PAREXEL®
YOUR JOURNEY. OUR MISSION.™

KEEPING IT COOL: HOW TO KEEP THE COLD IN COLD CHAIN

Increasing number of products requiring temperature control ('cold chain')

- 3/4 OF BIOLOGICAL DRUGS
- 10-15% SMALL MOLECULES
- ALL VACCINES
- BIOLOGICAL SAMPLES & DIAGNOSTICS TOOLS

COST OF SHIPMENTS WASTED DUE TO TEMPERATURE EXCURSIONS

$2.6BN x 4% = $100M

$2.6BN: Cold chain logistics & distribution market size 2015[1]

4%: Shipments wasted due to excursions

1 Outsourced market size only, does not include supplies managed by pharma companies themselves.

Increasing regulatory guidelines on temperature-sensitive drugs and traceability of any IMP including:

- EU Guidelines of 7 March 2013 on Good Distribution Practice of Medicinal Products for Human Use
- CFDA (China FDA) – Good Supply Practice for Pharmaceutical Products
- World Health Organization - Annex 9 - Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products
- USP 1079 Good Storage and Distribution Practices for Drug Products

DELAYS AND TEMPERATURE EXCURSIONS CAN LEAD TO:

- Additional manufacturing and shipment costs
- Patient retention issues if drug is not available at scheduled visit
- Impact on patient safety due to delays or compromised drug

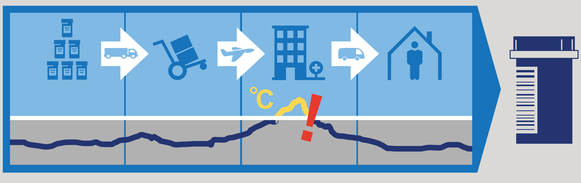
THE SUPPLY CHAIN OF CUSTODY: FROM MANUFACTURER TO PATIENT

MANUFACTURER → DEPOT → CLINICAL TRIAL SITE → PATIENT'S HOME

Conventional temperature logging:

- Different systems used across manufacturing, depots, couriers and sites
- Excursions not detected until shipment arrives and data is download
- Difficult to aggregate multiple excursions to perform end to end quality control
- No tracking to patient's home

With GSM/GPS enabled real-time temperature & location monitoring:



- ☑ **Traceability**
- ☑ **Cost & risk reduction**
- ☑ **Patient safety**
- ☑ **Compliance**

- Systems and data integrated across the supply chain
- Potential to extend monitoring to patient's home
- Excursions, delays and removal from geo-fenced areas detected in real-time, enabling immediate remedial action
- End-to-end audit trail from manufacturer to patient for accumulated excursion management and regulatory reporting
- Logistical trend data from multiple studies enabling supply chain predictability and process improvements

To discuss your clinical trial supply chain challenges, and to learn how PAREXEL can help with integrated services, technology, facilities and regulatory expertise, email us at: info@PAREXEL.com

Source of statistics:: Clinical Trial Supply and Logistics: World Industry and Market Outlook 2015-2025, Visiongain, 2014