



The challenges of cold chain logistics

Ensuring temperature control along the
total supply chain

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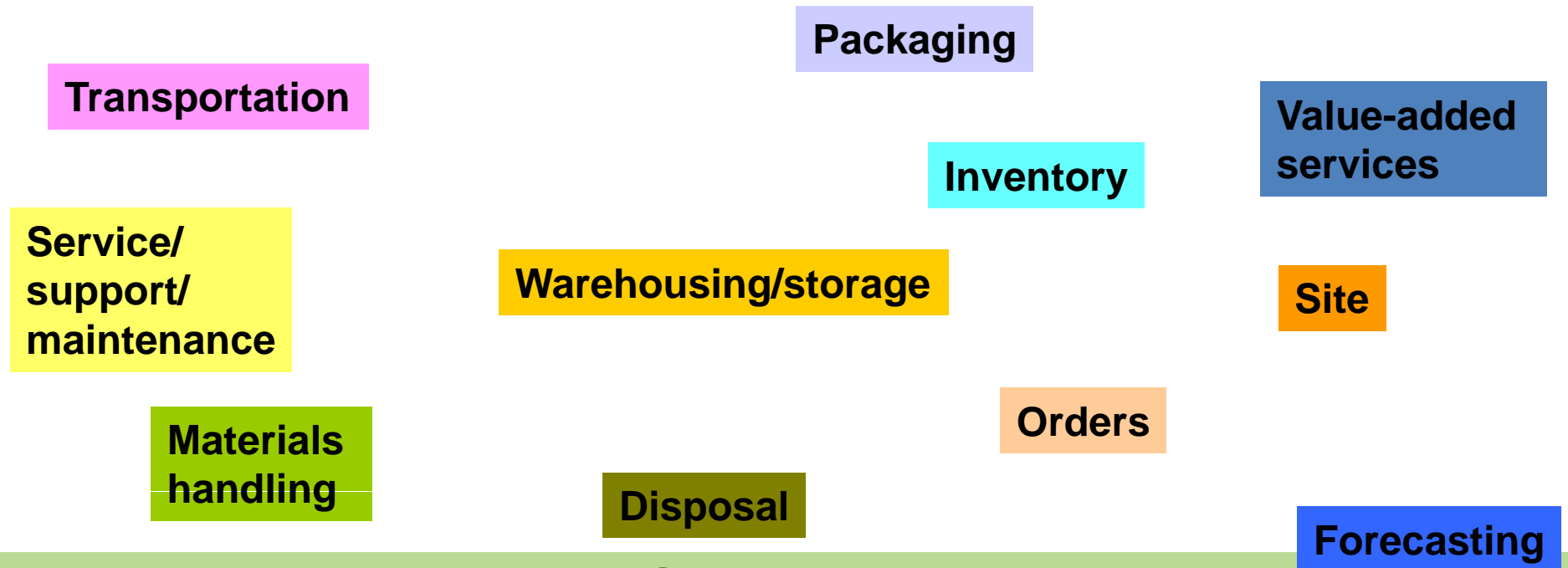
Summary of presentation

- **Logistics operations for Life Science products**
- **Business and corporate responsibility drivers**
- **Packaging systems**
- **Temperature monitoring systems**
- **Containment systems (reusable containers and pallet systems)**
- **Transport systems: road, air, sea**



PharmaLogistics

- Deals with the handling, movement and storage of pharma products from supplier to consumer



Temperature groups

On the label

“Do not store over 30°C”

“Do not store over 25°C”

“Do not store over 15°C”

“Do not store over 8°C”

“Do not store below 8°C”

“Protect from moisture”

“Protect from light”

Means

from +2°C to +30°C

from +2°C to +25°C

from +2°C to +15°C

from +2°C to +8°C

from +8°C to +25°C

no more than 60% relative humidity in normal storage conditions; to be provided to the patient in a moisture-resistant container.

to be provided to the patient in a light-resistant container.

Source: WHO Technical report Series No. 908, 2003

Business drivers

- Of the greater than AUD\$1,120 B of pharmaceutical product sold worldwide in 2005, about 10% biopharmaceuticals
- Biopharma prods are temperature sensitive
- Short time frame to realise profits
- Cost reduction (inventory)
- Global supply chain (manufacture site \neq packaging site \neq market)
- Expansion to new markets (eg. China, India)
- Expansion to urban operations

Overall...

- Re-inspection
- Delays
- Product written off
- Cash loss
- Breach in GMP, SOPs, GDP, 21 CFR Part 11, WHO, USP

CSR case

Indonesia: T<0 during vaccine transport (50% of freezing occurrences per year)



North Australia: T<0 in vaccines are detected 4 times more than heat exposure during transport & storage



South Australia: During 2001/2002, 9,700 vaccine doses (\$128,500) were wasted in due to cold chain issues



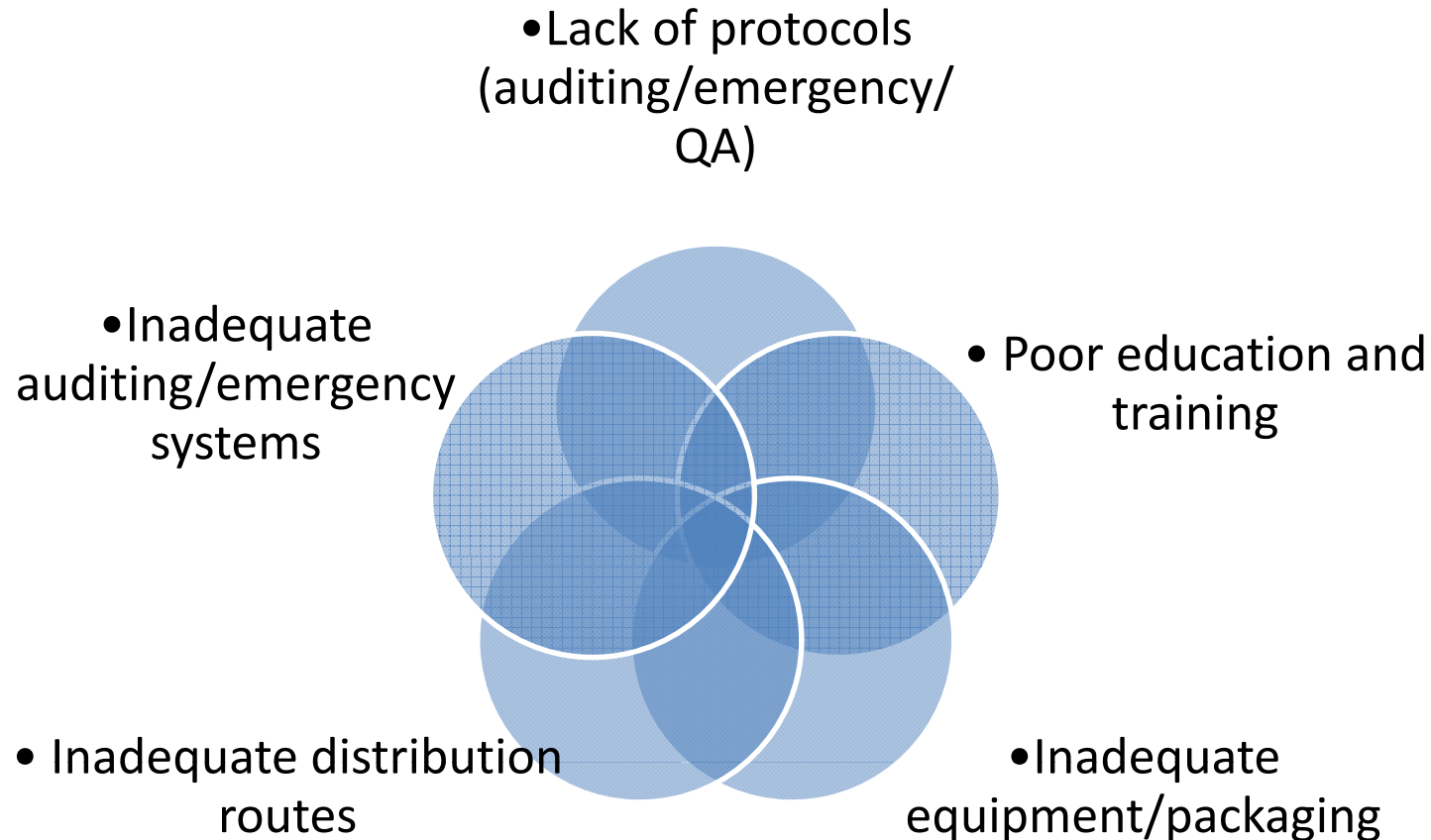
New Zealand: Temperature abuse of vaccines may have been the culprit in measles epidemics (1991)



Some products (epinephrine, diazepam, Lorazepam) show a reduction in potency after temperature abuse

WHO: “Overcoming freezing in the cold chain”, Feb 2003; CDC Bulletin, Aug 2002

Weakest links in the cold chain



What is needed?

- Safe temperature guidelines for pharmaceutical products
- Systematic risk assessments of temperature abuse
 - during the whole chain
- Define specific storage/transport guidelines and level of public intervention in regulatory matters
- Holistic regulations on the transport of pharmaceutical products. This is especially true for international trade regulations

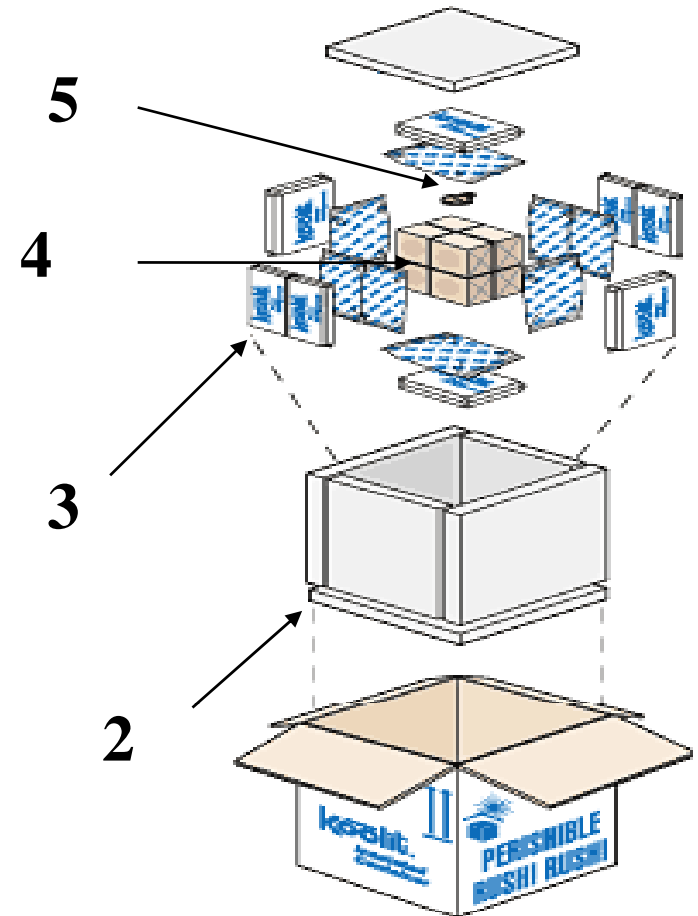
Packaging systems



Thermal Package

Should comprise:

- (1) Outer container
- (2) Insulation covering all 6 faces
- (3) Temperature control agent
- (4) Product located at the centre of the package
- (5) Temperature monitor



Characteristics of thermal packaging systems



- Normally used once, then discarded
- Stand-alone cooling system
- Usually, no means to add heat if required
- Able to travel by road, sea or air (40-120 hrs)
- Small capacities (eg. less than 100 L)
- Can include embedded temperature control/recording means
- Suitable for integration with other technologies (eg. RFID, high/low oxygen concentrations)

Temperature monitoring technology

	ESCORT iLog	HOBO H8	JR RECORDER	NOMAD OM-41	DS1923 THERMOCHRON I-BUTTON
Manufacturer/Supplier	ESIS PTY LTD http://www.esis.com.au/	ONSET http://www.onsetcomp.com/	AVATEL http://www.avatel.com/	OMEGA http://www.omega.com/	DALLAS SEMICONDUCTOR http://www.maxim-ic.com
Sensor type	Thermistor	Thermistor	Thermistor	Thermistor	Thermistor
Measurement range (°C)	-40 to +70	-20 to +70	-45 to +125	-20 to +70	-20 to +85
Claimed accuracy (+/- °C)	0.3	0.7	0.5	0.7	0.5
Resolution (°C)	0.1	0.4	0.5	0.4	0.5
Capacity (memory)	32,000 samples	7,943 samples	64,000 samples	7,943 samples	8,192 samples
Sampling frequency	1 sec to 255 min	0.5 sec to 9 hrs	1 sec to 24 hrs	0.5 sec to 9 hrs	1 to 255 min



Temperature monitoring technology

VERITEC



KOOLTRACK



FOURIER SYSTEMS



TEMPTALE 4

COLE-PARMER

LOGTAG



TINYTAG



TI and TTI monitoring technology

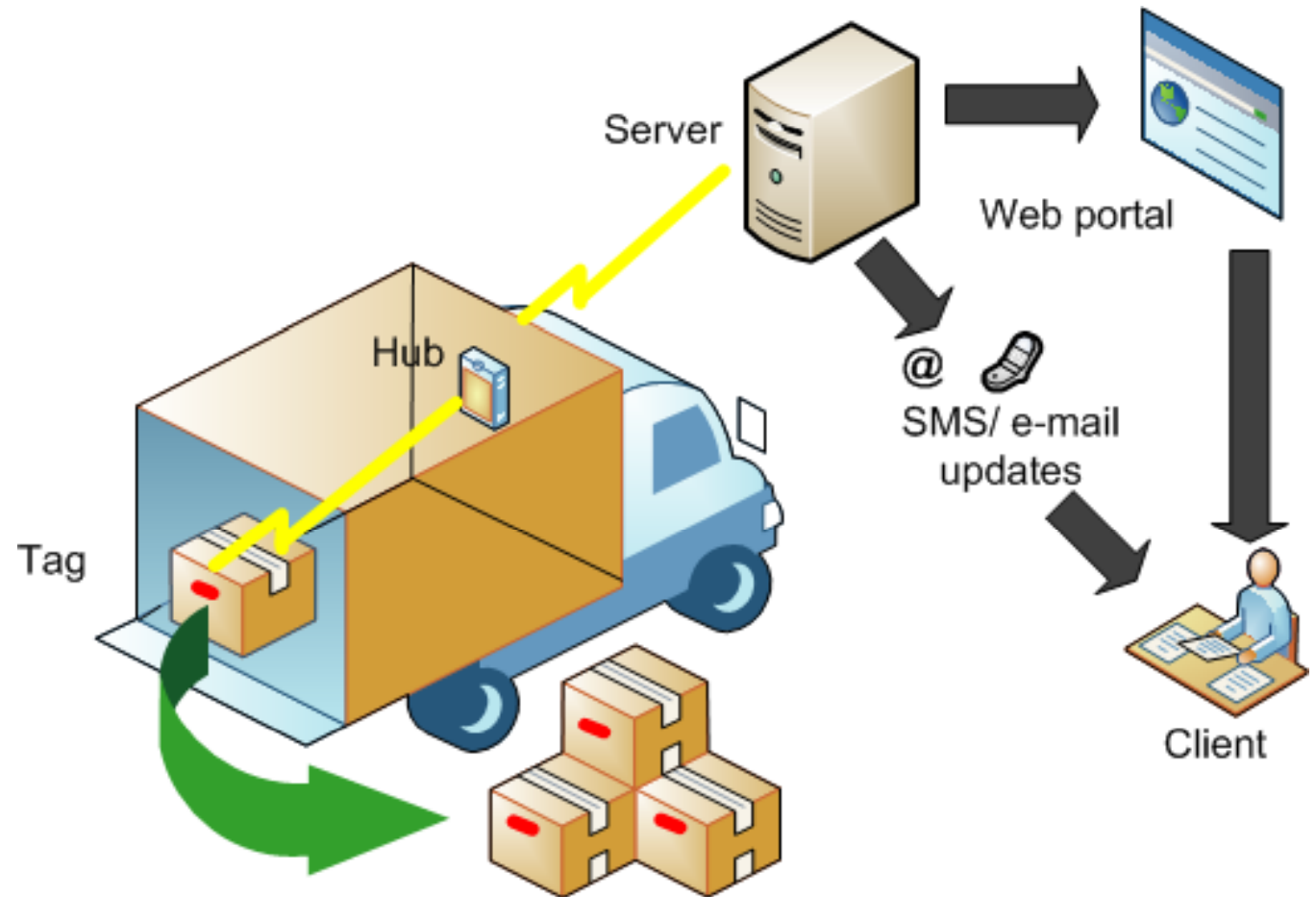
Name and type	Change in TTI noticed by user	Principle	Temperature or time limits		Dimensions
			Upper limit	Lower limit	
3M Monitor Mark® 9860A	Diffusing blue front along the length of a porous wick	Diffusion of coloured substance if temperature measured is higher than melting point of octyl octanoate	-15 °C	-20 °C	95 mm x 19 mm; thickness= 2 mm
VITSAB CheckPoint™ labels	Colour change of label, caused by a decrease in acidity of active substance	Enzymatic hydrolysis of a lipid substrate (occurs at -18 °C)	4 days	Variable ¹	22 mm x 36 mm; thickness= 0.8 mm
WarmMark™ 51034	Colour change of label, caused by a decrease in acidity of active substance	Enzymatic hydrolysis of a lipid substrate (occurs at -18 °C)	12 hrs	Variable ¹	19 mm x 46 mm; thickness= 1.5 mm)



Wireless monitoring technology

Electronic Track & Trace Technologies

- RFID and wireless
- Wireless systems that allow for non-contact reading



Wireless monitoring technology

Company	Supply chain link	Application	Pilot trial year	Approximate Implementation Costs	Reason for RFID uptake
Envirotainer (Sweden)	Air freight	Tracking air shipments of temperature sensitive goods	2002	Unknown	Competitive advantage
DHL (Europe)	Delivery and logistics company	Monitoring temperatures of refrigerated vans	2007	Unknown	Quality assurance for pharmaceuticals
ASD Healthcare (US)	Pharmaceutical manufacturer	Monitoring of refrigerators and individual packages at hospitals	2007	Unknown	Quality assurance throughout the chain
TNT (The Netherlands)	Logistics and global express services	Tracking temperatures of health-care, pharmaceutical and chemical goods as they move along the supply chain (Asia only)	2006	\$500,000	Supply chain of TNT's Life Science Regional DC in Singapore to a distribution hub in Bangkok, Thailand, plus shipments flown from the Singapore DC to a hub in Shanghai.

Packaging systems

- The Greenbox ([Entropy Solutions, Inc](#))
- Pre-molded urethane and molded channels that disperse internal air more uniformly ([Envirocooler](#))
- [NanoCool](#)TM (sorption cooling device)
- Radiant barrier + 2 PCM (2 phase changes at 2 different temperatures)
- [Chip-vacua](#): 1st flexible VIP (Matsushita)

Containment systems



Food Chain Intelligence
KNOWLEDGE...INNOVATION...ACTION





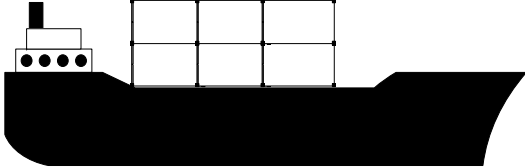
Containment systems

- Reusable
- Stand-alone/hybrid cooling system
- Able to travel by road, sea or air (120 or more hrs)
- Medium capacities (eg. less than 400 L)
- Can include embedded temperature control/recording means
- Suitable for integration with other technologies (eg. RFID, high/low oxygen concentrations)

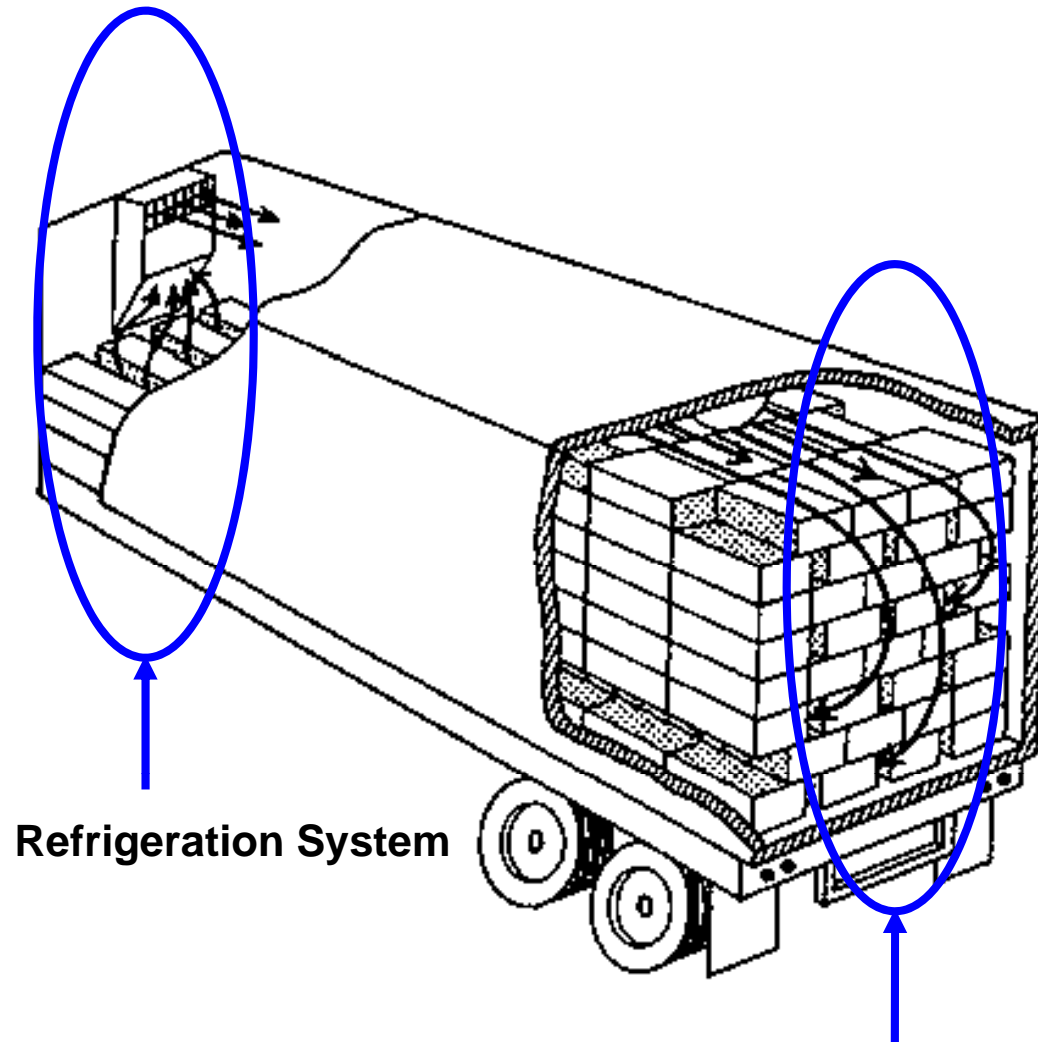
Containment systems

- Thermal container ([Kodiak](#)): Hard plastic casing enclosing foam-encased vacuum insulation panels
- [Thermo Chill™](#): pallet insulated covers
- TCP Reliable: thermal control panels
- Cold Chain Technologies: [KoolTemp™](#) insulated pallet containers
- [ActivHeat®](#): Lamina Medica (15 to 30°C)
- [Qpod™](#): Refrigeration unit mounted into pallet

Transport systems

<u>TRANSPORT MODE</u>	<u>TYPICAL VOYAGE TIMES</u>
 <p><u>VAN OR COMPARTMENT IN MULTI-TEMPERATURE TRUCK (URBAN/SHORT-DISTANCE DISTRIBUTION)</u></p>	1 TO 12 HRS
 <p><u>TRUCK/TRAILER/SEMI-TRAILER (SHORT/LONG-DISTANCE DISTRIBUTION)</u></p>	12 HRS TO 3 DAYS
 <p><u>RAIL (LONG-DISTANCE DISTRIBUTION)</u></p>	3 TO 16 DAYS
 <p><u>AIRPLANE (LONG-DISTANCE DISTRIBUTION)</u></p>	1 TO 100 HRS
 <p><u>SHIP (LONG-DISTANCE DISTRIBUTION)</u></p>	3 DAYS TO 2 MONTHS

Road Transport



Multi-temperature trucks



Urban multi-temperature vehicles

☞ **Multi-compartment distribution offers financial rewards for small shipments with different temperature requirements**

☞ **As shipments decrease in size, multi-compartment distribution benefits increase**

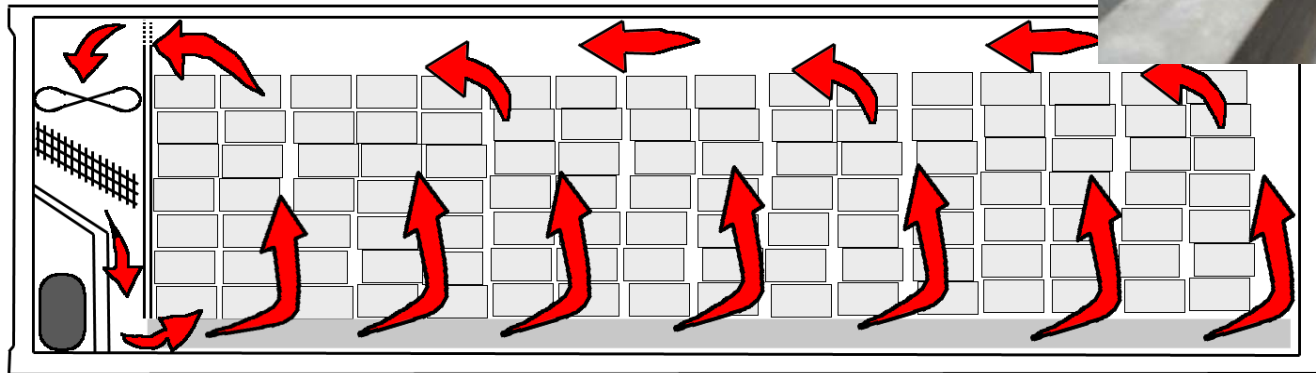
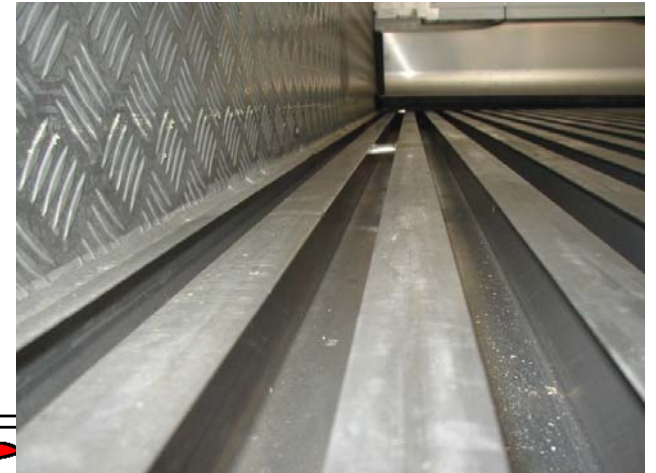
☞ **Global boost of online (internet) shopping**

Containers



Container configuration

- Air delivery and return at one end
- Air delivery at floor
- Floors designed to distribute air

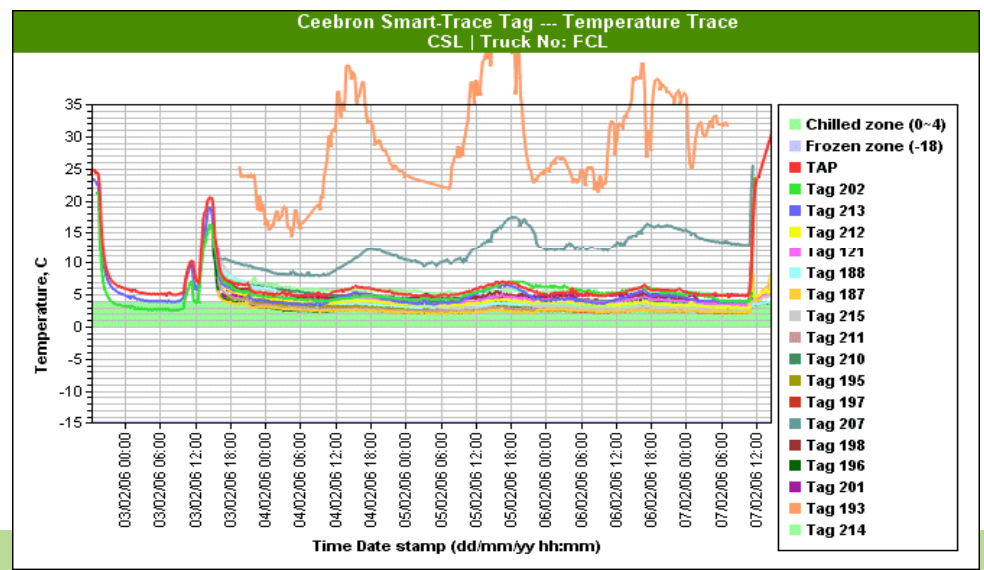
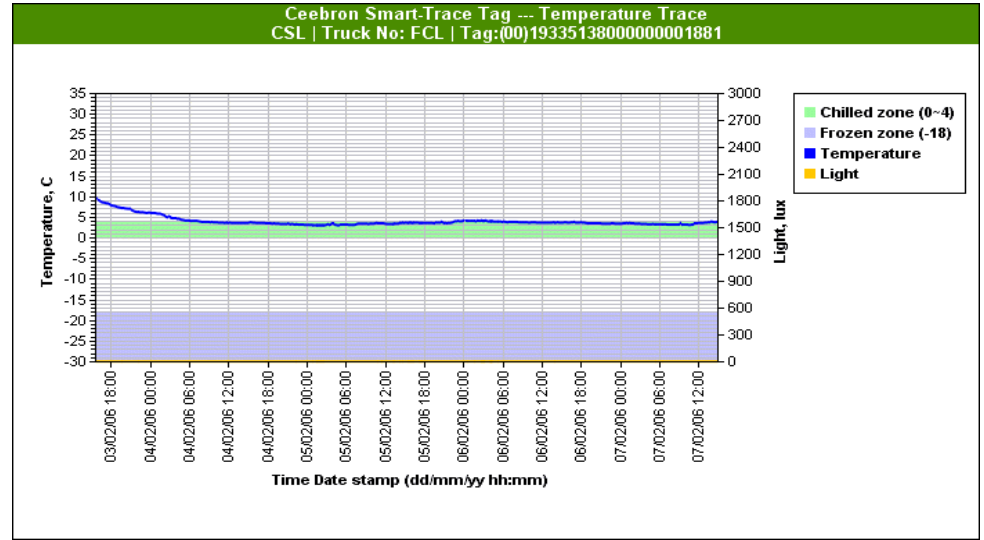
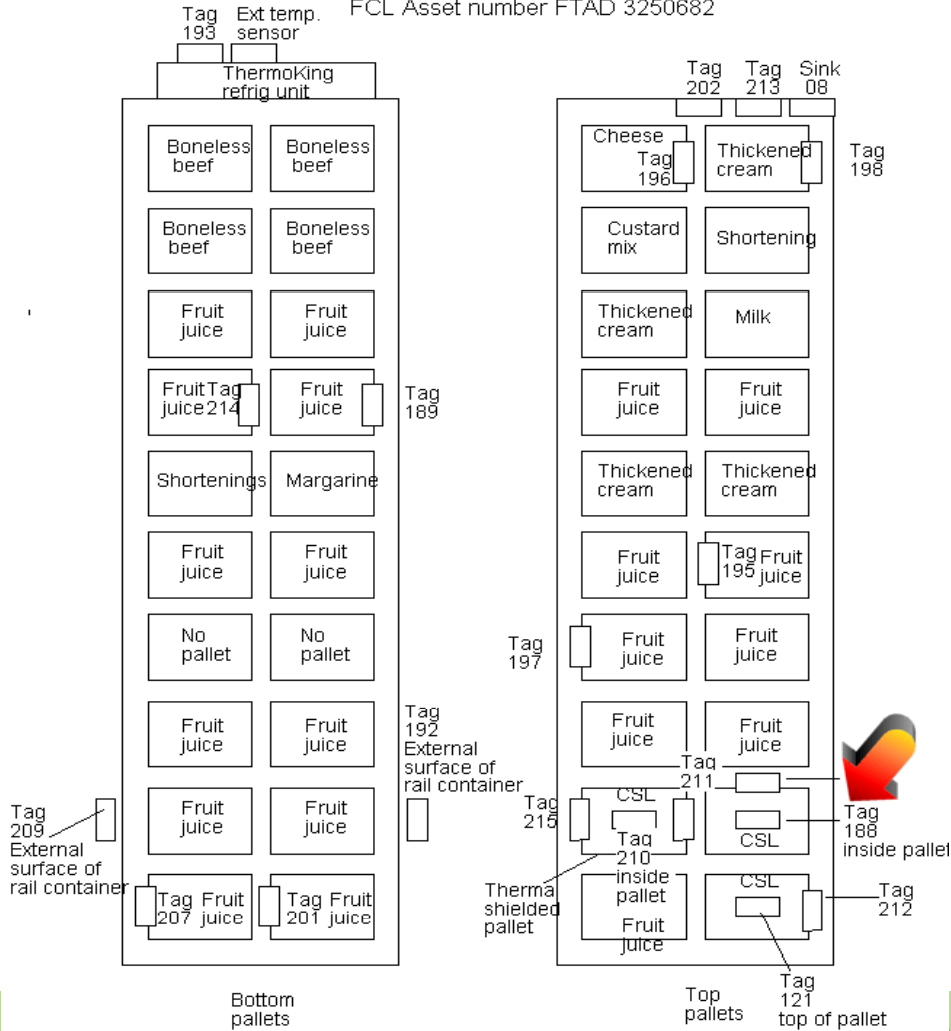


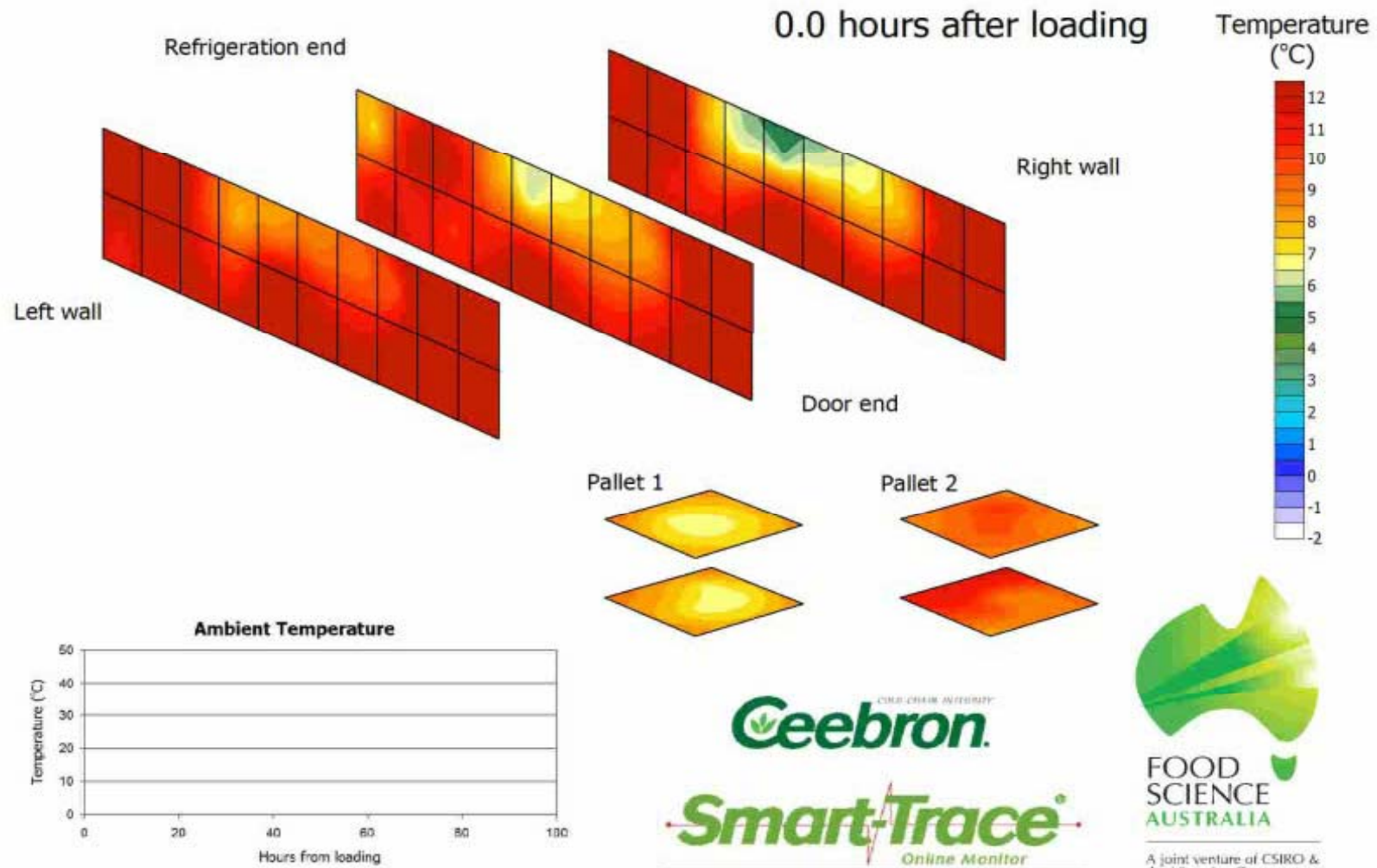
Rail Transport



Example: Field Trial with mixed loads

Tag layout For Field Trial 4
CSL Consignment /FCL transport
Melbourne (3 Jan) to Perth (6 Jan)
 FCL Asset number FTAD 3250682





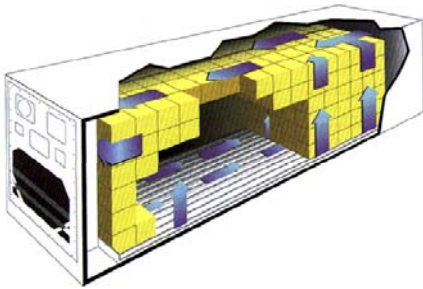
Innovation in service

FEDEX Temp-Assure Validated AirSM: validated airfreight process for temperature-sensitive shipments



Conclusion: a pharmaceutical supply chain...

- **Requires more than just technology**
- **Entire change in culture and mindset**
- **Will consist of a verified and 'in-specification' supply chain**





Thank you

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