

# COLD CHAIN- LESSONS LEARNED



Prepared by: Cold Chain Consultants  
Andrew Meyers



Australia

Hong Kong

USA

Canada

UK

Singapore

Switzerland

Netherlands

India

# INTRODUCTION



## **My Role -Lead all global projects -100%Pharmaceutical Temp supply chain**

- Supply chain gap audits
- Investigate and correct continuous failures
- Save the quarantined stock
  
- Design global GDP compliant supply chains
  
- Design and Qualify Thermal Packaging and temperature monitoring
- End to end factory to patient temperature qualifications

Implementations to prevent the above



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UK

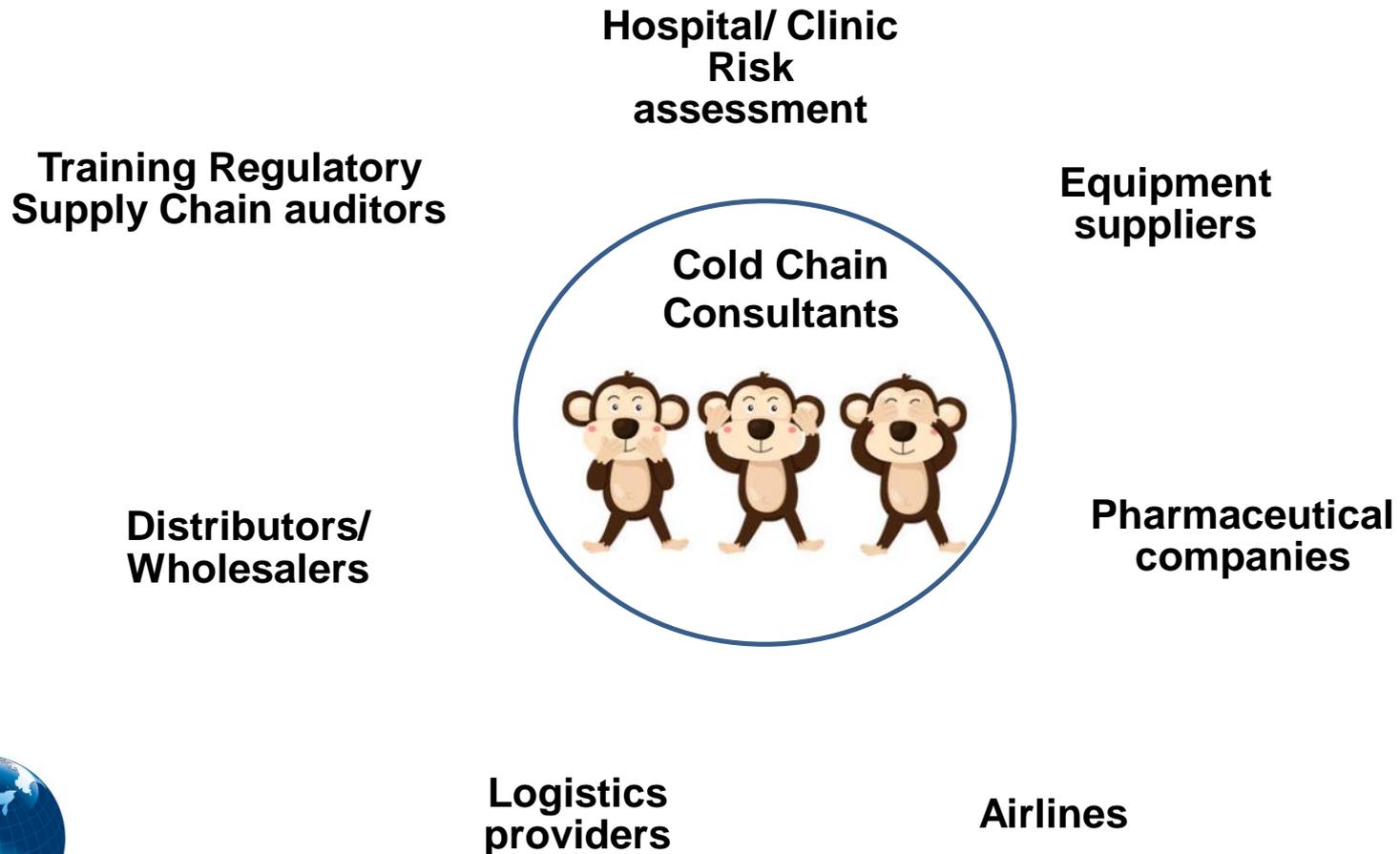
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**WE'VE SEEN ALL THE FAILURES  
HEARD ABOUT ALL THE DISASTERS  
WILL TELL HOW TO AVOID THE PROBLEMS**



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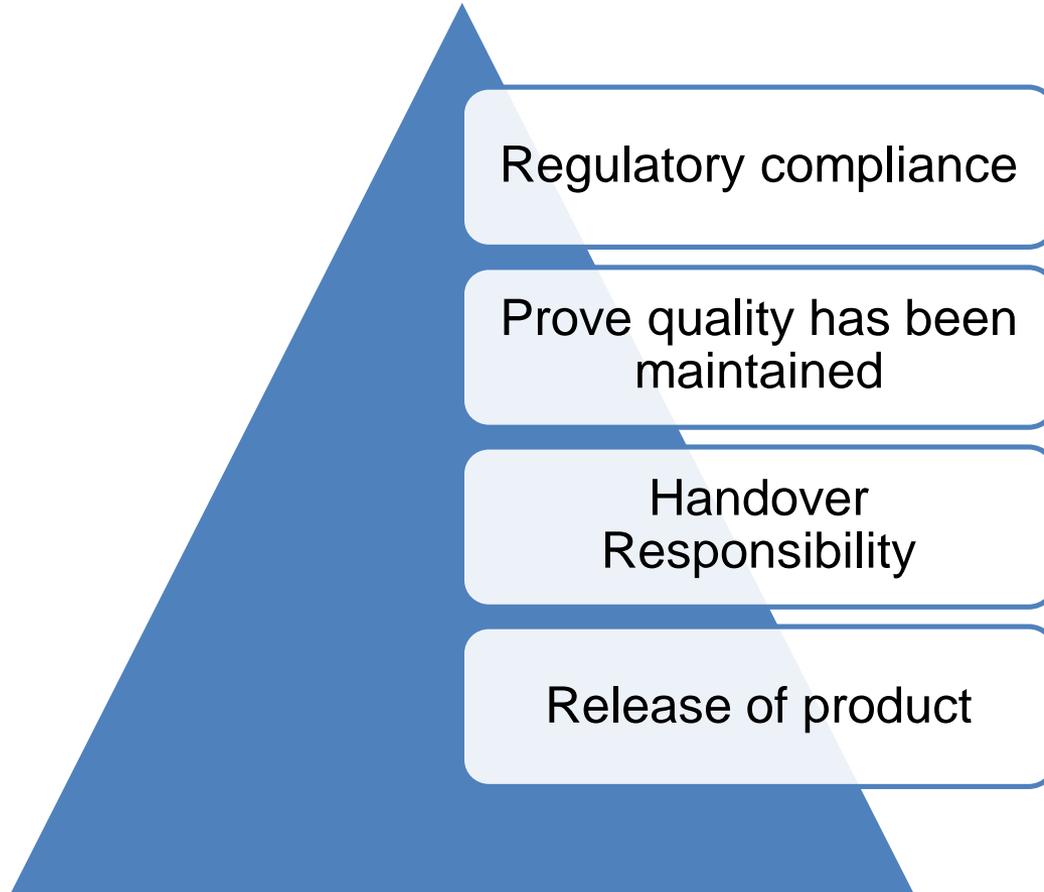
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# PURPOSE OF TEMPERATURE DATA



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# 10 YEARS IN 10 MINUTES



## Most Important Lessons on Temperature Supply chain and Monitoring

**The EU GDP guidelines are redefining the Global supply chain.**

- **Dec 2014 Adopted by PICs (Pharmaceutical Inspection Co-operation Scheme) - 48 member countries**
- **Now considered a Global benchmark**



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# DATA – THE MEDICAL RECORD OF THE HEALTH OF YOUR SUPPLY CHAIN



- Is it credible?
- Will it serve the purpose?
- Can it be challenged?
- Is it calibrated data?
- How will it be collected?
- Where will it be stored
- How safe is it ?
- Who's qualified to access it?
- Who's trained to Use it?
- How easily can it be accessed?
- Can a full set of end to end data be assembled quickly?
- Will the receiver trust the data



# BEST FRIEND OR WORST NIGHTMARE



## Data Visibility - Will it

- Make an informed or uniformed decision?
- Who's qualified to make that decision?
- Stop your shipment from on forwarding?
- Return the shipment?
- Cause –Moving into a freezer to cool room?
- Someone to delete or dispose of the data
- Reject the shipment
- Claim for discount
- Credibility
- Product recall
- License issues
- Law suit



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# LESSON LEARNT -1



## TEMPERATURE DATA

**Will highlight every fault and failure in the supply chain**

**Qualify the supply chain and the processes First**



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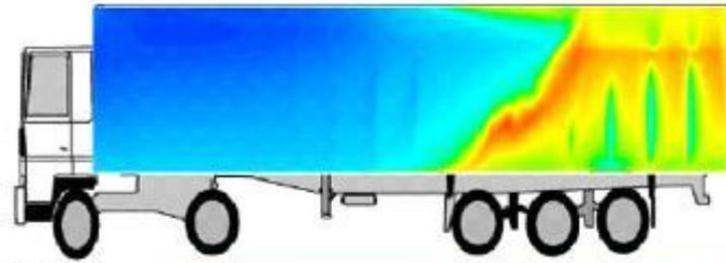
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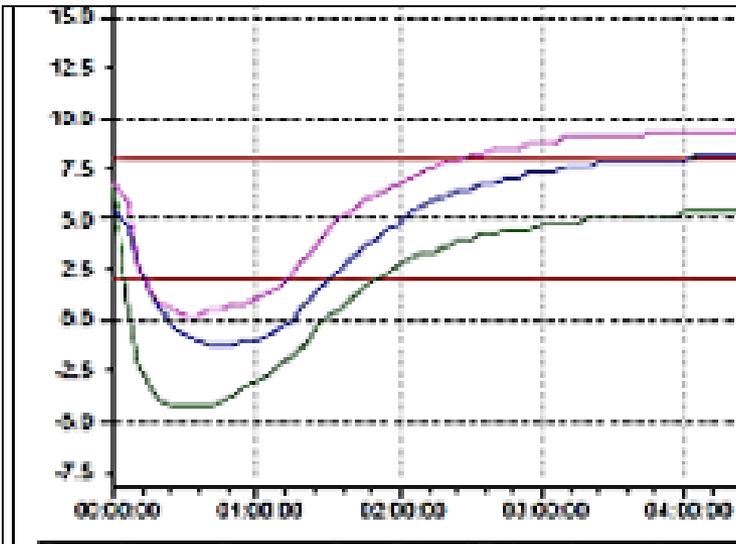
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# EXAMPLES



**Unqualified Loading Procedure**



**Packaging not qualified for purpose**



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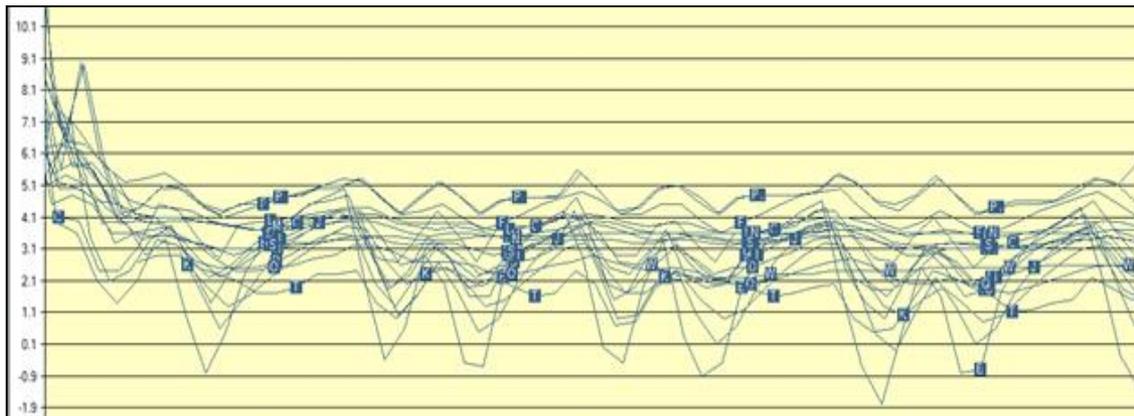
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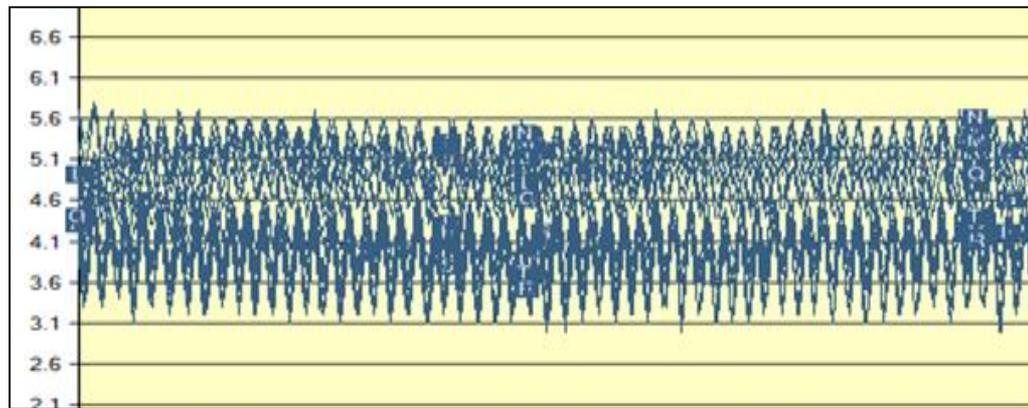
# CCC-Cold Room Rectification



**Before**



**After**



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# LESSON LEARNT - 2



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# VARIABILITY AND RISK



- Temperature supply chains have 70+ variables which must be considered.
- Each of which will contribute to success or a failure
- 95 % of excursions are set up to occur before your shipment leaves the warehouse



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# LESSON LEARNT - 3



## Route Cause of Failures

These will create more temperature excursions than equipment failures.

- Operating Procedures
- Complex systems



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# INDUSTRY CHALLENGES



- Every country creating their own system
- No global system to cover entire supply chain
- Unknown data integrity
- Fragmented data in different formats
- Complex equipment
- Complicated procedures
- Too many suppliers
- Designed for major route and fail in last mile



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# LESSON 4

## KEEP IT SIMPLE

- Built a uniform global system
- Build from furthest point
- Design what you actually need not what you think you need
- Non Language specific
- Uniform Standards
- Uniform operating procedures
- Engage suppliers with a two way commitment
- Commitment from customer reduces price
- Implement top down

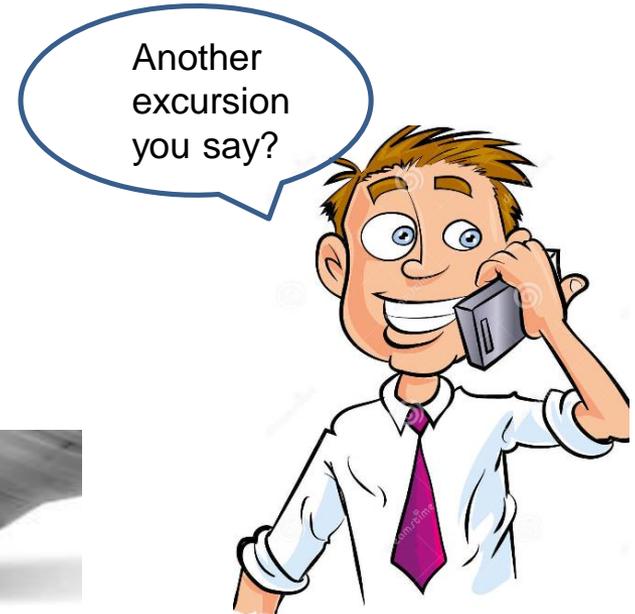
WHY YOU NO STICK TO PLAN??!!1!!!



# LESSON 5

If you haven't learnt from lessons 1, 2, 3 and 4  
Our team will expect your call

+852 532 00460  
[andrew@coldchainconsultants.com](mailto:andrew@coldchainconsultants.com)



A close-up illustration of a hand holding a grey marker, writing the words "Thank you" in a cursive script on a white surface.

