Chairman’s Opening Remarks

Kevin O’Donnell, Technical Director, Tegrant Corporation, ThermoSafe Brands
Connecting Time & Temperature-Sensitive Air Cargo for Excellence

Chairman’s Opening Remarks

Kevin O’Donnell, Technical Director, Tegrant Corp. Chair, IATA Time & Temperature Task Force
Supply Chain is the continuum of entities spanning the storage and distribution lifecycle of a product to the end user

- ICH Q10
“30+ Global regulations, guidelines and position papers on Good Distribution Practices related to temperature-controlled distribution of drug products.”

- David Ulrich, Director of Quality, Abbott Laboratories
PDA Conference, March 1, 2011
“The maintenance of the chain of storage and transportation conditions should be supported by written agreements among the distributor, importer, wholesaler and the transportation provider in order to preserve drug safety, quality and efficacy.”

-Health Canada GUI-0069, Jan 2011
“...life-cycle management of a drug product involves more than one entity along the supply chain, all involved should ensure the quality of the product to its point of use creating a contiguous supply network that is collaborative and emphasizes preventive measures to protect drug product quality.”

- United States Pharmacopeia Expert Committee on Packaging, Storage & Distribution
Connecting Time & Temperature-Sensitive Air Cargo for Excellence
Welcome Address

Oliver Evans, Chief Cargo Officer, Swiss International Air Lines
Panel: State Of The Industry In Time and Temperature Air Cargo

Moderator: Karl Kussow, Manager Quality, FedEx Custom Critical
Panel: Alan Davis, Supply Chain Temp. Control Leader, Johnson & Johnson
Marcel Fujike, VP Development & Product Management Global Airfreight, Kuehne + Nagel Management
Jack Lo, Cargo Product & Marketing Manager, Cathay Pacific
Gion-Pieder Pfister, Vice President Cargo Europe, Swissport International
Objective of the Panel

- Identify the state of the industry
  - Are the current regulation & requirements sufficient?

- Understand the issues, concern & opportunities
  - Standpoint of the Shippers, Freight Forwarders, Ground Handling Agents, Airlines

- Interactive Discussion
  - Ask Questions
Perishables

- Are time sensitive and/or temperature sensitive commodities
From Guidance to Regulation

PCR Chapter 17 – Air Transport Logistics for Time and Temperature – Sensitive Healthcare Products

New Time and Temperature Sensitive Label

IATA Perishable Cargo Regulations (PCR) Industry standard

Establishment of the Perishable Task Force

Perishable Cargo Manual (PCM) first published Recommendations

Healthcare products

2010

2007

2005

1996
Chapter 17: Air Transport Logistics for Time and Temperature – Sensitive Healthcare Products

New requirements, such as:

- Quality Management System
  - Service Level Agreements
  - Training
- New Label for Time and Temperature Sensitive Healthcare products
  - Not Mandatory
  - To be used when there is a specific agreement in place
  - Slow adoption and not widely spread so far
Stakeholder Perspectives

- Shipper
- Airline
- Forwarder
- Ground Handler
Shipper’s perspective

- There is a need for enhanced environmental control capabilities within the air transport system
- Multi-party quality agreements that clarify handoff between each responsible party during transit will mitigate risk of temperature excursions: Shipper / Freight forwarder / Ground handler / Airline
- Shippers seek assurance that airline capacity will grow with demand without increasing costs
- Need innovative solutions for CRT (Controlled Room Temperature) shipments to meet increasing demand without increasing costs.
Airline’s perspective

- Improved cold chain operation requires basic infrastructure investment by the air freight industry.

- There are many variables challenging consistent service such as different infrastructure at different cities, and different quality regulations in various markets: a global lobby is needed.

- Good cold chain handling will require a difficult culture change in the airline industry since it is expensive and is low volume compared to general freight.

- Improvements in shipping packing technology will mitigate risks in shipping environment
Forwarder’s perspective

- Cost / profits as driving factor: despite quality & regulations focus, often quality & reliability is compromised for price
- Skills / understanding of each other: logistics knowledge and pharma knowledge must be shared between pharma and transporters to create a robust transportation service
- Soft industry standards: need clear rules & guidelines that are followed - Chapter 17 remains quite a "soft" standard and reads itself as being a "recommendation" only
- Lot of parties & interfaces: low pharma knowledge, missing communication & interfaces, lacking infrastructure and time / cost pressure add risk to the cold-chain
Ground Handler’s perspective

► Best practices:
  ▶ Direct contact with the Manufacturers to understand their needs
  ▶ produce timely response to change
  ▶ Agreement on standards and local processes with reviews that involve
    all stakeholders in the logistics chain

► Changes needed:
  ▶ Big investment in cooling facilities, equipment, training and processes
  ▶ Consistent and clear Industry Standards (temperature ranges, labeling,
    messaging)
Three Consistent Themes

- Cost vs. Investment
- Consistent standards
- Communication, Knowledge, and Training
Costs vs. Investment

- Big investment in cooling facilities, equipment, training and processes
- Cost / profits as driving factor: despite quality & regulations focus, often quality & reliability is compromised for price
- Improved cold chain operation requires basic infrastructure investment by the air freight industry.
- Good cold chain handling will require a difficult culture change in the airline industry since it is expensive and is low volume compared to general freight.
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- There is a need for enhanced environmental control capabilities within the air transport system
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Consistent standards needed

- Consistent and clear Industry Standards (temperature ranges, labeling, messaging)
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Communication, Knowledge, Training

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- Agreement on standards and local processes with reviews that involve all stakeholders in the logistics chain
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Open Discussion
Networking Coffee Break

Sponsored by:

Mercator
2011–2012 ROADMAP:
Where are we, where do we want to go and how to reach there?

Andrea Graf-Gruber, Manager Business Process & Standards, IATA
Problem Statement

Transport of Time & Temperature sensitive cargo

- Requires more attention
- Associated risks generate costs
- New standards are lacking
- Existing standards needs to be reviewed
- End-to-end supply chain processes have to be clarified
- Label is not widely used as it is a recommendation
The Solution

Establishment of a **ROADMAP**

- Engage with the right Governance
- Define Key Performance Indicators (KPIs)
- Review all relevant IATA standards, recommendations
- Develop appropriate trainings
- Follow legislations and influence Regulators
- Communicate at relevant industry events
Governance
Time & Temperature Task Force (TTTF)

- Dedicated Task Force under the LAPB Governance to continuously address challenges of Air Transport Logistics for Time and Temperature Sensitive Healthcare Products

- Responsible for
  - Liaising with stakeholders from the healthcare industry
  - Recommending and maintaining standard processes
  - Developing & implementing guidance material
  - Coordinating with regulators & international organizations

=> Join the Task Force!
Key Performance Indicators (KPIs)

- Identify key performance indicators to understand where the industry stand
- Define target where we want to be at the end of the roadmap
- Allows to monitor the progress towards where the Industry needs to be
- Application of key performance indicators ensures the standards are met

=> Agree on KPIs with cold chain stakeholders
Standards & Regulations

- Carry out a gap analysis to determine what still needs to be achieved
- Get feedback from the industry
- Set up Best Practices
- Refine industry standards and define new standards
- Analyze the audits requirements
- Revise the Perishable Cargo Regulations
Training

- Key to move Time and Temperature Sensitive Cargo safely in compliance with standards and regulations
- Develop a training product that can be universally utilised
- IATA Training & Development Institute (ITDI) owns the Time and Temperature-Sensitive Healthcare Products Training with IATA Cargo
- Plan to develop a IATA Distance Learning course for Special Cargo
External Liaison

- Work with Regulators
- Keep up to date with on-going developments in the industry
- Raise awareness amongst supply chain stakeholders
- Participate in industry forums & events
- Coordinate with other trade associations such as FIATA

=> Review the Roadmap on a regular basis
IATA Roadmap – Time & Temperature Milestones 2011-12

- Review Governance
- Complete Roadmap
- Define KPIs
- Standards Review
- Revise Regulations
- Communicate at relevant industry events
- Review Training
Panel: Standardization & Training to Ensure Efficient, Quality, Safe and Secure Time & Temperature Air Cargo

Moderator: Aynur Rasulova-Rzepa, Special Cargo Controller, Emirates SkyCargo

Panel: Kenneth Bell, Dir. Service Delivery, Hong Kong Air Cargo Terminal Ltd.
Shirley Ann Feld, Associate Director Global Quality Transport, Sanofi-Aventis
Trevor Howard, Mgr, Dangerous Goods and Special Cargo, Air Canada Cargo
Bart Pouwels, Director Business Development, Amsterdam Airport Schiphol
Importance of Standards

Why are standards needed?

- Levels the playing field for our members and industry partners
- Keeps the speed in air cargo business processes
- Increases safety: less problems leakages or damages
- Ensures consistency of service, transparency and effective/proactive communication
Importance of Standards

- Who sets the standards?
  - IATA on behalf of its members to avoid conflicting government rules
  - Live Animals and Perishables Board

- What do the standards contain?
  - Industry experience, knowledge and know-how

- Who is involved?
  - Airline members, government representatives, supply chain and industry partners
Importance of Training

Why is training needed?
- Ensure efficient cold chain operation

Who sets the training?
- IATA Training & Development Institute (ITDI) owns the Time and Temperature-Sensitive Healthcare Products Training with IATA Cargo
Importance of Training

What do the training contain?
- Introduction to the IATA PCR, Chapter 17
- Distribution processes and procedures, acceptance and handling
- Label requirements for healthcare products

Who is involved?
- All stakeholders of the supply chain
Standardization & training to ensure efficient, quality, safe and secure time & temperature air cargo

Mr. Bart Pouwels
Director Business Development, Amsterdam Airport Schiphol
Amsterdam Airport Schiphol
Bart Pouwels, Director Business Development Cargo
What is Amsterdam Airport doing here?

- We try to understand and meet the needs of the Cold Chain

What have we heard so far?

- Key issues seem to be: **Temp. Excursions** and **Speed**
- As much as 54% of temperature excursions of healthcare freight occurs while in possession of the airlines
- 60% of the total time a package travels by air is spent at the airport
The Air Cargo Chain: Airport is a process facilitator

- Shipper
- Trucker
- Forwarder
- Trucker
- Shipment enters Airport area
- Customs
- Ground Handler
- Airline
- Customs
- Ground Handler
- Trucker
- Forwarder
- Trucker
- Receiver
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Open market for Handling companies
Inspectie Verkeer en Waterstaat

Opened for inspection by the Dutch authorities in compliance with the dangerous goods regulations
Keep Cool
Refrigerate upon arrival
+4°C to +8°C
ApplicChem

Keep Cool
Freeze upon arrival -20°C
ApplicChem
Chain Cooperation?

**Freight Forwarder + Handling Company:**

**FF:** “Why did you not deliver shipments to me within 3 hours?”

**HC:** “My standard delivery time is up to 8 hours”.

**FF:** “But I have an agreement to deliver within 3 hours”

**HC:** “I only have an agreement with my airline”.
Shipper about his Freight Forwarder:

“My FF informs me that once shipments have passed Customs Control there is nothing you can do to Recall them”.

Handling Company:

“A recall of shipments is daily business on passenger flights and can also be done on Full Freighter flights”.

“Airlines can precisely tell us where TTSP are on each individual pallet”.
Speed at Schiphol

A collaborative approach between shipper, freight forwarder, airline and airport authority

ACN: Air Cargo Netherlands + Government inspectorates = PPP
SmartGate Cargo
innovates government inspections, security procedures and logistic processes

Streamlined supply chain processes
One-stop-shop monitoring process
State-of-the-art information systems
Optimal infrastructural design

SmartGate Cargo
creates safe & secure trade lanes
Let us all discuss.

Thank you!

Pouwels_B@schiphol.nl
Standardization & training to ensure efficient, quality, safe and secure time & temperature air cargo

Open Discussion
Networking Luncheon

Sponsored by:

SKYTEAM CARGO
How to Follow and Influence Legislations by Liaising with Regulatory Bodies?

Dr. Mary G. Foster, Pharm D, VP Quality, Catalent Pharma Solutions

Dr. Riekert Bruinink, Dutch Health Care Inspectorate / Chairman, Netherlands / PIC/S GDP Working Group
IATA TTTF
Connecting Time & Temperature Air Cargo for Excellence

Mary Foster, PharmD
March 6-10, 2011
USP Chapter Developmental Funnel

Working Committee
Expert Panels
Working Committee

Regulators
Working Committee
Expert Panel +
Working Committee
USP Review
Pharmacopeia Forum
Agenda

How to Follow and Influence Legislations by Liaising with Regulatory Bodies

- 5 Steps to success
- Developmental funnel
#1 Communication

**Working Committee**

Active program of communication

- Must provide opportunity to meet locally, regionally, globally
- Must undertake understanding of share best practices
- Influence the work of the association as a whole
- Discuss trends, where there are failings
- Debate policy
- Determine impact on the industry and discuss common issues/concerns
Active Program of Communication

• Must provide opportunity to meet locally, regionally, globally
• Must undertake understanding of share best practices
• Influence the work of the association as a whole
• Discuss trends, where there are failings
• Debate policy
• Determine impact on the industry and discuss common issues/concerns

USP Packaging Storage & Distribution Expert Committee

• International scope - vigilance in reaching out
• Constant work to improve: perfect practice, perfect practice ...
  • Multiple regulators – local, regional, outside own country
#2 Relationships

**Working Committee**

Develop and maintain relationships

- Continues to champion the cause – even when discussion are not easy
- Working groups agree enhanced processes internally and get regulators to join
Develop and Maintain Relationships

**Working Committee** | **Regulators**

- Continues to champion the cause – even when discussion are not easy
- Working groups agree enhanced processes internally and get regulators to join

**USP Packaging Storage & Distribution Expert Committee**

- Regulators input – are/are not creating regulation

[**Regulator feedback:** ...*alternative means of complying with the intent...*]

[**Regulator feedback:** *readily* cleanable]

- Regulator’s job vs. time with committee (rejection)
  - External experts vs. Expert Panels
  - Single words – document breakers

[**3 agencies – 3 terms on agreements:** *Quality* vs. *Technical* vs. *Written*]
#3 One Voice

Working Committee

A single voice influencing policy development

- New requirements using new terms – alignment both internally and externally
- Use of international links
A Single Voice Influencing Policy Development

Working Committee

- New requirements using new terms – alignment both internally and externally
- Use of international links

Expert Panel +

USP Packaging Storage & Distribution Expert Committee

- Industry groups – disconnects
  
  [If you write this you will close our doors ...]

- Small vs. large – one size fits all

- Regulatory bodies – differing mindsets
  
  [US State Boards, FDA, DEA, company policy, global requirements]

- Compromise for practical outcome

  Back in: Mean Kinetic Temperature
#4 Networking

Unparalleled networking mechanism

- Discovering best practices
- Understanding what’s next
Unparalleled Networking Mechanism

Working Committee

• Discovering best practices
• Understanding what’s next

USP Packaging Storage & Distribution Expert Committee

• Risk management
• Supply chain security – new networks with non-pharma regulatory requirements: work with airlines and auditing process
  • Various agency regulation and changes – staying current
    • Various agency inspection process
#5 Standard Way of Working

Pharmacopeia Forum

Standard way of working - Code of Practice

- Ensure comprehensive, robust and meets the expectations for time and circumstance
- Making major contribution to quality or not in
- Independent auditing – USP liaison
- End to end consistent process
Standard Way of Working – Code of Practice

Pharmacopeia Forum

- Ensure comprehensive, robust and meets the expectations for time and circumstance
- Making major contribution to quality or not in
- Independent auditing – USP liaison
- End to end consistent process

USP Packaging Storage & Distribution Expert Committee

- Data to support: Is expert’s opinion enough? Need published study? How much science is needed?
  - Comments back: New cargo screening requirements
    - Should be vs. Are vs. Must be
    - Regulator input: Nice to have
**Regulatory Interface Process**

**Responsibilities**
- Meet routinely
- Ensures transparency
- Consider feedback
- Review global regulatory changes
- Prioritize actions to be taken
- Assess input (external) impact and provide recommendations

**Responsibilities**
- Review
- Revise, edit, change when appropriate
- Ensure appropriate for compliance
- Ensure own country
- Communicate back if there are concerns or roadblocks

**Expectations**
Responsibility to ensure we are engaged in the process, we have regulatory contacts engaged and the outcome is acceptable to all parties.
Developmental Funnel

- Do your homework
- Emphasize the facts
- Watch your pace
- Focus on the present
- Don’t be pushy
- Agree on the blueprint, not the recipe
- Keep in touch
- Deal with change
more products. better treatments. reliably supplied.™

Catalent Pharma Solutions
14 Schoolhouse Road, Somerset NJ 08873 USA

(866) 720 3148  info@catalent.com  www.catalent.com
Developments in EU Good Distribution Practice Regulations

IATA World Cargo Symposium
Time and Temperature management
8-10 March 2011 Istanbul

Riekert Bruinink
Dutch Healthcare Inspectorate
Chairman PIC/S GDP Working Group
and Member EMA GDP Drafting Group
AGENDA

• 1. Developments / Good Distribution Practice is more important
• 2. Outlining the new EU GDP regulations in general
• 3. Transportation in the new EU GDP guidelines
• 4. Key temperature control aspects for cold chain products related to storage and transportation (present and draft new EU GDP guideline)
• 5. Implementation of revised Good Distribution Practice guidelines
1. Developments / GDP is more important

- Many players involved in today’s distribution (virtual, outsourcing, brokers)
- Lack of harmonisation: global level
- Lack of harmonisation: EU level
- Distribution activities changed and more complex - from national to global
1. Developments / GDP is more important

• Counterfeit an increasing threat to public health over the past few years not only in developing countries.

• Within the EU an increase of nearly 400% in 2006 compared with 2005 – 3.000.000 medicinal products (articles)

• New legislative requirements: Legal EU proposal to combat counterfeit medicines for human use 11 March 2008
2. The new EU GDP regulations in general (EMA)

European Medicines Agency (EMA)

Start GDP drafting group december 2008

Participants from 10 countries

Revise GDP Guide
Harmonising procedures

www.ema.europa.eu
2. The new EU GDP regulations in general : EMA work in progress

• Draft GDP guide 90 %

• Compilation of community procedures (drafts)
  * Format for wholesale autorisation
  * GDP certificate
  * Procedure GDP non compliance
  * GDP inspection report format
  * Guideline training GDP inspectors
2. The new EU GDP regulations in general:
Structure draft new EU GDP Guide

Chapters (draft)

1. Quality management
2. Personnel
3. Premises and equipment
4. Documentation
5. Operations
6. Complaints, returns, falsified medicines and recalls
7. Contract operations
8. Self-Inspections

Chapters (draft) / Annexes (no draft)

9. Transportation
10. Specific provisions for Brokers

Annexes (?)
1. Temperature control during storage and transport
2. Computerised systems
3. Tracking and tracing/ safety features
2. The new EU GDP guidelines in general: important changes

- Validation
- Risk management
- Contracts / outsourcing
- Computerised systems
- Qualification suppliers
- Transportation
3. Transportation and the new EU GDP guideline

• Transportation by vehicle, by boat, by train and by plane

• The required storage conditions for medicinal products should be maintained during transportation

• New GDP guideline gives more guidance
3. Transportation and the new EU GDP guideline.

- All handling people should be trained in the relevant areas of GDP
- Written procedures should be in place for the operation and handling during transportation
- Deviations during transportation should be reported to the distributor
- Contracts should comply with requirements contained within Chapter 7
4. Key temperature control aspects for cool chain products

Temperature aspects for storage in the EU GDP Guideline 1994

Art 12: “Medicinal products should be stored at the right temperature. Temperature should be monitored and recorded periodically. Records of temperature should be reviewed regularly.”

Art 13 “When specific temperature storage conditions are required, storage areas should be equipped with temperature recorders or other devices that will indicate when the specific temperature range has not been maintained. Control should be adequate to maintain all parts of the relevant storage area within the specific temperature range.”
4. Key temperature control aspects for cool chain products

Draft new EU Guide chapter 3 storage

• Storage areas should be temperature mapped
  - seasonal variations
  - prior to use
  - repeat

• Location temperature monitors based on mapping

• Alarmsystems should be in place
  - testing periodically
4. Key temperature control aspects for cool chain products.

Draft new EU Guide chapter 3 storage

- all equipment should be maintained to a suitable standard
  - preventive
  - log book

- Temperature monitoring devices should be calibrated regularly

- Records should be sustained
4. Key temperature control aspects for cool chain products

Temperature aspects for transportation in the EU GDP guideline 1994

art 20: “Medicinal products should be transported in such a way that they are not subjected to unacceptable degrees of heat.”

art 21: “Medicinal products requiring controlled temperature storage should also be transported by appropriately specialised means.”
4. Key temperature control aspects for cool chain products

Draft new EU Guideline chapter 9 transportation

• The cold chain should be maintained until the customer by validated temperature control systems.

  - thermal packaging
  - temperature controlled containers
  - refrigerated vehicles
4. Key temperature control aspects for cool chain products.

Draft new EU guideline chapter 9 transportation.

- refrigerated vehicles
  - temperature mapping
  - monitoring temperature
  - temperature print out
  - written procedures

- selection thermal packaging
  - criteria
  - validation
  - labeling
5. Implementation of revised EU GDP guideline: When a new guide?

- Now 90% is finished
- February 2011: discussion in GMDP group
- Public Consultation procedure in EU March-October 2011
- Processing comments by GDP draft group before Februari 2012
- Adoption by European commission April 2012
- A new EU GDP guide: June 2012
5. Implementation of revised EU GDP guideline

- Implementation in the national legislation
- Implementation in daily practice within 2-3 years
- A lot of things are not new and already common practice for several companies
- Education of inspectors 2012-2013
- GDP-inspections based on new EU guide 2013/2014
Sometimes it takes a lot of time to implement GDP..
THE END...

THANK YOU FOR YOUR ATTENTION

QUESTIONS?
Solutions

COOL CHAIN ASSOCIATION

Youri Busaan, Deputy General Manager, Airport Paris-Vatry S.e.v.e.

CARGO 2000: COOL CHAIN ANALYSIS

Lothar Moehle, Regional Director EMEA, Cargo 2000
World Cargo Symposium
Istanbul

Youri Busaan
Deputy General Manager
Paris-Vatry Airport
March 2011
MANAGING THE COOLCHAIN!

COMMON STANDARDS
A RECOMMENDATION OR OBLIGATION?
Facts about the CCA

- Founded in February 2003
- Goal: harmonize the global movement and handling of temperature sensitive products (PTSP) to the benefit of the consumer and the supply chain participants
- Established the standard Cool Chain Quality Indicators (CCQI) in 2005 that covers all logistic providers handling PTSP
- Has members representing all parts of the logistic cool chain from all over the world
- It is the aim of CCA to make the CCQI Standard a part of the selection criteria for retailers & brand-owners to find their supply chain providers
How we work

- the Working Committees are made up by the association’s members. Each committee is assigned to address specific subjects which are to be reviewed and debated by the members of the association or taken up with third parties such as governments, other institutions or organizations.

- the CCA organizes workshops dealing with special topics and invites related parties to discuss and to present their views.

- provides a platform to discuss critically and open problems for possible improvements in the cool chain – Think Tank.

- publishes its quarterly newsletter, the Cool Times, which includes articles concerning current issues and information about its members and their concerns.
Let’s face it

- Our Industry faces 30% waste from harvest to the consumer while real food prices rose by 64% between 2002 and 2008.

- There is an enormous need for reducing waste along the cool chain.

- There is a huge potential, e.g. the wrong handling of strawberries during transport can lead to 90% waste in comparison to correct handling which results in only 10% waste.

- As a rule, 1 hour delay in pre-cooling leads to one day of shelf life reduction.
## Strawberry trial

### Economic Implications of Strawberry Pre-cooling and Shipping Trials (All US$)

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<td>Available for store sales</td>
<td>50.0%</td>
<td>50.0%</td>
<td>50.0%</td>
<td>50.0%</td>
<td>8.3%</td>
</tr>
<tr>
<td>Below standards/not able to sell</td>
<td>0.0%</td>
<td>50.0%</td>
<td>33.3%</td>
<td>50.0%</td>
<td>41.7%</td>
</tr>
<tr>
<td>Day Two Condition</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Available for store sales</td>
<td>40.0%</td>
<td>0.0%</td>
<td>13.3%</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Below standards/not able to sell</td>
<td>16.6%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>60.0%</td>
<td></td>
</tr>
<tr>
<td>Sold %</td>
<td>90.0%</td>
<td>50.0%</td>
<td>63.3%</td>
<td>50.0%</td>
<td>8.3%</td>
</tr>
<tr>
<td>Waste %</td>
<td>10.0%</td>
<td>50.0%</td>
<td>36.6%</td>
<td>50.0%</td>
<td>91.7%</td>
</tr>
<tr>
<td>Actual Revenue</td>
<td>$74,499</td>
<td>$47,309</td>
<td>$52,401</td>
<td>$41,368</td>
<td>$6,892</td>
</tr>
<tr>
<td>Wholesale Cost ($1.65/Clamshell)</td>
<td>$34,214</td>
<td>$34,214</td>
<td>$34,214</td>
<td>$34,214</td>
<td>$34,214</td>
</tr>
<tr>
<td>Gross Margin from Sales</td>
<td>$40,249</td>
<td>$13,154</td>
<td>$18,186</td>
<td>$7,154</td>
<td>($27,322)</td>
</tr>
<tr>
<td>Operating Costs Expense</td>
<td>$13,031</td>
<td>$13,031</td>
<td>$13,031</td>
<td>$13,031</td>
<td>$13,031</td>
</tr>
<tr>
<td>Shipping Cost Expense</td>
<td>$5,184</td>
<td>$5,184</td>
<td>$5,184</td>
<td>$5,184</td>
<td>$5,184</td>
</tr>
<tr>
<td>Total Expenses</td>
<td>$18,215</td>
<td>$18,215</td>
<td>$18,215</td>
<td>$18,215</td>
<td>$18,215</td>
</tr>
<tr>
<td>Net Profit</td>
<td>$22,034</td>
<td>($11,061)</td>
<td>($29)</td>
<td>($11,061)</td>
<td>($45,352)</td>
</tr>
<tr>
<td>Lost Profit from Waste</td>
<td>$8,274</td>
<td>$41,369</td>
<td>$30,337</td>
<td>$41,369</td>
<td>$75,848</td>
</tr>
<tr>
<td>Profit Potential Realized</td>
<td>72.70%</td>
<td>36.50%</td>
<td>-38.50%</td>
<td>-36.50%</td>
<td>-150.25%</td>
</tr>
</tbody>
</table>

**Note:** The strawberries were shipped in reefer trucks, with thermal blankets. The thermal blankets may have created a NEGATIVE effect in some cases where the blankets prevented truck cooling of partial or no pre-cooled loads.

No Delay = No wait in the field.  Partial Delay = 3 hours +/- wait in field before pre-cool.  Partial Pre-Cool = pre-cooled 50 f only.
In our Industry there is up to 30% waste due to:

- Lack of Common Procedures
- Lack of Training
- Lack of Communication Standards
- Lack of measuring criteria for the unbroken supply chain
- .............

We can do better - together
What about Pharma?

- the pharma industry faces similar challenges as the perishable transportation industry
  - need of maintaining temp from shipper to consignee
  - temperature sensitive products
  - quick transport on a global scale as a pre-requisite
  - social responsibility
Special Characteristics of Pharmaceuticals

- **Time Sensitive:**
  Short life spans which are made even shorter by improper storage conditions

- **Temperature Sensitive:**
  Changes in temperature can make the pharmaceutical ineffective and can cause more health damages

- **Treatment Sensitive:**
  Rough handling destroys value and effectiveness

- **Potential Health Risks:**
  Risks from improperly handled products and contaminated products

- **Product feature:**
  High value already at small quantities
  High brand knowledge and loyalty
Reduced potency of vaccines because of wrong storage leads to reduced immune responses and inadequate protection of the patient.

Vaccines are precious and expensive so that wrong handling cannot be accepted.

Compliance with the terms of the license (i.e. storage between 2-8°C) needs to be fulfilled for liability reasons.

High sensitivity towards temperature changes and exposure to ultraviolet light (source: Practice Nurse 11/21/2008).

High risk of theft leading to financial losses, wrong utilization of pharmaceutics and brand destruction.
CCA and Germanischer Lloyd has produced a new industry standard and yardstick for reliability, quality and proficiency in perishable and temperature-sensitive products: **Cool Chain Quality Indicators – CCQI’s.**

CCQI is an open and auditable industry standard that employs a benchmarking system to establish transparent and comparable quality measures – a world premiere.

Germanischer Lloyd is one of the world's leading classification societies and has been setting standards in engineering, safety and quality for more than 135 years. For the CCQI Standard, Germanischer Lloyd will exclusively audit and certify applicants.
Mandatory practices

Each organisation needs to demonstrate a variation of mandatory practices.

Examples are:

- Available cool chain policy
- Temperature stipulation on all documents
- Defined acceptance points and handover instructions
- Suitable staff training

We can do better - together
CCA: Definition of Cool Chain Operations

Production

Example: Airfreight

Consumption

Road Transport

CCQI

Truck & Trailer Transport

Storage / Handling

CCQI

Short / Long Term Storage

Transport to Aircraft

CCQI

Apron Handling at Airport

Air

CCQI

Aircraft Transport

Road Transport

CCQI

Storage / Distribution

Transport to Terminal

Air

Transport
Common goals

- Harmonization of the Cool Chain
- Learn from each others experience
- Reduce waste
- Improve the benefit for the Cool Chain, the client and the patient
- Use the possibility to increase sales
- Supply higher quality for lower costs
- Offer a guaranteed quality to improve health care around the world

Moving forward - together
Is this choice of airport and its airside & cargo handling capabilities based on what the sales division has decided or what the operations division can deliver & guarantee?

- Curfew restrictions
- Distance of parking position to the warehouse
- Time from aircraft to truck
- Is the airport equipped with the correct infrastructure (cool rooms?)
- Are required inspections available h24?
- Are the employees managed and trained according to the standards?
Air Freight Industry – some characteristics:

- **Fragmented** (many players)

- **Insufficient cooperation / collaboration** between players (all have own agenda) – sub optimization – no transparency

Many **excellent initiatives** to improve the chain (Cargo 2000 – Coolchain) however all are based on free adherence.

Cargo is often a **by-product** and receives little management attention.
Air Freight Industry – has everything in house:

- Take the example of successful IATA programs such as IOSA
  - A safety initiative with uniform procedures & processes and unique and agreed upon communication channels.
  - With execution of such programs quality comes (almost) automatically

Air Freight Industry – is a very competitive one:

- Examples: AOG – DGR – VAL….

   Even when they are being transported or handled by companies with a lesser focus on cargo!

Why: All these products have a higher safety / regulatory element with well set procedures, a very good quality label and are generally speaking great revenue drivers (For ALL parties)
Why is often a pallet with perishables treated in the same way as a normal general cargo shipment?

Wrong storage leads to reduced immune responses and inadequate protection of the patient due to the reduced potency of vaccines or liability issues!
Would it not be in everybody’s interest in improving this chain and handle these shipments with the same professionalism as a Dangerous Shipment?

Resulting in: Perishable Goods Declaration, Acceptance Check, Pallet Build up, Storage conditions in warehouse, Ramp processes, NOTOC / NOTOD, Training, etc….

What about air freight?

Increased Transparency, Processes, Customer Value, Revenue
Make the agreed LAPB standards mandatory for perishables for all IATA Airlines, handling companies & Agents?

As an airline look more to solutions that your operations are comfortable with and know the local handling company can do the job or invest accordingly! (Including the choice of airport)

IATA has a key-role in the continued development of initiatives like Cargo 2000 and Coolchain however with regard to the implementation phase one may need to go further then just recommendations.

Thank You!
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Tel: +33 3 2664 8235
Fax: +33 3 2664 8200
www.parisvatry.com

A SEAMLESS PERISHABLE SUPPLY CHAIN
THE ULTIMATE AIM
Presentation

Time and Temperature Management Track
Introducing C2K organization
Presently existing members
Concerns of stakeholders?
Next steps?
Benefits of being a C2K member
Introducing C2K organization
Presently existing members
Concerns of stakeholders?
Next steps?
Benefits of being a C2K member
In a complex world of global sourcing, reduced inventory and just in time, Shippers have clear expectations of the air freight industry:

- Reliability
- Predictability
- Pro-active Shipment Management
- Service

Shipper are evaluating the entire transportation chain and not only the carrier or only the forwarder.
What is C2K?

- Founded in 1997
- Not for profit Members’ Association
- IATA sponsored initiative
- Aimed at improving the quality
- With the mission to create and implement a quality management system for the global air cargo industry
Introducing C2K organization

Presently existing members

Concerns of stakeholders?

Next steps?

Benefits of being a C2K member
## C2K Members

**Airlines**

<table>
<thead>
<tr>
<th>Airline</th>
<th>Symbol</th>
</tr>
</thead>
<tbody>
<tr>
<td>Air Bridge Cargo</td>
<td>[+ ]</td>
</tr>
<tr>
<td>Air Canada</td>
<td>(*)</td>
</tr>
<tr>
<td>Air France</td>
<td>(*)</td>
</tr>
<tr>
<td>Alitalia</td>
<td>(*)</td>
</tr>
<tr>
<td>American</td>
<td>(*)</td>
</tr>
<tr>
<td>British Airways</td>
<td>(*)</td>
</tr>
<tr>
<td>C.A.L</td>
<td>[+ ]</td>
</tr>
<tr>
<td>Cargolux</td>
<td>(*)</td>
</tr>
<tr>
<td>Cathay Pacific</td>
<td>(*)</td>
</tr>
<tr>
<td>Delta</td>
<td>(*)</td>
</tr>
<tr>
<td>Egyptair</td>
<td>[+ ]</td>
</tr>
<tr>
<td>Etihad</td>
<td>(*)</td>
</tr>
<tr>
<td>Finnair</td>
<td>[ t ]</td>
</tr>
<tr>
<td>Iberia</td>
<td>[+ ]</td>
</tr>
<tr>
<td>KLM</td>
<td>(*)</td>
</tr>
<tr>
<td>Korean</td>
<td>(*)</td>
</tr>
<tr>
<td>Lufthansa</td>
<td>(*)</td>
</tr>
<tr>
<td>Martinair</td>
<td>[+ ]</td>
</tr>
<tr>
<td>Polar</td>
<td>[+ ]</td>
</tr>
<tr>
<td>Qantas</td>
<td>[+ ]</td>
</tr>
<tr>
<td>Qatar Airways</td>
<td>[+ ]</td>
</tr>
<tr>
<td>SAS</td>
<td>(*)</td>
</tr>
<tr>
<td>Saudi Arabian Airlines</td>
<td>[+ ]</td>
</tr>
<tr>
<td>Singapore</td>
<td>(*)</td>
</tr>
<tr>
<td>South African Airways</td>
<td>[+ ]</td>
</tr>
<tr>
<td>Swiss</td>
<td>(*)</td>
</tr>
<tr>
<td>Turkish Airlines</td>
<td>[+ ]</td>
</tr>
<tr>
<td>United Airlines</td>
<td>(*)</td>
</tr>
<tr>
<td>Virgin Atlantic</td>
<td>[+ ]</td>
</tr>
</tbody>
</table>
C2K Members

Forwarders

- Agility Logistics (*)
- Aramex [+]
- Cargomind [t]
- CEVA (*)
- DHL Global Forwarding (**)
- Geodis – Wilson (*)
- Hellmann [+]
- Kuehne + Nagel (**)

- OHL [+]
- Panalpina [+]
- Schenker AG (**)
- SDV Intl. Logistics (*)
- UPS Supply Chain Solution [+]
- Uti [+]
- Yusen Logistics Co., Ltd (**)

(*) indicates active membership.
(+|t) indicates active membership but with specific conditions.
(**) indicates special membership status.
### Industry Associates

#### Ground Handlers
- AACT [+]
- Asia Airfreight Terminal (*)
- Australian Air Express (*)
- Aviapartner (*)
- Cargo Center [+]
- Cargologic (*)
- CSC India [+]
- Groundforce (*)
- Hong Kong Air Cargo Terminals Ltd. (*)
- International Cargo Centre Shenzhen (*)
- Kenya Airways GHA Div. [+]

#### Airports
- Amsterdam Airport Schiphol / Cargonaut [+]

#### Trucking Companies
- Wallenborn [ t ]
C2K Industry Associates

**IT Providers**

- British Telecom (*)
- Cargo Flash Infotech [+]
- CCN (*)
- Champ Cargosystems (*)
- Descartes Global Logistics Network (*)
- GLS (*)
- IBS
- Mercator [+]
- Riege Software (*)
- Traxon (*)
- Unisys (*)

(*) = active Members who obtained the C2K Quality Certificate

(**) = active Member who obtained Phase 2 certification

[t] = Members who are presently testing the C2K Quality Management System

[+] = Associated Members who are yet to implement the C2K Quality Management System
Introducing C2K organization

Presently existing members

Concerns of stakeholders?

Next steps?

Benefits of being a C2K member
In our Industry there is up to 30% waste due to:

- Lack of Common Procedures
- Lack of Training
- Lack of Communication Standards
- Lack of measuring criteria for the unbroken supply chain

Quote from Presentation of CCA
C2K – is providing an answer

- Every shipment gets a plan
- Every plan has milestones
- Members receive alerts when milestones fail
- Enhanced ability to re-plan and or recover
- Detailed records are available for process analysis and improvement

The Route Map

- Origin Processes
- Destination Processes

<table>
<thead>
<tr>
<th>Phase 1</th>
<th>Planned FWB</th>
<th>Planned RCS</th>
<th>Sched DEP</th>
<th>Sched ARR</th>
<th>Planned RCF</th>
<th>Planned NFD</th>
<th>Planned DLV</th>
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</thead>
<tbody>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Actual FWB</th>
<th>Actual RCS</th>
<th>Actual DEP</th>
<th>Actual ARR</th>
<th>Actual RCF</th>
<th>Planned NFD</th>
<th>Actual DLV</th>
</tr>
</thead>
</table>
C2K – is providing an answer

- Every shipment gets a plan
- Every plan has milestones
- Members receive alerts when milestones fail
- Enhanced ability to re-plan and or recover
- Detailed records are available for process analysis and improvement

The Route Map  Phase 1

Origin Processes  Destination Processes

Planned FWB  Planned RCS  Planned DEP
Planned ARR  Planned RCF  Planned NFD  Planned DLV

Actual FWB  Actual RCS  Actual DEP  Actual ARR  Actual RCF  Planned NFD  Actual DLV
Introducing C2K organization

Presently existing members

Concerns of stakeholders?

Next steps?

Benefits of being a C2K member
C2K – What’s next?

• **Implementation of Phase 2:**

<table>
<thead>
<tr>
<th>Phase</th>
<th>Chain Definition</th>
<th>Monitoring Level</th>
<th>Visual Representation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Airport to Airport</td>
<td>Master AWB Level Shipment Planning and Tracking</td>
<td><img src="image" alt="Visual Representation" /></td>
</tr>
<tr>
<td>2</td>
<td>Door to Door</td>
<td>House AWB Level Shipment Planning and Tracking</td>
<td><img src="image" alt="Visual Representation" /></td>
</tr>
<tr>
<td>3</td>
<td>Door to Door</td>
<td>Shipment Planning and Tracking at piece level with E-Doc Tracking</td>
<td><img src="image" alt="Visual Representation" /></td>
</tr>
</tbody>
</table>

**QCargo Network is …**

A new C2K initiative to facilitate business connectivity for small and medium freight forwarders in a controlled Quality environment

• **Alignment of C2K + e-freight:**

• **Expansion of C2K for:**
  - Perishable products
  - Security related products
  - Air Mail services
Introducing C2K organization

Presently existing members

Concerns of stakeholders?

Next steps?

Benefits of being a C2K member
What are the benefits of C2K? (1)

- Increase client retention & growth with enhanced service
- Increase new business based on “preferred supplier” status provided by quality performance backed by reliable data
- Decrease the time spent for manual track & trace activities and for the management of irregularities
- Increased quality for warehouse and trucking operations because of standardized processes and fewer failures.
- Improve processes towards paperless shipping management.
- Reduce claims.
- Airlines and forwarders harmonize processes and standards which ensures reliable and timely delivery of freight.
- Training of operational staff on identical standardized processes
What are the benefits of C2K? (2)

- C2K planning is improving capacity utilization for aircraft, warehouse and trucking space.
- Reduction in cycle times.
- Using same quality monitoring and reporting logic airlines and forwarders rely on identical data to discuss quality improvements.
- Ability to benchmark quality performance from “neutral” source.
- Constant monitoring of true performance ensures a high level of service and adjustments to requirements of different stakeholders.
- Proactive information for shipper and consignee in case of deviation from transport plan.
- Visibility / Control = Quality improvements = Less claims.
- Well developed system with size able data of + 1 million reported transactions per month.
In conclusion

- Measurement & Reporting are key elements of the System
- Data enables to initiate corrective actions and eliminate quality issues
- Enables to deliver benchmarks based on identical data / reports
- Is a well developed Quality Management System, ready to apply from the industry to the industry
- Members are audited and certified
- Is a global organization, where all stakeholders of the airfreight industry are working together on quality improvements
- Is open to interested parties to join and help to further improve – in particular for stakeholders of handling perishable goods and cargo
- Has reached out to shippers / customers to be part of this initiative
Thank you
Networking Coffee Break

Sponsored by:

![EurTradeNet Logo]

![KEWILL Logo]
Solutions (continued)

AUDITS

Nina Heinz, Head of Quality, LifeConEx, LLC

Aynur Rasulova-Rzepa, Special Cargo Controller, Emirates SkyCargo

ULDs

Todd DeVore, Vice President – Government & Disaster Preparedness, AcuTemp Thermal Systems
Can the Industry Standardize Auditing of Facilities?

Time & Temperature Management Track
WCS in Istanbul, March 2011
A Matter of Degree

- How much risk are you able to afford?

Successfully meeting cold chain transportation requirements is not a random process, it is achieved by detailed planning, supporting resources, leveraging infrastructure, competence and ability to execute.

- LifeConEx, as the Lead Cold Chain Solutions Provider (LCCSP), understands that quality and control in the cold chain logistics industry are critical and can affect your company and patients directly.

✓ Reduction in Temperature Deviations
✓ Regulatory Compliance
✓ Faster Product Release
✓ Cost optimized
Reducing the Risk and Mitigating the Impact of Process Deviations

- **Product-focused trade lane assessment**
- **End-to-End Integrated Process Mapping**
- **Customized Quality Agreement (SOP) Implementation**
- **Contingency Planning for efficient Intervention Management**
- **Live 24/7/365 Global Proactive Process Management**
- **Multilingual with Culture-Specific Knowledge**
- **Quality Assurance Reporting and Investigations**
- **Central Quality Control Hub**
Sending Temperature Sensitive Products with Confidence

OUR SERVICES

1. All product temperature ranges
2. All international and domestic modes
3. All shipment sizes and weights
4. All product types
5. All packaging types
6. All geographical areas
Implementing IATA PCR Ch. 17: Rules to Reality

- Delicate balance between:
  - interests of the healthcare industry faced with increasing regulatory measures for global distribution of temperature sensitive healthcare products
  - airlines struggling to maintain profitable growth in a difficult market environment where profit margins are decreasing and cost saving a means of survival.

- How are the guidelines of IATA ch. 17 being “lived” in the “real world”?
Managing Cold Chain Service Providers

- Pharmaceutical companies are focusing not only on GMP, but more and more also on GDPs to ensure that the product arrives up to the patient in good condition.

- Quality risk assessments done of transportation service providers to determine level & frequency of performance management including:
  - Questionnaires/Vendor form
  - On-site audits
  - Contractual written agreements (SLA, TA, etc.)
  - SOPs
  - Review Meetings

- Supply chain partners include airlines, freight forwarders, 3PL/4PL, etc.
40+ Airport Assessments Worldwide

Key:
- Blue Circle: Airports we work with
- Yellow Circle: Audit complete
- Orange Circle: Audit Planned
Objectives:

- to evaluate the services, specific processes and facilities required for the transport of temperature sensitive goods
- to check compliance with the written information provided by the carrier in the LifeConEx internal knowledge data base
- to identify areas for improvement, initiate corrective actions and check results of corrective measures
Examples of Elements included:

- Warehouse: cool room facilities (capacity, temperature set, calibration, alarms, etc.), housekeeping & security
- Staff: subcontracted ground handlers, employee training
- Working procedures for handling temperature-sensitive healthcare products
- Exception management: shipment monitoring, communication
- Airport infrastructure and tarmac transportation
- Local government customs & healthcare authorities
- And more …
Airline Service Offers for Temperatures Sensitive Healthcare Shipments

- Competence centers in strategic locations managing all “special” cargo & located at the central hub
  - Coordination of both internal and external communication 24/7
  - “Experts” handling irregularities (real-time and post-shipment) and ensuring SOP compliance (incl. local responsible persons)

- Standard procedures & trained staff

- Defined storage conditions on the ground (i.e. limited tarmac time, limited exposures to ambient conditions, cool room facilities)

- Required storage temperatures in-flight (i.e. Notoc)

- Additional service for active container
  - Container leasing directly through the airline
  - Procedures and trained staff to provide container handling including proper handling, dry ice replenishment and battery replacement/charging (as required)
  - Regular temperature and voltage checks (i.e. container check sheet)
Challenges Faced by the Airlines & Ground Handlers

- Local government/airport restrictions
- Limited infrastructure
- Cost pressure
- Numerous subcontracters
- Low volume/high value shipments
- Confusing instructions
- High complexity
- Demand for product segregation
Deep frozen and +2 to +8°C cool rooms are becoming quite common yet standards vary greatly.

+15 to +25°C are extremely rare yet the expectation is that this will be more and more of a focus by the regulatory bodies in the coming years.

Need for training and more training – at operational working level!

In-flight cargo hold temperatures are still a big unknown.

The number of audits is increasing – can centralized auditing based on ch. 17 be coordinated through IATA?
Lessons Learned

- Regular customer audits due to requirement from health authorities to demonstrate subcontractor management
- Better understanding of the reality vs. paper as well as the challenges faced by many airlines
- Experience gained very valuable in evaluating key risk factors and how to best manage these
- Don’t believe the hype as only seeing is believing!
- Major hubs airports do not always meet expectations while others have been pleasant surprises (no assumptions!)
- Even the best on-site assessment and SOP is only as good as the reality of each individual shipment.
Quality Assurance with Airlines & Ground Handlers

- Verify SOP compliance at each touch point (phone, email or provider system information)
- Report all agreed-upon metrics with accurate records
  - Real-time data wherever possible
  - Storage locations and conditions
  - Active container temperature readings
  - All process deviations and potential threats to the product
- Timely intervention when required to protect the product
- Post shipment management of process deviations (internal & external)
- Regular performance reviews among all parties
HEALTHCARE AUDIT WORKING GROUP

Mrs. Aynur Rasulova-Rzepa
Special Cargo Controller, Emirates SkyCargo
Why a new Working Group

Today’s concern

- Numerous auditing of airlines by pharmaceutical companies and freight forwarders
- Lack of a common audit format that would minimize the disruptions caused by frequent audits and increase their effectiveness

Solution

- Temporary working group under the guidance of the Time and Temperature Task Force
Mission of the Working Group

- Recommend an industry common format for healthcare audits
  - to be used by healthcare companies and freight forwarders
  - for auditing airlines’ and possibly Ground Handling Agents’ (GHA) capabilities for handling Healthcare as per the PCR Chapter 17 standards and requirements
  - to reduce the total number of audits per year of each airline/GHA
  - create a common repository of information for all parties interested in specific airlines/airports/GHA’s capabilities.
Objective of the Working Group

- Replace current independent audits with the IATA/healthcare approved audit format/process
- Reduce number of audits and duration of such audit
- Standardize the audit process and assessment rating
- Meet the requirements of the different stakeholders

=> Involve stakeholders of the supply chain
What do you think?
Temperature Controlled Transport – Active Unit Load Devices

Presented by:
Todd DeVore – Vice President, Government and Disaster Preparedness
AcuTemp Thermal Systems
9 March 2011
Istanbul, Turkey
Key Points

• Design Considerations
• The Qualification Continuum
• Validation and Selection
• Training Assistance
Design Considerations

- Thermal Integrity
- Heating & Cooling Capacity
- Airflow, Air Distribution and Load Development
- Temperature Control Accuracy
- Monitoring and Alarming Capability
- Load To Container Matching
Thermal Integrity

Thermal Losses Have A Large Impact On Shipment Integrity:

- Increase Risk Of Product Deviations
- Increased Duty Cycle On Container Active Systems
- Reduced Battery Duration
- Operates With A Wider Temperature Tolerance

Example of thermal loses due to poor design, materials and construction
Design Considerations

• Thermal Integrity
• **Heating & Cooling Capacity**
• Airflow, Air Distribution and Load Development
• Temperature Control Accuracy
• Monitoring and Alarming Capability
• Load To Container Matching
Heating And Cooling Capacity

Ambient Operating Range

Extreme Cold

Extreme Hot

Container Set Point*
(4 °C to 25 °C)
Design Considerations

• Thermal Integrity
• Heating & Cooling Capacity
• **Airflow, Air Distribution, and Load Development**
• Temperature Control Accuracy
• Monitoring and Alarming Capability
• Load To Container Matching
Airflow And Air Distribution

Airflow Around The Product Within The Container Is Critical To Maintain Consistent Temperature Mapping
Worst Case Load Development

- Low Volume, Low Mass
- High Volume, Low Mass
Design Considerations

- Thermal Integrity
- Heating & Cooling Capacity
- Airflow, Air Distribution and Load Development
- **Temperature Control Accuracy**
- Monitoring and Alarming Capability
- Load To Container Matching
Temperature Control Accuracy

3-Day Shipment from Europe to USA (East Coast)
Winter (January)
Design Considerations

- Thermal Integrity
- Heating & Cooling Capacity
- Airflow, Air Distribution and Load Development
- Temperature Control Accuracy
- Monitoring and Alarming Capability
- Load To Container Matching
Monitoring and Alarming Capability

Graphical Output of Shipment Directly on the Container Screen.

Internal Data Logging Of Shipment, with Direct USB Download.

Icon Based Visual Alarming on the Container Screen.
Design Considerations

- Thermal Integrity
- Heating & Cooling Capacity
- Airflow, Air Distribution and Load Development
- Temperature Control Accuracy
- Monitoring and Alarming Capability
- Load To Container Matching
Load To Container Matching

- Properly Matched Payload And System Is Optimal
  - Optimizes Battery Life
  - Optimizes Temperature Variation
  - Minimizes Transport Costs

- Powered Systems From 150 Liters To RAP Size
The Qualification Continuum

- DQ: Design Qualification
- IQ: Installation Qualification
- OQ: Operational Qualification
- PQ: Performance Qualification
- Re-Q: Requalification
Design Qualification

Requirements Document
- Shipping Temperature
- Shipping Duration
- Primary Package
- Secondary & Other Packaging

Design Testing Protocols
- Temperature Mapping
- Thermal Test Profile
- Air/Product relationship
- Duration
- Develop Specifications

Design Test Data
- Product Temperature vs. Time
- Ambient Temperature vs. Time

Design Testing Analysis & Report
- Product Temperature Evaluation against Acceptable Criteria
- Temperature mapping of System
Installation Qualification Considerations

- Intent is to verify that a system complies with the proposed design, and that support systems are in place
  - Documentation Verification
  - Equipment Installation Verification
  - Preventative Maintenance Verification
  - Calibration Verification
  - Configurable Parameter Verification
Operational Qualification Considerations

• Intent Is To Verify That Active ULD Provides The Expected Results In A Laboratory Environment When Simulating Real-World Conditions:
  - Temperature Control In All Ambient Extremes
  - Power Loss Hold Over Time
  - Open Door Recovery
  - Alarm Conditions
  - Container Standard Operating Procedure Verification
Performance Qualification Considerations

• Intent Is To Verify That Active ULD Provides The Same Results In Real-World Situations As Expected From Laboratory (OQ) Situations:

  ▪ Verify Reproducibility
  ▪ Include Actual or Seasonal Temperature Variations
  ▪ Maximum And Minimum Product Load Configurations
  ▪ Mobile Systems Subjected To The Rigors Of Transportation And Handling
Re-Qualification Considerations

• Should Be Performed If Any Change In Performance or Design Is Noted
• Should Be Performed If Any Change In Shipment Route Or Methodology Is Noted
• Should Be Performed If Any Change In The Products Acceptance Criteria Is Noted
• Manufacturer Or Service Provider Should Be Able To Provide Re-Qualification Documentation
Training Assistance

- Equipment Manufacturers Typically Provide Training
- Benefits Of Accreditation
  - Assurance Of Product Understanding
  - Assurance Of Proper Handling Knowledge
  - Assurance Of Proper Pack-out Knowledge
  - Assurance Of Shipment Activation & Termination (Data-Logging)
  - Assurance Of Serviceability and Maintenance Knowledge

- Example:
  - Enhanced Qualified Users Program
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Chairman’s Closing Remarks

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