

TempTrust™ packaging systems, by Infitrak, are supported by a complete portfolio of services to get your packaging & processes validated, qualified and compliant

TempTrust was developed by Infitrak

Trusted leader in cold chain management

Since 2002 Infitrak has designed and developed comprehensive cold-chain solutions that protect a product's integrity and ensures patient and consumer safety. Infitrak is the only company with all three areas of compliance-based, temperature controlled services and products: packaging, consulting, and real-time monitoring. This translates into a team that is with you all the way from raw materials to end user. For more information, visit us at www.infitrak.com.



Transportation Process Assessment

A transportation process assessment reviews all involved processes and conditions for the analysis of existing standards and of collected environmental data involved during the transportation processes of products. Infitrak can provide the customer with a compliance gap analysis on the transportation process assessment, and consequently with an action plan to level up the compliance of the distribution and transportation process.

Temperature Profile Analysis

A Temperature Profile Analysis determines the handling, temperature and transport time for selected thermal sensitive products and determines the various shipping time lengths in order to establish acceptance criteria. Infitrak designs temperature profile analysis protocols (by season and transportation mode), assists in the execution of the analysis, analyzes the collected data and, based on its data compilation and analysis model, provides seasonal temperature profiles specific to your transportation process.

User & Functional Requirements Development

URS/FRS development provides a high level description of the user's expectation of the project scope, with emphasis on equipment and material parameters, and process performance parameters. The Functional Requirements Specifications (FRS) is also a specification document, which builds on the URS (User Requirements Specifications) and provides a basic narrative on what functions the process and its control system are expected to perform. Infitrak provides assistance for the development of User Requirements Specifications and develops Functional Requirement Specifications for your transportation and packaging needs.

Design Testing

Design testing is performed to develop a specific package design, modify an existing package design or establish equivalent results between package components. It ensures functional requirements are met by the proposed package or system design. The outcome of design testing assures a high confidence for successful operational qualification (OQ) of a specific package or system design. Infitrak's packaging laboratory performs design and design testing for temperature-controlled packages. We develop new specific package designs based on URS/FRS, modify existing package designs or establish equivalence results for package components.

Thermal Package Qualification (OQ, Operational Qualification)

Thermal Package Qualification is documented testing that demonstrates with a high degree of assurance that a specific process will meet its predetermined acceptance criteria. Infitrak's packaging laboratory performs complete Operational Qualification (OQ) of temperature controlled packaging system based on pre-approved OQ protocols, and provides thermal OQ protocol/report packages for package designs.





TempTrust Packaging Services

Complete solutions for qualified packaging

Physical Design and Operational Qualification

Physical design and operational qualification testing is designed to demonstrate that a specific process will meet the predetermined acceptance criteria in terms of fragility, shock and/or vibration requirements. Establishing appropriate packaging tests and test levels will help minimize distribution damages. Infitrak's packaging laboratory provides Physical testing and qualification services based on ASTM standards and ISTA guidelines.

SOP Development

Written procedures (SOPs) are essential quality documentation to ensure product quality and integrity. It typically includes temperature profile analysis, conditioning gels, configuration of packaging systems, performance qualification of packaging systems, and inspection of packaging materials and components for re-use. Infitrak provides consultancy services for writing SOPs for your distribution and transportation process.

Gel Conditioning Process Validation

Gel conditioning is a critical step and process to ensure the thermal performance requirements for a temperature controlled package. Infitrak provides gel conditioning process validation protocol based on your process, assists in the execution of validation runs, analyzes all collected temperature data and provides gel conditioning process validation report.

Performance Qualification (PQ)

Performance Qualification is documented testing that demonstrates a specific process will meet its predetermined acceptance criteria. Qualification testing (PQ) should be performed by following an approved predefined protocol, and PQ testing results should be documented in a formal report. PQ testing consists of consecutive replicate field transportation tests to demonstrate the process is effective and reproducible. The testing includes: ambient temperature variances, representative transport load configurations, defined packing configuration(s), calibrated temperature monitors or loggers, and sufficient number of tests to assure reliable results. Infitrak provides a complete solution for the thermal Performance Qualification (PQ) of your system(s). We provide thermal PQ protocol and associated SOPs, assist in execution of the PQ protocol, analyze the collected temperature data and write the final PQ report.

Return, Reuse and Refurbishment Consulting

The reuse or refurbishment of packaging components and materials requires a well controlled process. Quality inspections and acceptance criteria should be in place to evaluate the reuse or refurbish of packaging materials, in order to maintain both thermal and physical performances of temperature controlled packages. Written procedures should be in place to control this reuse/refurbish process. Infitrak assists you in establishing procedures and controls for the reuse and refurbishment process you may want to implement in your operations.

Inventory and Logistics Management

Inventory and logistics management for packaging components and materials (shippers, refrigerants, etc) is critical to avoid shortages in packaging components and materials and delays during the shipping process. Infitrak provides inventory and logistics management services for all packaging components and materials to ensure a constant and secure supply in packaging systems.



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