The Weakest Link
"Pharmaceuticals in the Cool Chain"
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Categorizing Packaging Systems

Temperature Control

Passive

Active

Refrigeration

Heating & Cooling
Protection Increases with Employed Technology...

**Passive Temperature Control**
- Gel Packs and Semi Active Shippers
  - 1980’s
- Fiberboard Boxes and Styrofoam Insulation
  - 1950’s

**Active Temperature Control**
- Active Cooling & Heating
  - 2004
- Active Refrigeration/Compressor Technology
  - 2010
- Active Cooling Dry Ice High Tec Passive
  - 1995
The Effects of Insufficient Packaging – A Case Study

Logger 1
inside, middle of carton…

…protected by substantial insulation

Logger 2
inside, top
Case Study: Shrink Foil

Logger 3
outside, on top of carton, beneath foil

Logger 4
outside, on top of foil as ambient reference
Case Study: Blister Foil

Second shipment…

same placement of loggers but additionally protected by blister-foil
Storage Conditions…

Overnight at 2°C to 8°C cold storage

Over 5 hrs. at tarmac conditions - then back to cold storage
Results with Regular Shrink Foil Are:

- Ambient
- Center of shipment
- Under lid
- Under shrink foil

22 min.

35°C
... and with Reflective Blister Foil:

![Graph showing temperature changes over time with labels for different locations: Under lid, Under shrink foil, Ambient, and Center of shipment. The graph highlights a peak at 35°C after 179 minutes.]

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Let’s Compare the Two Loggers Under Shrink Foil and Under Blister Foil…

ΔT = 19.5°C
Do Thermo-Foils Offer Similar Protection from Low Temperatures?

Storage at 15°C to 25°C

Overnight at -20°C cold storage
Do Thermo-Foils Offer Similar Protection from Low Temperatures?

79mins

Shrink Foil
Blister Foil

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What it takes to provide a proper analysis

1. Getting the info of a Temp Deviation to the right people
2. Compile all available data, clarify time zones, ensure editable data, packaging, value etc.
3. Make the data comparable
4. Investigate possible service gaps, initiate CAPA’s
5. Handover & explain report
6. Compile final report, monitor CAPA’s
7. Compile & handover report, explain report
8. Close file
Transportation Analyses and Finding Out What Happened...
Transportation Analyses and Finding Out What Happened...
Transportation Analyses and Finding out What Happened…
Root Cause and CAPA’s…

2h exposure 20h exposure
Warehouse Requirements for Temperature-Sensitive Pharmaceutical Shipments

1. **Chill Room 3**
   Temperature +5° to +15° C (+41° to +59° F.)
   approx. 2,000 square feet

2. **Temperature-controlled warehouse space**
   Temperature +15° to +25° C (+59° to +77° F.)
   37,500 square feet

3. **Chill Rooms 1 and 2**
   Temperature +2° to +8° C (+35° to +46° F.)
   approx. 8,500 square feet

4. **Deep frozen cell**
   Temperature −20° to −12° C (−4° to +10° F.)
   approx. 500 square foot

- exclusive Competence Center Temperature Control (CCTC) supervision team – on call 24/7
- equipped with state-of-the-art cool storage rooms
- exclusive ramps for delivery and goods acceptance
Movements of Healthcare Shipments in Frankfurt
Any Questions?
Back up

Staging
Staging

- Approx 60min Prior to departure
- For safety, security and verification
Staging

- Approx 60min Prior to departure
- For safety, security and verification
Back up

Engine Blast
Engine Blast Contour (Break Away)

AXIAL DISTANCE BEHIND AIRPLANE

CONVERSION FACTOR
1 MPH = 1.6 km PER HOUR

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Engine Blast Contour (Take Off)
Backup

Air conditioning
Air conditioning
Air conditioning (Main Deck)
Air conditioning (Main Deck)

Cold: 18 °C  
Hot: 29.5 °C  
Center: 23.8 °C
Air conditioning (Cargo Hold)

FORWARD OVERHEAD PANEL
Air conditioning (Cargo Hold)

FWD
LO: 4.4 °C
HI: 21.0 °C

AFT
Cold: 4.4 °C
Hot: 35.2 °C
Center: 19.8 °C
Air Conditioning (Synoptic)
Air Conditioning System (Cockpit Display)
Air Conditioning Packs (Inlets)
Air Conditioning Packs (inlets & outlets)