Risk or Reward – Exploring the Challenges of Manufacturing and Distribution Operations in Emerging Markets

Room: 1E16 ~ 2:00PM - 3:30PM
Wednesday, March 30, 2011

Carla Reed – Tunnell Consulting
Phil Priest – GSK
Leonidas Orjuela – Audisis Vale

How This Presentation is Structured

- Risk and reward in emerging markets – Strategic overview
  Carla Reed, Tunnell Consulting

- Brazil – Key player in Global Life Sciences Industry
  Leonidas Orjuela – Audisis Vale

- Dispelling the myths and legends – Perception or Reality?
  Phil Priest – GSK

- Steps to take to avoid the pitfalls

- Questions
Tunnell Consulting – Our Company and Our People

- Founded in 1962
- Employee Owned
- Headquarters in King of Prussia, PA
- Solutions that Exactly Meet Client Needs
- Experienced, Multi-Disciplinary Staff
- Integrating Technical, Process and Organizational Skills
- Sustainable Knowledge Transfer

Opportunity and Risk in Emerging Markets

- Industry consolidation and focus on cost reduction
- Trend towards outsourcing, joint ventures, contract mfg.
- Supply chain complexity – particularly in emerging markets
- Challenges in BRIC – MT countries (Brazil, Russia, India China – Mexico and Turkey)
- Chain of custody issues
  - Counterfeit and diversion
  - Product protection – Cold Chain
    - Requires a new approach – OUTCOME Sourcing!
Emerging Markets
Old World
Becomes New!

Brazil
Brazil has been inhabited for at least 8,000 years by indigenous people!
Discovered by Spanish in April 1500 – later colonized by Portuguese

Russia
More than 1,200 years of recorded history – Global ‘super-power for centuries – Russian
Revolution of 1917 and subsequent ‘cold war’ isolation created by ‘iron curtain’

India
Evidence of human activity over 75,000 years ago!
Ancient cultural history – Golden Age of Middle Kingdom!

China
Homo erectus inhabited what is know as China a million years ago!
Earliest written record dates back to Shang Dynasty in 1500 BC

Mexico
First populated more than 13,000 years ago this region produced several complex
indigenous civilizations before being conquered by the Spanish in the 1500’s

Turkey
Land of Turkey is ancient but civilization relatively new – Turkish migration between
6th and 11th century

Consider Opportunities in BRIC-MT
(Brazil-Russia-India-China-Mexico-Turkey)

Brazil – Economic Superpower in Latin America

News & Observer – Saturday March 19th, 2011:
» “Over the next decade Brazil’s middle class is expected to explode, creating an army of
consumers eager to spend their disposable incomes on American products”
» “Quintiles opened an office in Brazil in 1998 – today the Durham based pharmaceutical
services company employs 190 people and is running 35 to 40 clinical tests on experimental
drugs”

Other interesting data points:
» Increased demand for brand name drugs (versus generics)
» Cost of conducting clinical trials in Brazil is one-fifth of cost in the USA or the EU – however
regulatory approval process is much longer – and there are concerns related to IP
protection . . .
» In the past Brazil tended to use tariffs and tools to limit foreign competition – these barriers are
slowly coming down (although issues with Brazilian customs are still common – be meticulous
with documentation!)

But more on this in a moment when Leonidas shares his perspectives
Russia – Rules, Regulations, and Restrictions

High growth market – 20 percent in 2008 to $17 billion and by another 13 percent in 2009 to $19.2 billion (and growth continues!)

High Risk – High regulation by Health and Social Development Ministry

Russia’s regulatory policy for pharmaceuticals excessive – but out of step with international regulations.

Consider:
» Random fees and requirements to re-register products every five years
» Demands for redundant clinical testing
» Little government enforcement for counterfeit drugs
» Weak enforcement of IP, data and trademark protection

April 13, 2010 – new law on circulation of drugs approved by State Duma and Federation Council and signed by President of Russian Federation provides detailed description of registration and approval requirements (effective September 1, 2010):
» Foreign manufacturers must conduct clinical trials in Russia prior to registration
» No amendment to restrict access to clinical trial data for generic manufacturers
» New measures to protect health of clinical trial participants – with minimum amounts for compensation for damages

(Source: The Pharma Letter – 22 September 2010)

India – A Double-Edged Sword!

India, together with China supplies more than 40 percent of the active pharmaceutical ingredients (API) used to make U.S. pharmaceuticals. This is expected to double within the next 15 years!

According to a report released by the Organization for Economic Cooperation and Development (OECD) 75 percent of fake drugs supplied have ‘some origins’ in India – followed by 7% in Egypt and 6% in China:
» India is a leading manufacturing location for legitimate, brand name global pharmaceutical companies
» Although there is a law in India against selling fake drugs for domestic use these regulations do not apply to export market!!!!
China – Opening Pandora’s Box!

From 1998 to 2007, China’s pharmaceutical export trade increased from $3.4 billion to $24.6 billion.

China is an important supplier of some key ingredients:
- Example – Artemisinin, a vital component of the best antimalarial drugs.
- The Chinese Academy of Military Medicine helped develop artemether-lumefantrine, considered the most effective antimalarial drug on the market. (A paradox as China is the primary source of counterfeit malaria drugs!)

Concerns: In general measures for protecting intellectual property are weak in Asia. Ethical standards are also low compared with Europe and the USA – a particular concern in view of the severe damage to reputation and international standing that can result from suppliers’ oversights:
- After the launch of General Product Safety Directive in 2004, the number of serious risk notifications in the EU almost doubled from 386 in 2004 to 701 in 2005.
- Half of these risk notifications were related to products from China.
- The European Commission also reported that 71% of counterfeit goods originated from Asia in 2004. China accounted for 54% of this total.

China has a very poor record for health and safety standards in manufacturing:
- Infringements of regulations relating to minimum wage, working hours and employment of under age workers, remain common in Asia in general – and China in particular.
- Some factories are even believed to be falsifying records and coaching workers on how to answer auditors’ questions.

(Source: American Enterprise Institute for Public Research – April 2009)

Mexico has become an area of concern for authorities related to ‘illicit trafficking’. However – there are many opportunities for ‘legitimate drugs’.

Opportunities:
- Mexican market comprises mainly ‘foreign’ companies with few domestic players
- Sales of pharmaceutical categories are very similar to the West – many growth opportunities

Challenges:
- Delays and challenges in registration of new products
- Intellectual property issues
- Counterfeit is a growing problem
Turkey – Changes, Controls, Reduced Profits Create Market Uncertainty

Turkish government implemented reforms under the name of 2003-2013 health transformation program

- 3 separate social security systems unified under single program – SGK:
  - Free health care services for elderly, with all workers included in the national health care system (more beneficiaries – more cost to Government).
- New government “reference price policy” for drugs:
  - Decreased spending by government – drugs sold in Turkish market should not exceed cheapest products in EU countries.
- Drug registration and pricing approval process previously under single authority now subject to two institutions, resulting in additional delays in new product introduction:
  - MOH was given the authority of registration approval.
  - SGK was authorized for the reimbursement process.
- Implemented “data exclusivity and patent protection” – new drugs can only be launched in Turkey within 2-3 years of EU launch:
  - Total period is 6 years (including time in EU) meaning data exclusivity is an effective 3 years and new brands in Turkey have generic threat 3 years after launch.
- Serialization project – aimed at counterfeit protection – additional cost to industry of USD200mm

Bottom line – 25% decrease in pharmaceutical revenues – spending increased by 25%, in 2010

(Source: Business Turkey Today – March 2011)

Mother Nature Can Be Unpredictable
Recent Events in Japan Highlight Global Impact of Environmental Disasters

Risk Factors for Consideration in Emerging Markets

- Network Strategy – Technology Transfer across internal and external operations
- Global quality and regulatory compliance:
  » Clearly defined service level agreements and quality management systems
  » Understanding of origin / destination rules and regulations
  » Documentation and labeling requirements – anywhere to anywhere
- Supplier Qualification Programs:
  » Providers of raw materials and components
  » Suppliers of logistics services
- Chain of Custody issues:
  » Counterfeit and Diversion
  » Product Protection – Cold Chain compliance
Risk Factors for Consideration in Emerging Markets (Continued)

- **Network Strategy – Integration across internal and external operations**
- **Global quality and regulatory compliance:**
  - Clearly defined service level agreements and quality management systems
  - Understanding of origin / destination rules and regulations
  - Documentation and labeling requirements – anywhere to anywhere
- **Supplier Qualification Programs:**
  - Providers of raw materials and components
  - Suppliers of logistics services
- **Chain of Custody issues:**
  - Counterfeit and Diversion
  - Product Protection – Cold Chain compliance

Network Strategy – A High Level Perspective

- **Effects of a Single Plant Closure:**
  - Multiple tech transfers to internal sites and CMOs
  - Global regulatory filings for each transferred product
  - Special projects – remediation of troublesome processes, method upgrades, capital investment, process adaptation, remediation of gaps between filing vs. current process

- **Effects of Network Consolidation:**
  - Hundreds of Tech Transfers to internal sites and CMOs
  - Numerous Special Projects
  - Several years of Global Regulatory Filings
  - A significant temporary increase in workload for site and corporate functions
Considerations for Risk Identification / Mitigation

Network Strategy – Technology Transfer across internal and external operations

Global quality and regulatory compliance:
  » Clearly defined service level agreements and quality management systems
  » Understanding of origin / destination rules and regulations
  » Documentation and labeling requirements – anywhere to anywhere

Supplier Qualification Programs:
  » Providers of raw materials and components
  » Suppliers of logistics services

Chain of Custody issues:
  » Counterfeit and Diversion
  » Product Protection – Cold Chain compliance
Global Quality and Regulatory Compliance

- Work with local partners – focus on end result – OUTCOME Source!!
  - Industry Specific Compliance:
    - GMP
    - USP VI materials
    - FDA / EMEA / ANVISA / SFDA / other global regulatory bodies
  - Safe and Secure Supply Chain:
    - Supplier security – internal controls and Service Level Agreements
    - Chain of Custody – controls and monitoring requirements
    - Product safety:
      - Testing / Traceability
      - Detailed product recall requirements and planning document
  - Global Capabilities:
    - Global Trade Compliance – HTS classification
    - Customs regulations / denied parties / FCPA / other
    - CTPAT and related security regulations

Risk Factors for Consideration in Emerging Markets (Continued)

- Network Strategy – Technology Transfer across internal and external operations
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Supplier Qualification Programs

- This is a critical success factor:
  - Requires an extended view across supply network – supplier’s supplier
  - Include carriers, forwarders, and their community of extended partners
  - Clearly defines roles, responsibilities facilitate open communications

Supplier Performance Management Program

- While audits / assessments are an important part of supplier programs, they are not sufficient in themselves to assure that the desired outcomes are met.
- There must also be a robust risk management and continuous improvement infrastructure in place to insure:
  - Ability to respond to the changing demands of marketplace
  - Avoid unwanted ‘surprises’
  - Maintain effective working relationship with the trading partner community
Risk Factors for Consideration in Emerging Markets (Continued)

- Network Strategy – Technology Transfer across internal and external operations
- Global quality and regulatory compliance:
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Counterfeit – Time for a Definition

- Counterfeit legal drugs include falsely labeled drugs that could include:
  - Products that have expired
  - Drugs where the active ingredient has been:
    - Diluted
    - Adulterated
    - Substituted
    - Completely misrepresented
    - Sold with a false brand name
China – Growing Awareness of Product Risk, Quality, and Counterfeiting

- After the launch of General Product Safety Directive in 2004, the number of serious risk notifications in the EU almost doubled from 388 in 2004 to 701 in 2005.
- Half of these risk notifications were related to products from China.
- The European Commission also reported that 71% of counterfeit goods originated from Asia in 2004.
- China accounted for 54% of this total.

Cause and Effect – What are Some of the Issues?

- In general measures for protecting intellectual property are weak in Asia.
- Ethical standards are also low compared with Europe and the USA – a particular concern in view of the severe damage to reputation and international standing that can result from suppliers’ oversights.
- China has a very poor record for health and safety standards in manufacturing:
  » Infringements of regulations relating to minimum wage, working hours and employment of under age workers, remain common in Asia in general – and China in particular
  » Some factories are even believed to be falsifying records and coaching workers on how to answer auditors’ questions
Concerns – Inadequate or No Authentication

- Purchasers in the global drug distribution chain need to ensure that the product they are purchasing is the genuine article (i.e., authenticate the product).
- Each stage validates that what was received is authentic.
- Self Assessment for Risk Avoidance – Have I got the right process? Are my partners adhering to the right processes to support me?

What is Required: Process Overview

Each pedigree is written to as product moves through supply chain
Illustrative Purposes Only
Source: Chainlink Research
The term Cold Chain originates from the terminology for the ‘chain of custody’ in the production, packaging, distribution, and control of temperature sensitive product. This includes the traditional areas of supply chain, to include raw material acquisition, transformation and manufacturing processes, packaging and product protection, storage, and distribution.
### Possible Causes of High Temperature Excursions at Destination and Interim Airports

<table>
<thead>
<tr>
<th>Cause</th>
<th>Recommended Corrective Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Container sitting on tarmac prior to transfer or storage</td>
<td>Quality Agreements or Quality aspects of supplier agreements should be established with each carrier stating the requirements on how material is to be handled and stored during:</td>
</tr>
<tr>
<td>Container placed in hot, non-temperature-controlled storage facility / warehouse</td>
<td>1) Transfer at airport of origin</td>
</tr>
<tr>
<td>Container in close proximity to jet engine after unloading</td>
<td>2) Arrival at interim airports (including handling when flights are delayed or cargo is being re-balanced)</td>
</tr>
<tr>
<td>Container placed in direct sun light for extended periods of time</td>
<td>3) Arrival and transfer at destination airport</td>
</tr>
<tr>
<td>Excessive transfer time in hot ambient conditions</td>
<td>4) Holding prior to pick up for final delivery</td>
</tr>
<tr>
<td></td>
<td>5) Handling during final leg to customer</td>
</tr>
<tr>
<td></td>
<td>6) Full traceability of product during all points of transit.</td>
</tr>
</tbody>
</table>

The Quality Unit responsible for qualifying third party logistics providers should use similar criteria in their evaluations and ensure that SOPs exist which address these issues.

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### Radiant Temperature Effect of Airport Tarmac

NOTE: This temperature graph was taken from an airport in the UK in May, 2007.
USP<1079> ‘Good Storage and Shipping Practices’

While completing qualification studies of controlled temperature shipping packages and systems it is necessary to utilise temperature profiles that are expected to be typical for the type of package based on a number of factors including:

- Temperature conditions at origin and destination
- Seasonal temperature (winter versus summer)
- Transport routes and modes
- Total duration of transit
- Duration and location of handling and stop-over points
- Overall product handling
### Brazil in Numbers

<table>
<thead>
<tr>
<th>Currency</th>
<th>R$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exchange Rate – 1 Dollar</td>
<td>R$ 1.65</td>
</tr>
<tr>
<td>Gross Development Product (GDP)</td>
<td>US$ 2.21 Trillion</td>
</tr>
<tr>
<td>GDP Growth</td>
<td>7.5 (2010), 1% (2009), 5.1% (2008)</td>
</tr>
<tr>
<td>Unemployment Rate</td>
<td>5.7%</td>
</tr>
<tr>
<td>Workforce</td>
<td>103 Million</td>
</tr>
</tbody>
</table>

### Brazil in Numbers (Continued)

<table>
<thead>
<tr>
<th>Member of the BRIC Countries</th>
<th>Brazil, Russia, India, and China</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population</td>
<td>190 Million Inhabitants</td>
</tr>
<tr>
<td>Language</td>
<td>In Brazil, a Single Language is Spoken by More Than 190MM</td>
</tr>
<tr>
<td>IMF (International Monetary Foundation)</td>
<td>10th Shareholder in IMF</td>
</tr>
<tr>
<td>ISO Certifications</td>
<td>6,000 Companies are ISO Certified in Brazil</td>
</tr>
<tr>
<td>Culture</td>
<td>Multi-Cultural and Multi-Ethnic Country</td>
</tr>
</tbody>
</table>
## International Commerce

<table>
<thead>
<tr>
<th>Imports</th>
<th>US$ 181,638 Billions (2010)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Countries Brazil Imported More (2009)</td>
<td>USA (16.1%), China (12.6%), Argentina (8.7%) and Germany (7.6%)</td>
</tr>
<tr>
<td>Main Products Brazil Has Imported (2009)</td>
<td>Electronic Circuits, Transmitters and Receivers, Vehicle Parts, Pharmaceuticals, Automobiles, Fuel Oil, Natural Gas and Engines for Aircrafts</td>
</tr>
<tr>
<td>Commercial Organizations Brazil Takes Part</td>
<td>MERSOCUL, UNASUL and OMC (Commerce World Organization)</td>
</tr>
</tbody>
</table>

## International Commerce (Continued)

<table>
<thead>
<tr>
<th>Exports</th>
<th>US$ 201,916 Billions (2010)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Countries Brazil Exported More (2009)</td>
<td>China (15.8%), USA (10.5%), Argentina (8.4%) and E. Netherlands (5.3%)</td>
</tr>
<tr>
<td>Main Products Brazil has Exported (2009)</td>
<td>Iron Ore, Iron and Steel; Gross Petroleum Oils; Soy and Derivates; Cars; Sugar Cane; Aircraft; Ox Meat; Coffee and Chicken Meat</td>
</tr>
<tr>
<td>Trade Balance</td>
<td>US$ 20,278 Billions (SUPERAVIT)</td>
</tr>
</tbody>
</table>
### Business Opportunities

- Dermocosmetics for pharmaceutical companies
- New foreign investors coming to Brazil needing new sites, manufacturing outsourcing, consultants in Regulatory Affairs
- Fiscal benefits for investors in Pharmaceutical Pole in Anápolis – Goiânia (Brazil)
- Great opportunities for 2014 (World Cup) and 2016 (Olympic Games)
- Generic Medicines – Great investments from government in development of new drugs

### Pharmaceutical Market

- Pharmaceutical Brazilian market: US$ 17.7 billions per year
- Brazil is the 9th biggest market for pharmaceutical products
- Four Brazilian companies are among the 10 biggest pharmaceuticals companies in Brazil
- There are 540 pharmaceutical companies in Brazil – 90 producing similar drugs
Brazil

Ranking – Sales in USD

1) EMS*
2) MEDLEY (Sanofi-Aventis)
3) SANOFI-AVENTIS
4) ACHÉ*
5) EUROFARMA*
6) NOVARTIS
7) PFIZER
8) MSD
9) NEO QUÍMICA*
10) BAYER

(*)Brazilian companies Source: IMS October 2010

Pharmaceutical Products

Brazilian Exportations Evolution – US$ 1.1 Billion – Period: 2000-2011*
Pharmaceutical Industries in Brazil

Pharmaceutical Products (Continued)
Brazilian Importations Evolution – US$ 4.5 Billion – Period: 2000-2011*

*Jan/2011
Pharmaceutical Market in Brazil
Sales in R$1000 – Period: 1997-2009

Transformation Industry and Pharmaceutical and Vet Products – Month Period: November 2009-2010
Brazilians Consumed US$ 3.78 Billion in Generics in 2010 – Growth of 37.7%

- 20% of drugs sold in 2010 was generics
- Sales increased 37.7% between 2009 and 2010
- The main reasons were:
  » Economy growth
  » Increase of population income
  » Launch of new products to market

Generics Market

- Generics prices – 45% less expensive than the reference drugs
- Between 2002 and 2009 sales jumped from R$ 588MM to R$ 4.8 billion
- In the same period – Registration of generic products in the Health Ministry increased from 213 to 2,972
THANKS FOR YOUR ATTENTION!

Risk or Reward?
Exploring the Challenges of Manufacturing and Distribution Operations in Emerging Markets

Phil Priest,
Vice President
Head of Site, Zebulon
GlaxoSmithKline

INTERPHEX 2011
March 30, 2011
Background

• Head logistics for multinational pharma company’s International division
• Created import / export logistics operation to manage pharmaceutical exports from China to Europe
  – One of first multinational companies to export finished packs from China to Europe
• Team established regional logistics hubs in Dubai to support Africa and Middle East and in Panama to support Latin America

Perception or Reality? – No. 1

“Chinese labor wage rates are growing so fast that Chinese sourcing will not make sense for western companies in the relatively short term.”

Source: IMF economic survey
Perception or Reality? – No. 1

“Chinese labor wage rates are growing so fast that Chinese sourcing will not make sense for western companies in the relatively short term.”

<table>
<thead>
<tr>
<th>Percentage Share of Income or Consumption</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relative affluence</td>
</tr>
<tr>
<td>Share</td>
</tr>
</tbody>
</table>


A few personal insights
• Easy to find warehouse operations staff and train them
• Difficult to find high-quality logistics managers, and manager turnover is high
• Significant management salary inflation to remain attractive

Perception or Reality? – No. 2

“Importation to emerging markets is difficult and products can get damaged, held for long periods at borders, or worse.”

A few personal insights
• Importing to Brazil
  - An importer must deal with multiple formal trade documents, certificates, labels, import duties, sales taxes, and tariffs as well as random full inspections at port of importation
  - Average import time to Brazil (from arrival to release to ship from bond) = 21 days
• Letters of Credit (LoCs)
  - Many emerging market wholesalers have unknown credit risks requiring LoCs
  - Ensuring LoCs are correct is critical when you want to move goods
  - One of my shipments was held up for almost 18 months because of discrepancies with an LoC and eventually had to be destroyed because it was close to its expiry date
Perception or Reality? – No. 2

“Importation to emerging markets is difficult and products can get damaged, held for long periods at borders, or worse.”

A few personal insights

• Airlines at remote locations can cause problems
  – In one instance, an airline split a shipment because its hold was too full, leaving half of the cargo on the runway for 5 days; we had to destroy almost $0.5 million of product because of the inappropriate storage conditions

• Damage-in-transit losses can add up across your network
  – The truck shown at right hit a railway bridge and damaged the product inside the container; we had to destroy $200,000 of product as a result

You must have good systems processes and excellent tracking and monitoring to protect the patient.
While in all of these examples we suffered some financial loss, no damaged product reached a patient because our systems were robust.

Perception or Reality? – No. 3

“Quality of products supplied to the US from Chinese and Indian operations is lower than that of western pharmaceuticals.”

In a recent survey of attitudes of western multinational pharma companies regarding Indian contract manufacturing, more than 50% rated their perception of infrastructure either below average or poor.

Source: Ernst and Young India “Taking Wings Survey,” 2009

Personal insight

• I have visited some Chinese and Indian operations where the standards were equal to that of any US facility
• The greatest number of personal interactions regarding US solid dose contract manufacturing and development in my facility have come from emerging market-based companies

Source: Ernst and Young India “Taking Wings Survey,” 2009
Steps to Take to Avoid the Pitfalls

Develop an Understanding of YOUR OWN Supply Chain

<table>
<thead>
<tr>
<th>Current State</th>
<th>Desired State</th>
<th>Innovation – Future State</th>
</tr>
</thead>
<tbody>
<tr>
<td>» Who are the players?</td>
<td>» Information sharing</td>
<td>» Virtual factory</td>
</tr>
<tr>
<td>» What are the risks?</td>
<td>» Monitoring and measurement</td>
<td>» Data synchronization</td>
</tr>
<tr>
<td>» What compliance issues do we need to take into account?</td>
<td>» Integrated flow of goods and information</td>
<td>» Asset optimization</td>
</tr>
<tr>
<td>» What check and choke points exist?</td>
<td></td>
<td>» Other</td>
</tr>
</tbody>
</table>
Desired Outcome – Supply Chain Visibility Across the Product Lifecycle

- Visibility to ownership or custody of a product at all stages of its lifecycle...
- Who touched it; who owns it; who is responsible now
- Audit trail:
  - Where a product has been
  - Last place a missing product was seen
  - Diversion from intended path
- Solutions:
  - Pedigree (Quality / Purity)
  - Authentication / Brand protection
  - Track and Trace
  - Returns – recall and destruction

Recommendations

- Pharmaceutical safety is both a philosophy and a core value that needs to be built into the process, inspected and monitored through stringent controls.
- Standards, policies, procedures, and processes to ensure the safety and security of the supply chain should be agreed to by all participants (no matter how small their role) and should be reinforced by clearly defined service level agreements and reporting mechanisms.
Understanding the Inter-Relationships Across a Global Network

1. **Educate the chain:**
   - It is critical that all supply chain partners are aware of their role in ensuring safety and compliance.
   - Service level agreements that are part of the legal terms and conditions of procurement and service contracts should be used to help ensure compliance.

2. **Demand data collection excellence:**
   - In many cases, the technical capabilities of suppliers – or lack thereof – can create constraints.
   - These should be understood and planned for, capturing required data elements and required information through media in place, and digitizing this as soon as possible.
Guiding Principles (Continued)

3. **Institute documentation and communication consistency:**
   » Documentation is critical to ensure that the correct packaging, storage and handling procedures are consistently applied
   » Communicate and share information with ALL participants in the chain of custody – taking into account language, literacy and other constraints

4. **Pay full attention to recall and destruction:**
   » It is all-important to ensure that members of the extended supply chain know what to do if the product has been compromised and spoiled
   » This should be clearly outlined in service level agreements between all players in the pharmaceutical supply chain
   » Take nothing for granted – insist on timely and accurate records for product recall, processing and destruction

Guiding Principles (Continued)

5. **Be obsessive in continuous monitoring:**
   » Outsourcing is no excuse for negligence
   » Best practice companies put in place data analysis processes and “human knowledge” collection procedures to spot specific red flags in their end-to-end supply chains
   » Changes in cost elements, participants, trade lanes and modes of transport should be investigated!
   » If it seems too good to be true, it probably is!