Almac’s Temperature Management Solutions include a suite of services to optimise temperature management for investigational and commercial products. These services aid clients in their compliance to Good Distribution Practices (GDP) and Good Manufacturing Practices (GMP) and can be provided either as a comprehensive program or as individual features that suit your clinical trial needs.
SUITE OF SERVICES

TRUSTING ALMAC WITH THE TEMPERATURE MANAGEMENT OF YOUR GLOBAL CLINICAL SUPPLY ALLOWS YOU AND YOUR TEAMS TO FOCUS ON CORE TASKS.

Adjudication of In-Transit and Clinical Sites excursions
- Collect all data necessary to make a decision (e.g. temperature data; shipment, facility and site details; contents of shipment or refrigerator)
- Make a decision on the acceptability of the drugs using stability guidelines provided by the sponsor company
- Update the Interactive Response Technology (IRT) with the result of the adjudication
- If necessary arrange for the material to be replaced

Compliance Management of Shipments
- Ensuring sites upload the temperature monitors by sending protocol specific alerts to sites
- Alerts can be event or calendar driven by the shipment and can include CRA/monitors, client etc.

"They make me feel like I’m the only person they are taking care of."

Small Biotech Company

Compliance Management of Sites
- Regular review of the site storage logs against reported site excursions
- Expedited processing of any unreported excursions to determine material acceptability
- Review of patient dosing for unreported excursions

Comprehensive GDP Monitoring (also referred to as End to End Monitoring)
- At a lot or med ID level, collection of temperature deviations from manufacture through dispensing to the patient
- Evaluation of cumulative deviations across all activities using stability data provided by sponsor (manufacture → receipt → production → storage at Almac and depots → distribution → storage at clinical sites)

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Using our proprietary Control Tower knowledge, Almac applies business intelligence to eliminate excursions occurring during transit and therefore reduces risk across the entire supply chain. Through the rapid adjudication of excursions, Almac ensures that an out of specification study drug is rapidly removed from the field.

KEY FEATURES OF ALMAC’S TEMPERATURE MANAGEMENT SOLUTIONS:
- Controlled process around adjudication of temperature excursion
- Ability to expedite the replacement of out of specification material
- Tracking of excursions at the med ID or lot level
- Collection of temperature data from manufacture to dispensing
- Site compliance management for uploading temperature monitors and site storage excursions
- Ability to run analytics across a number of key performance factors (for example: programs, protocols, products, countries etc.)

“This is a superior service which frees up time to allow me to concentrate on the planning/strategic part of my role.”

Large Pharmaceutical Company

KEY BENEFITS OF ALMAC’S TEMPERATURE MANAGEMENT SOLUTIONS
- Aids clients in GDP compliance
- Reduces risk of administering study drug that is out of specification
- Provides clients with a central database to store all temperature data
- Supports the emergence of biologic products with tight temperature bands
- Supporting software is monitor agnostic and can upload data from different monitor brands

“The Temperature Excursion model utilised by Almac is industry leading.”

Large CRO Company
All our clients have unique needs. That's why we develop unique solutions.

This is the ALMAC TOUCH®