Supply Chain Strategies for Pharmaceutical Product Integrity

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Agenda

Purpose and Objectives

Why important?

Topics

- ▸ Complex Network
- ▸ Product Security
- ▸ Temperature Control
- ▸ Serialization

Conclusion

Purpose

Create awareness and stimulate thinking about additional ways to continuously improve product integrity in the pharmaceutical supply chain

Objectives

➢Discuss the need for product integrity

➢Describe some of the complexity and risks in pharmaceutical supply chains

➢Provide ideas on how risks can be minimized

➢Stimulate thinking about additional ways to continuously improve

Perhaps no other industry has a stronger imperative to maintain product integrity than the Healthcare industry

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Why important?

1. Patients and providers trust the quality of the medicines that they use
   - ➤ Mishandled or counterfeit product is not easily identified
   - ➤ Potential risks range from lack of efficacy to death

2. Due to high product value, theft and counterfeiting occur
   - ➤ Stolen / counterfeit goods can enter the legitimate supply chain

3. Pharmaceutical products are developed and tested for specific temperature and humidity characteristics
   - ➤ Excursions from proper conditions may alter product quality
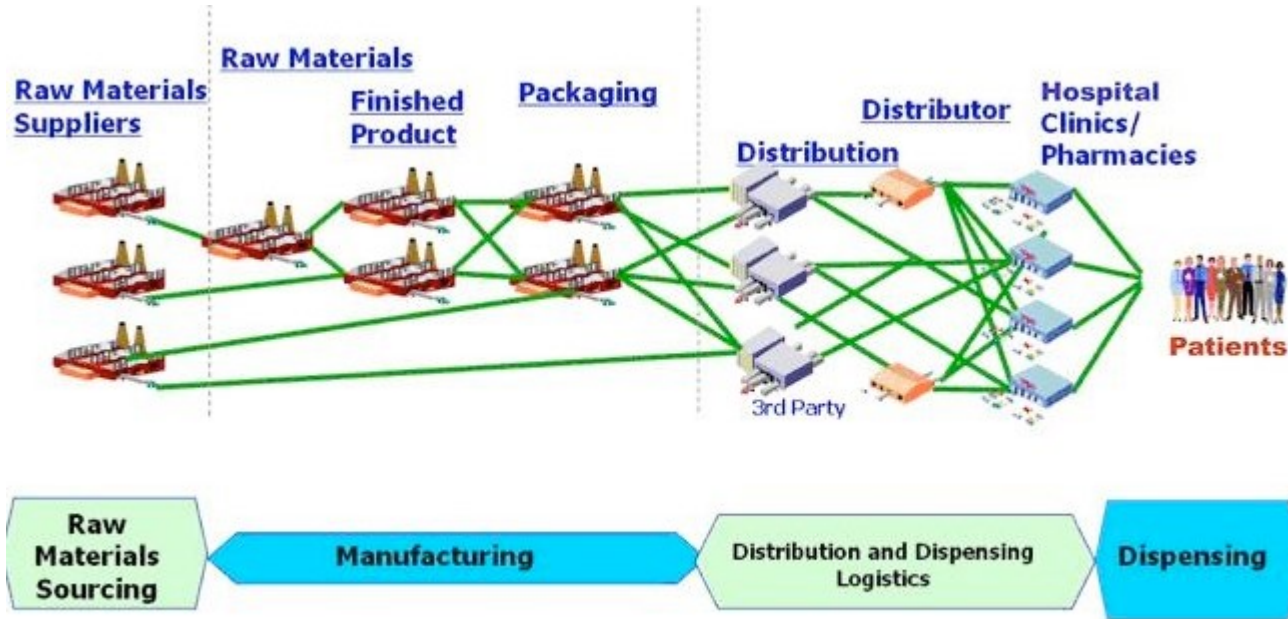
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Pharmaceutical Supply Chain

Source: Rx RESPONSE

Pharmaceuticals travel through a complex supply chain, with many handoffs, before reaching patients

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Product Security

➢ Freightwatch International reported that there were 754 cargo thefts in the US in 2015

➢ With an average of 63 cargo thefts per month, the US ranks as a high threat level area

➢ Pharmaceutical thefts accounted for 4% of all thefts with the average value being $240K

➢ Theft of Full Truckload accounted for 45% of the thefts with the average loss value of $410K

Despite the prevalence of cargo thefts and their impact, penalties are not severe, making cargo theft a prime risk to product integrity

Product Security (Continued)

Cargo Theft Case Study

➤ June 2009 a driver delivering a truckload of pharmaceuticals to a distributor stopped at a truck stop to eat and shower

➤ When returning to the parking area, he discovered the truck was missing

➤ Although there were only 18 pallets on the trailer, the value of the load was $10 million

➤ Since products could only be identified by batch number, a voluntary market withdraw was conducted to retrieve the batches involved resulting in a cost of $47 million

➤ October 2009, two individuals were arrested, the majority of the stolen cargo was recovered and subsequently destroyed

Product Security (Continued)

Risk Mitigation Remediation Strategies:

1. Discontinue use of freight brokers

2. Utilize asset based carriers with employee drivers

3. Carriers should specialize in high value load security

4. No "Red Zone" stops within the first 200 miles

5. Use team drivers on lanes exceeding 700 miles

6. Audit selected carriers to ensure proper procedures are in place

7. Employ freight monitoring on high value shipments

Product Security (Continued)

Risk Mitigation Remediation Strategies:

8. Dropped trailers and equipment swaps are not allowed

9. Tops of trailers should bear unique markings that would allow for aerial ID

10. Before moving and after stopping, drivers need to contact central monitoring

11. Security escorts are to be used in cases where monitoring is not used

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Temperature Control

Temperature control storage conditions are based on stability evaluations. Labeling is found on the package insert.

➢ Controlled Room Temp: 20°C to 25°C (68°F to 77°F)

➢ Refrigerated: 2°C to 8°C (46°F to 59°F)

➢ Freezer: -25°C to -10°C (-13°F to 14°F)

In order to maintain product integrity, storage conditions must be maintained. Deviations from the stated range may be allowed if supporting product data exists

Temperature Control (Continued)

What about when goods are in transit?

➢ There has been a great deal of work done on cold chain shipping

➢ Some common solutions include: Refrigerated trailers, active containers, passive containers and parcel shippers
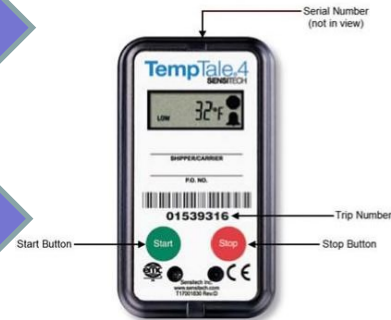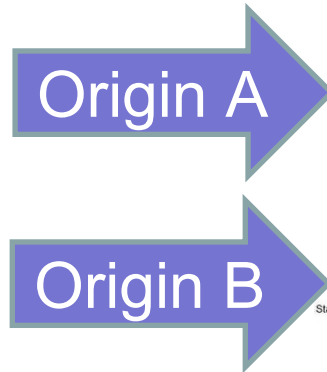
Temperature Control (Continued)

➤ Understanding ambient temperatures by mode and lane

5 modes

- 2 Day Airfreight
- LTL
- Next Day Saver
- Second Day
- Small Package - Ground

2 Origins

Origin A

Origin B

Temperature Control (Continued)

By comparison of product profiles and mode/lane profiles, informed decisions to ship under ambient conditions can be made

Benefits:

➢ Ensures Product Integrity

➢ Helps with customer inquiries regarding product being shipped in various temperature conditions

➢ Possibility of utilizing a different mode can save on cost, since trade-off can be made with cost of over-packing

➢ Optimize cost

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Serialization

To help fight the problems with counterfeit drugs, the US and other countries have enacted legislation to implement serialization

➢ In the US, the 2013 Drug Supply Chain Security Act (DSCSA) outlines the steps to build and operate a system to identify, track and trace prescription drugs

By January 1, 2015:

➢ Manufacturers must provide subsequent owners with transaction history (TH), transaction information (TI), and a transaction statement (TS) in <u>paper or electronic format</u>

➢ Wholesale distributors, dispensers, and repackagers cannot accept ownership of a product unless this information is provided

Serialization (Continued)

By November 27, 2017:

➢ Manufacturers must affix or imprint a product identifier to each package and homogeneous case of product

➢ Manufactures must provide subsequent owners with TH, TI, and TS in <u>electronic format</u>

➢ Manufacturers may receive verification requests regarding whether the product identifier in question corresponds to the product identifier affixed by the manufacturer, and must respond to requests within 24 hours

Serialization (Continued)

By November 27, 2019:

➢ Wholesale distributors may only accept returned products from a dispenser if the wholesaler can associate the returned product information with the TH, TI, TS

By November 27, 2023:

➢TH, TI, TS shall be exchanged in a secure, interoperable electronic manner

➢Transaction information shall include the product identifier at the package level

➢Systems and processes for verifying product identifier shall be required

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Serialization processes and technologies will be an important aspect of maintaining product integrity

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➢ Pharmaceutical supply chains are complicated involving many trading partners

➢ There are inherent risks to product integrity that must be continuously addressed along the entire supply chain

➢ We have only briefly discussed a few elements today

  ➢ Security

  ➢ Temperature Control

  ➢ Serialization

Image courtesy of zxsthisl

Pharmaceutical supply chains provide a key role in ensuring product integrity to patients. Continuous improvement will always be required.