

TK PharmaSolutions

Vital expertise for pharmaceutical
transport and storage

TEMPERATURE MANAGED TRANSPORT AND
COLD STORAGE SOLUTIONS FOR PHARMACEUTICALS



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Manage risk during pharmaceutical transportation with TK 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. TK 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.

PharmaSolutions: Thermo King GDP protocol

TK 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)**
System configuration and options
-  **INSTALLATION QUALIFICATION (IQ)**
Confirmation of DQ service contract
-  **OPERATIONS QUALIFICATION (OQ)**
Thermal mapping 3-temperature calibration training
-  **PERFORMANCE QUALIFICATION (PQ)**
Thermal mapping



Thermo King GDP validation protocol has been supervised and validated by an independent pharmaceutical company. This independent pharmaceutical company specializes 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.

Transforming success rates with our unique GDP Protocol

TK 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

TK 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 Stability duration: 2.5h

Guaranteeing the safe storage and distribution of your pharma shipments

The scale, critically, and quality of pharma shipments presents a unique challenge.

Supporting dynamic rollouts and delivering confidence in the integrity of each shipment are critical for pharmaceutical manufacturers and logistics providers for public health and patient safety. It is also vital to be able to demonstrate how each shipment – from production to patient – is managed with precise temperature controls. A precision that needs to be maintained over the entire cold chain, from the long haul to the last mile, across land, sea, and air.

In response, Thermo King offers the connected end-to-end active temperature-controlled transport and temporary storage solutions needed to guarantee product integrity and manage risk.

What's more, it's our promise to every pharma manufacturer that they can trust our technologies to protect their products with the temperatures required – from -70°C to +30°C.

Multiple options for multiple temperature requirements

Delivering billions of time- and temperature-sensitive products to the global community presents a hugely complex logistical challenge. Success will come to those with the capacity to ensure products are being handled, transported, stored, and monitored effectively – while consistently maintaining precise temperature control.

To support this endeavor, Thermo King has expanded its TK PharmaSolutions range to deliver complete coverage for every product on the move and at rest, covering temperature requirements from +30°C to -70°C.

These are solutions that help guarantee the integrity of every product shipped, thereby minimizing any product wastage and ensuring faster deliveries worldwide without compromising the health and well-being of patients.

With Thermo King, pharma manufacturers really can think globally and act locally, confident that product quality will never be compromised.





TK PHARMASOLUTIONS

TK PHARMASOLUTIONS

Transforming success rates in pharma distribution

25% of all vaccines produced globally
are compromised by incorrect
shipping.

WHO estimates suggest
more than 50% of vaccines
are wasted every year
because of temperature
control, logistics, and
shipment-related issues.

>50%

Billion
-35\$ The biopharma industry loses
approximately \$35 billion a year
due to failures in temperature-
controlled logistics.

Refrigerated Transport Solutions: From production to patient

Pharmaceutical cold chains involve many moving parts, ranging from how products are packaged and transported, to how they're stored prior to use. At Thermo King, our end-to-end transport and trailer solutions cover each step with proven temperature control technologies:

Refrigerated Transport Solutions: the range



**ROAD SOLUTIONS –
TRUCK & TRAILER**
(-30°C TO +30°C)

Overview
For long-haul road transportation and urban distribution, Thermo King has GDP certified technologies for every size of trailer and truck.

Products

- A-Series & SLXi-Series
Units for trailers that offer the highest cooling and heating capacities for both single and multi-compartment applications.
- TX-Series
With diesel or hybrid versions for large trucks, as well as electric standby during loading and unloading.
- V-Series & VX-Series
Designed for vehicles ranging from small vans to 7.5 ton-trucks, with tight temperature control and low noise operation.



**LAST MILE DISTRIBUTION –
VANS & SMALL TRUCKS**
(-30°C TO +30°C)

Overview
For inner-city deliveries requiring whisper quiet and full electric transport refrigeration, Thermo King delivers market-leading innovation that's proven to keep loads in optimal condition.

Products

- B- and E-Series
Fully electric, temperature control units for vehicles up to 3.5 tons that enable 24/7 last-mile city distribution.
- Cold Cube mobile refrigerated containers
Portable, fully electric powered, and highly mobile freezing containers available in 5 sizes and 16 standard configurations, with full Bluetooth connectivity.



OCEAN SOLUTIONS
(-70°C TO +30°C)

Overview
Thermo King supports the large volume shipments of medical and biological products by sea through standardized ISO refrigerated containers, which range in size from 440 cubic feet to 2950 cubic feet.

Products

- MAGNUM PLUS®
Designed for frozen cargoes requiring set points between -40°C to +30°C, and equipped with user-friendly controller to monitor performance and temperature.
- SuperFreezer
Fully electric, ultra-low temperature unit with set points between -10°C to -70°C to fit 10-40ft insulated ISO containers.



AIR SOLUTIONS
(0°C TO +25°C)

Overview
Thermo King and Envirotainer, the leading supplier of active containers, work in partnership to offer customers two units for pharmaceutical cold chains – both of which are approved by European and US aviation authorities (EASA and FAA respectively).

Products

- Air100-RNK e1 and Air200-RAP e2
Maintain product temperatures between +2 to +8 °C, controlled room temperatures between +15 to +25 °C or any chosen set temperature between ±0 and +25 °C in nearly any ambient condition appearing along global shipping routes. Both models utilize compressor cooling and electric heating technology to meet the extreme requirements of the pharmaceutical industry for shipments.

Cold Storage Solutions: covering every eventuality

As well as ensuring tight temperature controls for pharmaceutical products in transit, Thermo King also extends this protection to any number of storage points along the way.

Our Cold Storage Solutions can maintain temperatures of -70°C for an extended period of time, thereby helping significantly reduce the degradation of cargos – while also helping overcome challenges relating to accessibility in less developed locations.

Boost local capacity with powerful capabilities

EXCEPTIONAL PERFORMANCE

Access the highest possible cooling capacity in combination with precise temperature control.

ULTRA-LOW TEMPERATURE RANGE WITH THE TIGHTEST TEMPERATURE ACCURACY

Set precise temperatures between -70°C to -10°C to meet specific pharmaceutical demands, with an accuracy of $\pm 1^{\circ}\text{C}$.

LARGEST ULTRA-LOW STORAGE SOLUTION

Choose from 10 m^3 and 24 m^3 capacity, with the possibility to customize the interior for optimum ease-of-use.

FLEXIBLE AND ADAPTABLE DESIGN

Utilize easily stackable, ISO containers ranging in sizes 10 and 20 ft to scale capacity in line with demand.

BUILT-IN REMOTE MONITORING

Access real-time data monitoring from each unit, that's also compliant with the Good Distribution Practice (GDP).

READY TO GO UNITS

Cold Storage Solutions are immediately available, in stock, with impressively short delivery times.

Cold Storage Solutions: the range

MAGNUM PLUS®

- Tight temperature control and total protection where you need it.
- Box temperatures between **chilled and -40°C** in environmental conditions up to $+50^{\circ}\text{C}$.

SUPERFREEZER

- Ultra-low temperatures down to **-70°C** to guarantee product integrity.
- **Modular solution** that can be used as both stationary and mobile pharmaceutical distribution centers.

SUPERCHILLER

- Ultra-wide temperature range between **$+10^{\circ}\text{C}$ and -60°C** , SuperChiller is a great choice for non-mRNA vaccines or medicines.
- **Ultra-powerful modular solution**, combining cooling with storage capacity. Comes attached to a 10', 20', or 40' special insulated container.

GENSET

- Fully electric unit with diesel generator.
- Suitable for transit back-up.



Service offering: PharmaAssist & PharmaAssistPlus

In order to maintain the quality and integrity of medical and biological products during transport, TK 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 prioritized 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 authorized Thermo King dealer used.

The PharmaAssistPlus package

With PharmaAssistPlus, 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.

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.

Confidence when it matters

Turning real-time traceability into real-time protection

With Thermo King Connected Solutions, pharmaceutical manufacturers and distributors can access the real-time data they need to plan, run, and manage smarter rollouts. Utilizing GPS technology, users can track and trace a variety of factors that impact cargo integrity – from door openings and environmental temperatures to fuel levels and the condition of individual loads – and respond fast to any emerging problem.

Rely on technology that’s compliant with (GDP) Good Distribution Practice – every step of the way

All the equipment in TK PharmaSolutions range has been vigorously tested in line with GDP guidelines:

- At temperature ranges +15°C to +25°C; +2°C to +8°C; and temperatures below -20°C.

- Under extreme environmental 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.



24/7 VISIBILITY
Constantly monitor reefer status, load condition, and asset location.



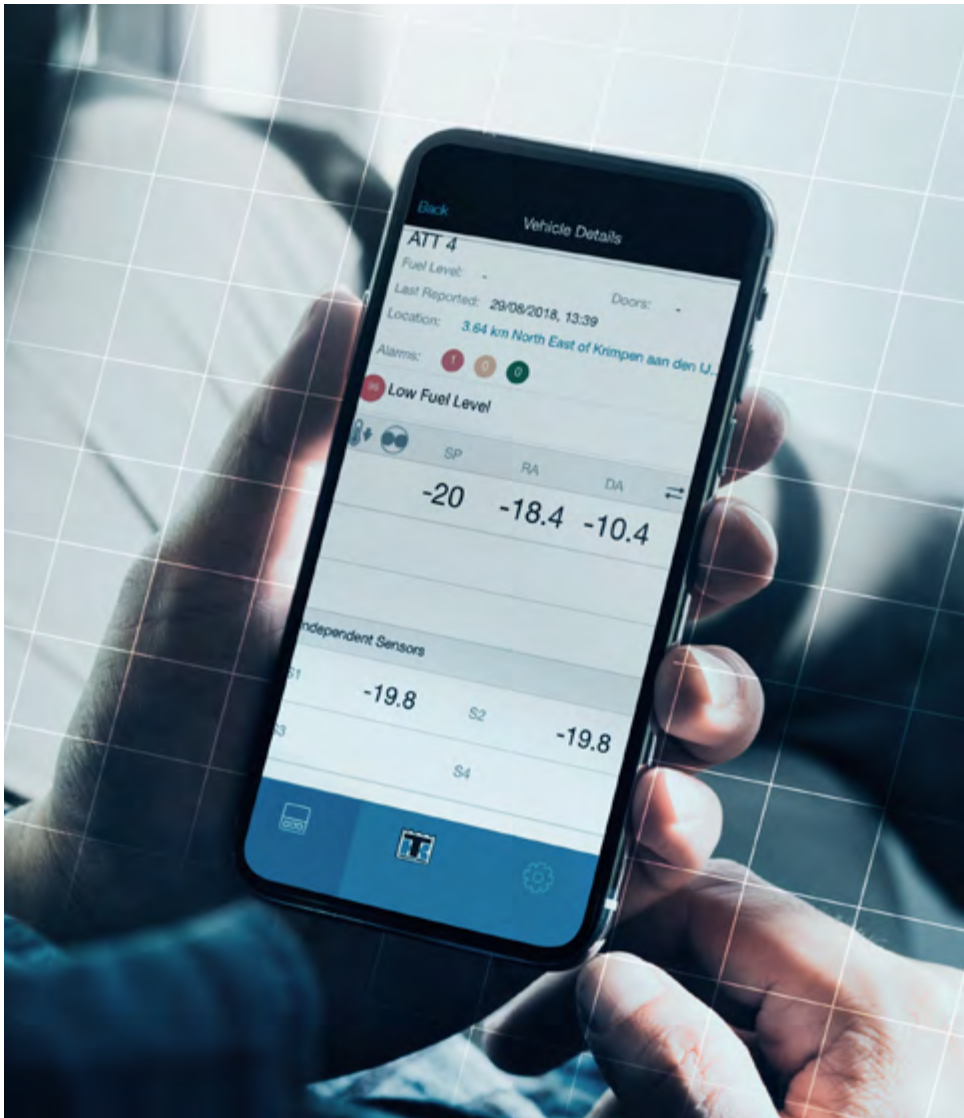
VACCINE TRACEABILITY
Demonstrate an audit trail of temperature compliance and asset security.



TWO-WAY INTERACTIVITY
React instantly to unexpected events and change settings from any location.



OPERATIONAL EFFICIENCY
Monitor vehicle uptime, and fuel usage to increase day-to-day fleet operations.



Expert support that’s always ready and waiting

Supporting our vaccine distribution technologies is an award-winning **international dealer network**, that customers can always rely on for immediate, experienced, and specialist support.



GLOBAL COVERAGE
including 500+ service points in 75 countries



NON-STOP AVAILABILITY
with 24/7/365 direct telephone access



RELIABLE SUPPORT
most locations can be reached within 2 hours

TK PharmaSolutions

- **END-TO-END GDP-COMPLIANT COLD CHAIN SOLUTIONS**
Ensure full regulatory compliance.
- **COMPREHENSIVE TEMPERATURE COVERAGE AND PRECISION CONTROL**
Protects even the most sensitive products.
- **REAL-TIME MONITORING AND CONNECTED VISIBILITY**
Enables instant corrective action.
- **BROAD MULTI-MODAL PRODUCT RANGE FOR EVERY SEGMENT**
Covers every transport scenario.
- **GLOBAL EXPERT SUPPORT AND SERVICE NETWORK**
Provides reliable worldwide support.



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
europe.thermoking.com

Find your nearest dealer on
dealers.thermoking.com

