

Cold Chain 101

The First Steps

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Compliance

- TGA's GWP (Good Wholesaling Practice)
- ISO 13485 (Medical Device)
- Pharma's GMP
- ISO 9001
- GDP (Good Distribution Practice)
- ICH
- Push is coming mainly from Pharma Head Office



Definition of *Cold Chain*

- WHO Annex 9
- PDA TR 53
- PDA TR 52
- PDA TR 39

Definition of *Cold Chain*

A **cold chain** is a [temperature](#)-controlled [supply chain](#).

An unbroken cold chain is an uninterrupted series of storage and distribution activities which maintain a given temperature range.

It is used to help extend and ensure the [shelf life](#) of products such as ... and [pharmaceutical drugs](#)

Wikipedia

Definition of *Cold Chain*

- Aust Gov Dept Health and Ageing:
Strive for 5
- ISPE Good Practice Guide:
Cold Chain Management
- USP 1079 / 1083

Cold Chain Components

1. Stability Data (Technical Documents)
 - Excursion Budget

2. Shipping System PQ (IQ and / or OQ)
 - Every shipment
 - Sample

3. Equipment
 - Thermometers
 - Refrigeration units
 - Air Conditioners
 - Temperature Monitoring System
 - Independant
 - Alarmed

4. Qualification / Validation

- Fridge Qualification IQ, OQ, PQ
- Ambient Room Qualification
- Freezer Qualification
 - Temperature Mapping
- Temperature Monitoring System (Humidity?)
 - Pre planned action response
- Route Qualification
- Container / System Qualification (IQ, OQ, PQ)
- Back up power

5. Quality Management System

- Vendor Qualification
- Calibration
- Maintenance
- Change Control
- CAPA
- Risk Assessment
- Documentation
 - Specific SOPs and WI
 - Quarantine SOP
 - Packing instructions
 - management of Coolroom

Compliance vs. Non Compliance




- Don't be distracted by the **Cost of Cold Chain Compliance**
- **Be distracted by the cost of Non Compliance**
 - What is the “Total Cost of Current System”
 - Stock Write Off's
 - Product efficacy
 - Stock Outages
 - Customer Dissatisfaction etc.....
 - Labour involved in investigations

Cold Chain Current Status

- Don't know what I don't know!
- **PQ Testing** - What is that?
- Pack some shipments up, put a **calibrated data loggers** in with the placebo product (put a logger on the outside of the shipper as well)
- Send to these to your **typical destinations**:
 - Closest
 - Furthestest away
 - Coldest
 - Hottest

You probably already knew if you were compliant or non compliant.

Results of PQ testing...

- Compliant  
- Non-Compliant 

- So now I know, what do I do?
 - Be responsible..
 - Acknowledge the problem
 - Fix it

How? Educate yourself

- Heaps of information on the internet
- Most companies use a mixture of systems
- Different types of materials/systems available
 - EPS, PUR, VIP, PCM



Be Realistic & Practical

- I need a solution that will:
- Withstand ambient temperature variations from -20 deg C to +50 deg C in one day.
- and..... if it gets puts behind a jet engine
- what if a forklift drives over it!

????????????

The Journey

- Companies like CoolPac will talk to you openly about what they think is the best solution
- Validation Documentation of existing systems are freely available
- Develop your own systems
 - Re-invent.... maybe not!
 - Maybe you do have time

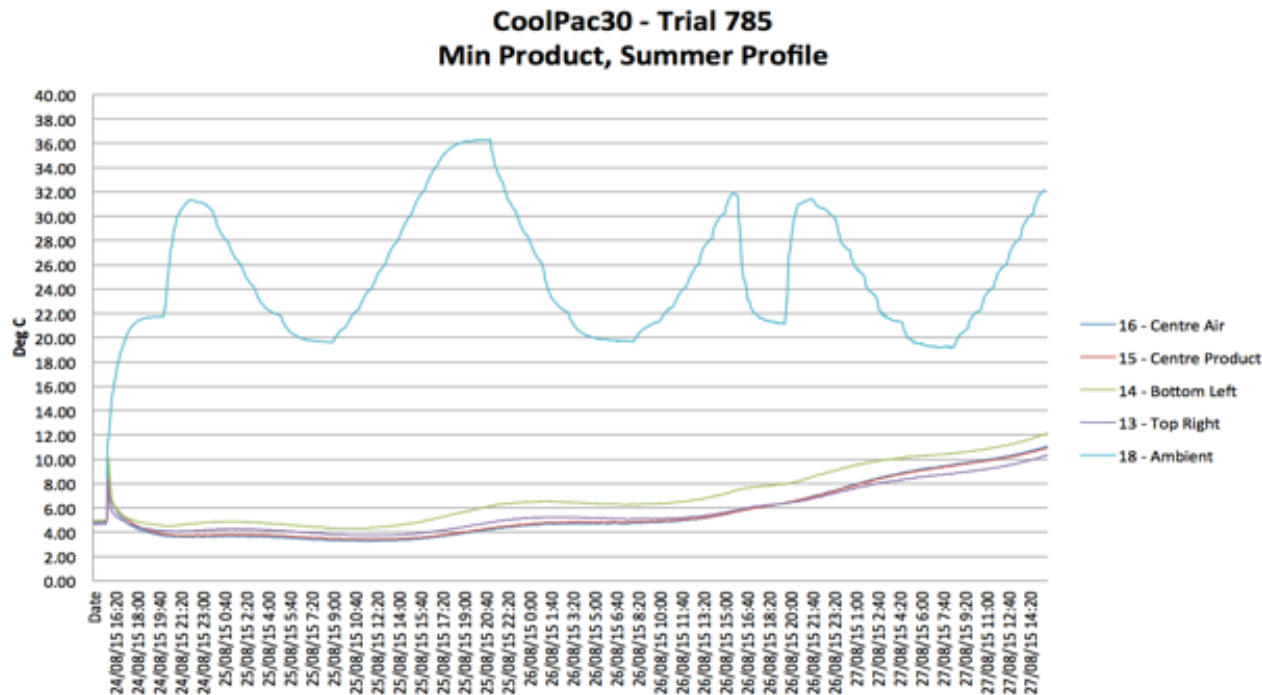
coolpac		Cold Chain Qualification Report for CoolPac30	
Project:	CoolPac	Document #:	402
		Revision	1.0

Cold Chain Qualification Report for CoolPac30

Prepared:	Signature identifies the author of the document (or modification to the document) and their acceptance that it is true and correct.	
Stephanie Gunn CoolPac Pty Ltd	Signature	Date 09/09/2015
Reviewed	Signature identifies the reviewer as the subject matter expert and their acceptance that the document has been prepared by qualified personnel, is complete & accurate, and it considers all aspects of product quality identified in the customer's requirements.	
Andrew Gibson CoolPac Pty Ltd	Signature <i>A.G.B.</i>	Date 09/09/2015

Ambient Profiles used in testing

- Make sure any documentation supplied to you has a realistic ambient profile used in the testing



Make sure your own backyard is in order...

- One of the most important parts of a good **Cold Chain starts inside your own warehouse**

- Fridges & Freezers have been **temperature mapped** and are continuously monitored



- If these areas are not stable then **you will have cold chain breaches.**

Once you have made a selection on what packaging system/s you will use/test. You will need to do:

- Formal Validation
- or
- Extensive PQ testing

Finally your Cold Chain is validated.. Sorry but its never over.

Cold Chain **Performance Qualification** should be done periodically.

This process picks up small things that creep undetected into the daily routines of Cold Chain Management in the warehouse.

- Operator Process's
- Freezing/Cooling of gels
- Time to Pack
- Preconditioning
- Despatching
- **Couriers** process after the goods have left your premises

We find that most often that if there is a problem, it most likely starts in your warehouse.

Thank you