions Practice Guidelines (GDP guidelines) of Medicinal Products for Human Use and the annex 15 to the EU guide of Good Manufacturing Practice to include:

- Design Qualification (DQ)
- Installation Qualification (IQ)
- Operations Qualification (OQ)
- Performance Qualification (PQ)

Thermo King GDP validation protocol has been supervised and validated by an independent pharmaceutical company. This independent pharmaceutical company specialises in regulatory affairs to the health care industry, with qualified GDP experts and pharmacists highly-experienced in the design and implementation of pharmaceutical related quality systems.



Thermo King GDP qualified and validated equipment

PharmaSolutions offers a range of equipment for temperature-controlled transportation, for trailer, truck and vehicle powered units, as well as ColdCube™ Thermo King containers. All equipment has been tested* following Thermo King GDP validation protocol in line with the GDP guidelines:

- At temperature ranges +15°C to +25°C; +2°C to +8°C; and temperatures below -20°C.
- Under extreme ambient temperatures from -30°C to +40°C to assure you of your cargo's safety in extremes of climate.
- Test of door openings, failure mode as a reference for customer's risk management analysis.

To confirm that the refrigerated equipment is performing to specification, tests have been conducted in a temperature-controlled chamber of the industry-certified Ingersoll Rand Engineering and Technology Centre (IRETC) in Prague. The research and development facility is certified ISO 9001: 2000; ISO 14001 and ISO 18000 and authorised for ATP certification.

*Tests developed and performed to include "worst case" conditions

Ambient temperature	+40°C	
Zone 1 setpoint	+20°C	
Zone 2 setpoint	+6°C	
Stability duration	2.5h	

Note: Drawing is representative of the testing but not scale.

Real-time tracking, monitoring and fleet management beyond incident response

The need to establish critical controls at all points of the supply chain is an increasing challenge for all pharmaceutical companies and their partners when handling and transporting medicines globally. With regard to transportation temperatures, the GDP guidelines say that medicines requiring controlled temperature storage should be transported by appropriately specialised means.

PharmaSolutions recommends the use of remote monitoring systems such as Thermo King's TrackKing™ to reduce the risk of damage, loss of quality and wastage of high value medical and biological products.

TrackKing™ is a web-based solution that uses GPRS and GPS technology to track and trace shipments in real-time.

- Remote monitoring and control of temperature setpoint, return and discharge air and load temperatures to prevent excursions outside manufacturer specifications.
- Pre-trip reports and scheduled pre-cooling to ensure transport containers are ready for loading.
- Log and record of temperature data during transport is also available through Thermo King dataloggers, which are compliant with European standards EN12830.
- TrackKing™ allows manufacturers, shippers and fleet operators to guarantee product integrity and on-time delivery.



PharmaSolutions offers 24/7 fleet monitoring services for end-to-end management of any refrigerated vehicle fleet.

By capturing data such as temperatures, operating modes or alarm codes, from the refrigeration unit controller, the round-the-clock fleet monitoring service enables proactive measurement and management of distribution operations with respect to the established KPIs.

Fleet management beyond incident response

	FEATURES	FUNCTION
	CARGO INTEGRITY WATCH	To continuously track cargo temperatures, setpoints and alarm codes and act upon deviations.
	UPTIME WATCH	To prevent unexpected breakdowns with proactive maintenance strategies.

Supported by Thermo King's unmatched service network, pharmaceutical manufacturers are assured of smooth distribution operations, while logistics providers are guaranteed maximum uptime for their fleet. There are more than 500 service points in 75 countries, each with highly trained technicians to service your equipment according to GDP standards. The 24/7 fleet monitoring service is becoming available as a customised service offering, a combination of a ThermoKare™ contract and TrackKing™.



Dealer Locator App

Thermo King has a global TK Dealer Locator mobile and PC application to enable you to find your nearest Thermo King dealer in more than 75 countries worldwide.

Check it out now @ dealer.thermoking.com



Service offering: PharmaAssist & PharmaAssistPlus

In order to maintain the quality and integrity of medical and biological products during transport, PharmaSolutions offers a set of services that support you in activities around quality risk management. Preventative maintenance and easy access to service history are other important priorities in our service contract range.

The following offerings are available: PharmaAssist and PharmaAssistPlus.



The PharmaAssist package

This solution offers you the comfort of our full range of services: all the benefits of preventative maintenance on your fleet and full coverage in case of breakdown. Inspections and services are adjusted to meet the GDP guidelines, including the obligatory annual sensor calibration. Due to the sensitivity of the cargo, we secure prioritised treatment and follow-up in case of breakdown.

The package covers all the costs of parts and services, whether scheduled or unscheduled, and regardless of the authorised Thermo King dealer used.

The added value

PharmaAssist also offers fleet managers full access to the Thermo King portal iKare, where the status of any of your units can be checked and all required documentation is available. It allows you to verify the next planned inspection, service or calibration as well as a full service history of the registered units.

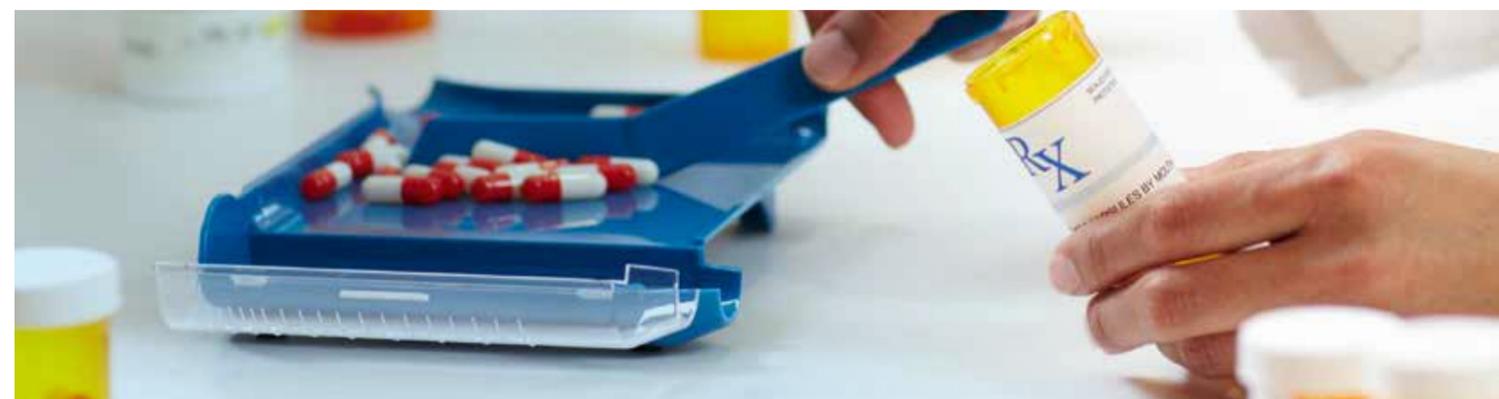
As part of the upcoming PharmaAssist Plus, customers can benefit from our 24/7 fleet monitoring service where our in-house experts monitor your vehicles while on-route, ensuring that the vehicle/cargo and driver have a safe trip and that the cargo temperature is monitored in relation to the set temperature. In case of deviations or alarm-codes, preventative actions are taken to secure the integrity of the cargo.

For more information please contact your Thermo King dealer or visit europe.thermoking.com

FEATURES	THERMO KING PharmaAssist	THERMO KING PharmaAssist Plus
Administration & centralised pricing	●	●
Access to online asset management system	●	●
Asset management	●	●
Call out and overtime	●	●
Travel for breakdown	●	●
Maintenance inspections*	●	●
Maintenance lubricants/filters/belts	●	●
Repairs	●	●
Leasing of TracKing™ box including communication & webservice charges & box repairs	○	○
Annual leak test	●	●
Annual 3-point sensor calibration	●	●
Travel for maintenance	○	○
Fleet consultancy and driver/fleet manager training	○	○
GDP renewal validation (each 3 years)	●	●
Pharma prioritised assistance and notification	●	●
24-hrs fleet monitoring and alert actions		●

* tailored to product family

● Included ○ Option



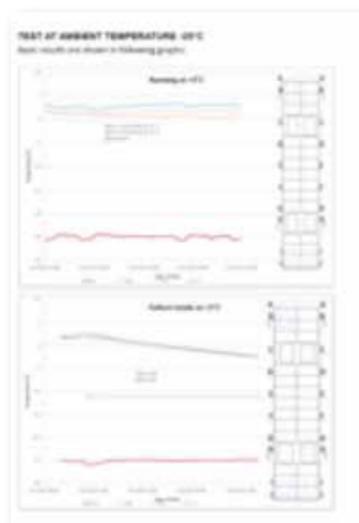
Qualification services

To confirm that the refrigeration equipment is performing to specifications, PharmaSolutions provides application engineering expertise through the industry certified Ingersoll Rand Engineering and Technology Centre (IRETC) in Prague. The research and development facility is ISO 9001: 2000, ISO 14001 and ISO 18000 certified and authorised for ATP certification.

Qualification services offered by PharmaSolutions cover the four stages of qualification and validation of equipment, design, installation, operational and performance qualifications. Tests are carried out in a controlled environment at extreme ambients.

- Thermography to visualise temperature spread within loaded vehicles
- Temperature spread and stability
- Thermal mapping of trailers and trucks from -35°C to +45°C
- Calorimeter tests of unit cooling and heating capacities

PharmaSolutions also offers customised qualification based on the customer's unique operations and quality standards.



qualification report

Training services to enable supply chain compliance

The key to successfully managing all the variables in the distribution chain lies in enabling stakeholders to learn, adopt and follow best practices. To enable compliance within the distribution chain, PharmaSolutions experts provide training on GDP guidelines and on areas that pose high risks to product quality:

- Efficient loading practices for optimum air circulation
- Operating procedures for the refrigeration equipment and management of system alerts

For fleet operators, drivers and distribution managers, PharmaSolutions delivers training on pre-trip procedures, including pre-cooling the vehicle to minimise temperature fluctuations. In addition, transport stakeholders can learn about preventative maintenance strategies designed to maximise uptime and reduce costly breakdowns.

Developing a culture of quality is often a continuous improvement process. Improve pharmaceutical quality management processes through factual and standards-based guidance from PharmaSolutions advisory services.

The Thermo King Professor Kool toolkit helps fleet operators and drivers optimise performance. With stand-alone, interactive and multilingual training modules, users can develop a better understanding of the fundamentals of refrigeration.

Check it out @ professorkooltoolbox.thermokinginfo.com





THERMO KING

Thermo King – by Trane Technologies (NYSE: TT), a global climate innovator – is a worldwide leader in sustainable transport temperature control solutions. Thermo King has been providing transport temperature control solutions for a variety of applications, including trailers, truck bodies, buses, air, shipboard containers and railway cars since 1938.

For further information, please contact:

europe.thermoking.com

Find your nearest dealer on

dealers.thermoking.com

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