

Vaccines and
Clinical Trials



Pharmaceutical



Hospitals and
Blood





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A decorative teal line graphic that starts on the left, rises to a peak, descends to a valley, rises to a smaller peak, and then descends towards the right. A grey horizontal bar is overlaid on the line, containing the main title.

Cold Chain Risk Aversion Planning

A Renewed Focus

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Welcome to the DeltaTrak webinar focused on Compliance and Risk, within the Life Sciences industry.

Agenda:

1. Take a quick look at two recently introduced regulations within the EU and China
2. How Risk is now becoming a big factor in any quality control program
3. A review of common areas to look at in Risk Assessment and Aversion planning.
4. How to establish a Risk Aversion, or Mitigation Plan
5. Specifics on how this relates to Cold Chain i.e. Management versus Monitoring your Cold Chain
6. Summary of what we covered and Take Away's
7. Question time

New Regulations – EU and China:

➤ **In March of 2013 the EU released new guidelines for GDP:**

- ✓ (EU -Guidelines of 7 March 2013 on Good Distribution Practice of Medicinal Products for Human Use – 2013/C 68/01) – Implementation period; 6 months after 8th March 2013

➤ **In June of 2013 the Chinese FDA implemented their new guidelines.**

- ✓ (China SFDA – Good Supply Practices guidance – Introduced on June 1, 2013) – Implementation Period: 3 years

➤ **Both of these new regulations are very similar in content and share recommendations for controlling and managing the supply chain:**

- ✓ Supply chain risk aversion planning – documented
- ✓ Environmental controls for cold chain products, like vaccines, and Bio-Logics
- ✓ Selection of Staff and on-going Staff Training
- ✓ Warehouse and Storage condition Management
- ✓ Environmental condition management of products during transportation – “source to patient”
- ✓ Controls to prevent falsified medicines from entering the supply chain
- ✓ A fully documented Risk Mitigation plan as part of the Quality Management System

A common theme – Harmonization Globally:

- Requirement for a fully document Risk Mitigation plan as part of the Quality Management System

What has changed?

- Existing regulations have been updated to include new detailed requirements around identifying risk and security.
- New regulations have renewed focus on overarching quality regulations related to risk, falsified medicines, and audits.

So - Two new, or enhanced areas:

- Renewed Emphasis on Security related to anti-counterfeiting and falsified medicines
 - e.g. HR3204 DQSA in USA Nov' 2013
- Renewed Focus on total Supply Chain Risk Aversion and Mitigation Planning

What are the Potential Risk Basics?

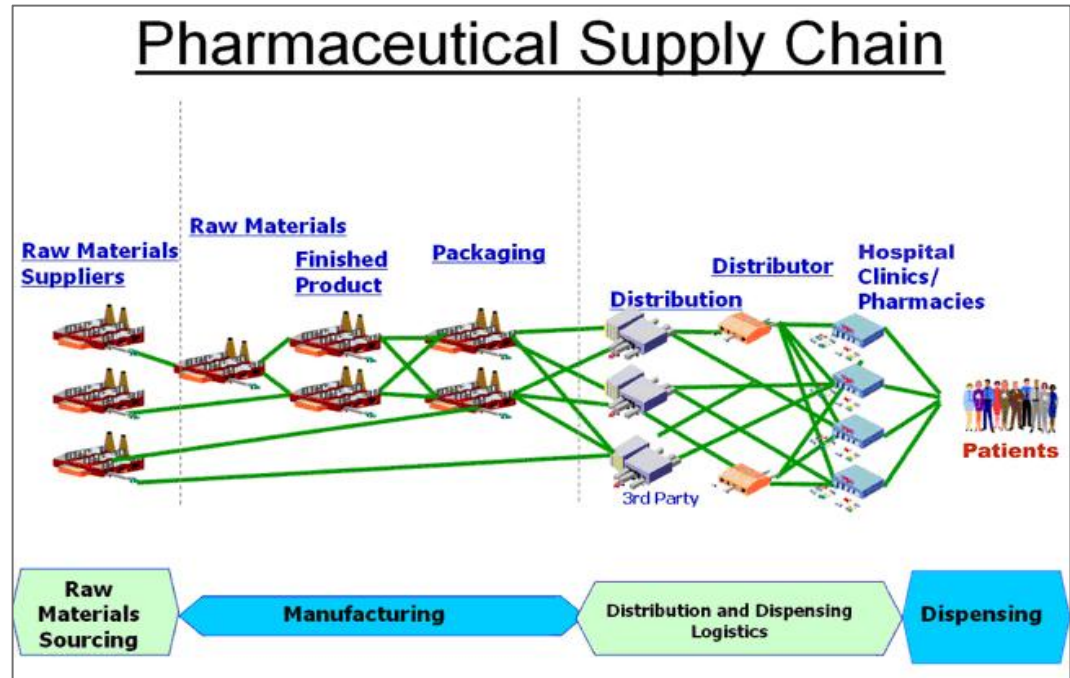
Let's look at Risk Assessment.

Where do you start?

Supply Chain is Complex!

However, risk in the supply chain can generally be broken down into 5 key areas:

1. Internal Risks
2. Network Risks
3. Industrial Risks
4. Environmental Risks
5. Compliance Risks



Common Risks in Cold Chain Logistics:

In any cold chain shipping and logistics routes or processes there are usually a number of common elements, or items that will exist. These could include:

- The cartons that are being used
- The carriers I am using – road, sea or air, and how many hand-offs and human elements
- The time of year and/or location in the world where the products are going to be shipped to
- Size and quantity
- What kind of condition monitoring is being employed – e.g. USB, Chemical, RFID, etc
- Data collection and storage procedures
Don't forget the "Cloud"!!!!

Risk Assessment – Identifying The Risks!

Where should I start?

Number 1 - From Past Experience.

Focus attention to where potential risk generating events are commonly encountered

These include for a short list:

- Any point where this is human intervention
- Any point where there is a product handoff point
- When you are shipping high-value items on a new route
- Country to country transfers
- Outsourced Data storage
- When you can't see what is happening inside the carton prior to receipt at the end point

Risk Mitigation – Making Plans

What should be included?

- Review and audit your supply chain to assess where risk does, or may exist
- Assess what the impact of these may be and create a list with the highest probability items at the top to address first
- Define your risk mitigation strategies for the highest level items and work down the list from High to Low
- Implement the strategies and document them

Risk Mitigation Plan's Effectiveness – How Should I Check?

How should you check for Compliance and Effectiveness?

- Monitor the supply chain and audit any intermediate partners, or vendors on a regular basis
- **“Look-out for Murphy!”**
- Get QA to conduct their own audit processes, throughout the supply chain and warehouses
 - Maintain good documentation and audit records
- Visit your vendors and suppliers – perform external on site audits, also a security audit on your “Cloud Services” provider
 - Maintain good documentation and audit records
- Maintain good performance records and make changes as necessary
- Create a visibility path to the executive level “sponsors”

But – What about Managing and Monitoring what goes on inside the carton?

Cold Chain – Management versus Monitoring

It is important to note that both these new guidelines/regulations, as well as many existing ones, require monitoring of the supply chain from “Source to Patient”:

- This includes, manufacturing (GMP), Distribution, Warehousing, Transportation, Local Storage and at Patient distribution point (GSP & GDP)
- Monitoring is in many ways – Forensic
 - Use of go/no go devices and you only know at the end what happened
- Management is having procedures and devices for Real Time Monitoring and a solution that allows intervention if problems are encountered – e.g. Temperature Excursions
 - Vaccines in a local storage refrigerator with a device that provides alarm alerts if problems occur
 - A monitoring device/system that allows a “look” inside the carton to get a real time view
 - An RFID, or WiFi/Cellular system that monitors a warehouse environment and provides real time alerts if, or when, problems occur

A point to Note: It is estimated that about 15% of all Cold Chain shipments do not have a monitoring device included with them – this is a Big Risk Area

- There will always be Risk in your supply chain
- Even though your Risk Management plan includes good SOP's and WI's make sure that people are adequately trained in these disciplines
- Conduct self audits regularly
- The cost of a Cold Chain Monitoring device or solution, is far less expensive than the cost of disposal of a temperature compromised shipment
- All Quality Systems and Risk Aversion Plans should have one over-arching goal
 - Patient Safety coupled with Drug Efficacy
- Final Point:
 - Do watch out for Murphy!

Thank You for your attention

Questions?

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