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
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
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
Cold Chain Components

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
Cold Chain Components

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
  • Furtherest 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
The Journey

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
The Journey

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
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
Continuous Monitoring

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