Cold Chain
A case study

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Agenda

- Summary of study
- Review ship to countries
- Import/Export of supplies
- Cold Chain Packaging
- Packaging of supplies
- Security
Case Study – Phase III Global Trial

Summary of Trial Logistics

- Materials packaged in the US, but shipped to multiple countries and depots
- Phase III Study
- 2-8C Temperature
- Large kit size created large shipping volumes
- Active and passive shippers used depending on application
Ship to Countries

- Determine where the materials are to be shipped
- Potential depot needs
- Review country specific regulations for import
  - Import Permit/License
  - Special Packaging/Labeling
  - Physical pack-out of materials
- Estimate the time traveled to the given countries
- Review method of shipping
  - Passive or active shippers
  - Air, Ground or Ocean
  - Monitoring devices
Know the ship to site requirements

- Review the capabilities of the receiving depots and their capacity to receive cold chain materials.
  - Does the depot have the capacity to store the supplies?
  - What type of shipment packaging can the depots handle? Active shippers, passive, phase change, etc.
  - Are there any country restrictions?

**Example:** Shipment to Russia – Airport could not handle active shippers, so Catalent had to ship via passive shipper. This required over 100 passive shippers to be delivered to the depot. Costly and time consuming….was it worth it?
Customs Valuation – 4 Hierarchical Valuation Methods

- Transaction Value;
- Transaction Value of Identical or Similar Merchandise (based on the transaction value of previously imported merchandise);
- Deductive Value (selling price in the US less certain post-importation costs);
- Computed Value (foreign supplier cost information for materials, processing, profit, general expenses, etc.)
Import/Export Regulations

- Export and import documents
  - Commercial Invoice
  - Import/export permits
    - DEA, USDA, MOH approvals, etc.
  - Importer (IOR) and Exporter (EOR) of Record
  - Planning....may take 3 months for an approved permit
Customs Valuation – Reduce your risk!

- Receive input from Finance, Procurement, Legal with regards to valuation
- Document method of calculation
- Have shipping documentation reviewed by Customs broker or Consignee prior to shipping
- Ensure all import license requirements have been completed – USDA, DEA, etc.
Packaging Decisions

- What type of packaging would you like to use for making the shipments?
  - Active – Shipper that maintains temperature via battery refrigerated power.
  - Passive – Shipper that maintains temperature through the use of refrigerated and frozen gel combinations.
  - Phase change – Reusable shipping systems to reduce shipping costs.
Validated shippers

- **Shipping “validation”**
  - Non-qualified – no documented testing to maintain temperature
  - Pre-qualified – documented testing performed to a shipping standard. Typically completed with water.
  - Validated – documented testing performed to a shipping standard with product.
Packaging Decisions - Monitors

- Temperature monitors?
  - Should they be used with all shipments, some of the shipments, never?

- Cost and quality – All of these decisions affect cost and the quality of the product. The higher the cost of the delivery system, in general, the more robust.
Kit Sizes

- Freight is calculated on either the physical weight of the materials, or the dimensional weight of the materials.
- Kit size will drive the shipping cost based on which ever of these two is greater
- Reduced kit size will reduce the cost of the shipment
Packaging

- Advantages to using packaging software
  - Reduce the size of the kit
  - Match the best shipper for the intended application

- Need to know prior to reviewing the final packaging configuration
  - How will most materials be shipped.
  - What type of cold chain packaging be used.
Shipper #1
216 Kits per Pallet
Pallet 80% Efficient
Same Kit - Shipper #2
240 Kits per Pallet 10%
Increase Pallet 90% Efficient
Security

- Know your shipper
  - Can the courier screen the materials?
  - Has the courier been audited?
  - Will the courier work with consignee to clear shipments?
  - How are the materials being while in the couriers presence

Example: Sponsor asked us to use a courier that we did not have any experience with, but were presented as an expert. Shipment was “misplaced.” Claim had to be filed for the lost materials.
Planning and flexibility

Be prepared to modify plans for weather, new country regulations, depot capacities, etc.

Example: European Volcano
Thank you!

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