



Supply chain management

is the key to top-line growth in the
21st century for pharmaceutical
and medical device manufacturers

“Many U.S. healthcare firms, both small and large, have been able to continue their success by looking at foreign buyers and overseas.”

U.S. Department of Commerce International Trade Administration¹

By Scott Szwast, Healthcare Marketing Director, UPS



Introduction



yet



It has been said that ‘demographics are destiny,’ and this is certainly true of the global growth of the middle class. Newly empowered consumers around the world are creating dynamic and expanding new markets for products that promise to sustain and improve the quality of their lives. International trade has become particularly important for pharmaceutical and medical device manufacturers because 57 percent of demand is now found outside of North America.² Foreign markets are also manifesting the fastest growth. Yet less than one percent of U.S. healthcare companies export.³ What factors hinder pharmaceutical and medical device organizations from participating in the large and growing global marketplace? Many companies cite two primary concerns as the impediment to taking their businesses beyond a solely domestic focus.

The first challenge for pharmaceutical and medical device companies is to secure regulatory approval for their product portfolios in new countries. Many healthcare-focused businesspeople remember the complex approval processes required for product launches in home markets and are daunted by fears of foreign certifications and the bureaucracies that administer them.

Interestingly, many healthcare and medical device companies are better suited to this challenge than their business development teams may initially believe. Because of the nature of their products, healthcare manufacturers are very experienced at working with diverse regulatory bodies to secure support for innovative new products. This is one of their unique core competencies. They have the systems, processes and expertise needed to work with healthcare regulators, and this foundation serves them well as they take their first steps out into the larger global healthcare market. Furthermore, many will find regulatory hurdles to be less stringent in foreign growth markets, with a faster and less costly path to product approval.

While the foreign regulatory approval can prove less challenging than many healthcare companies fear, the second challenge they face—effectively managing a global supply chain—frequently does justify their trepidation. Global supply chain management is typically not a core competency for many healthcare manufacturers. The pace of globalization, a key trend in most consumer and industrial sectors over the past two decades, is a more recent development in healthcare. Even the largest multinational pharmaceutical and medical device manufacturers find aspects of supply chain management trying.

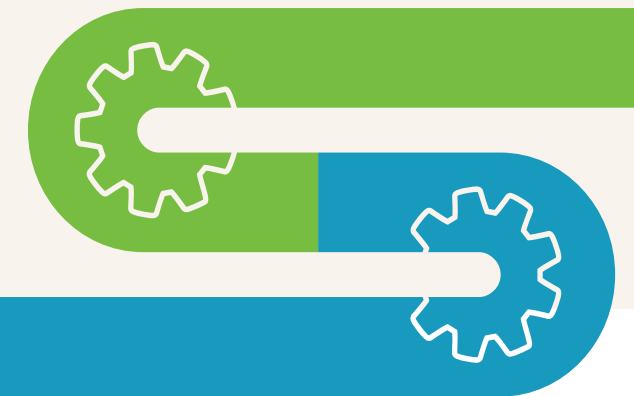
But like the regulatory approval challenge, supply chain management fears can be addressed with effective systems, processes, and expertise.

This white paper explores best practices in global healthcare supply chain management—what to focus on as an organization moves to reap the benefits of economically importing medical material and exporting products to fast-growing overseas markets.

Agility, adaptability, and alignment

When thinking about shipping pharmaceuticals and medical devices, companies tend to begin by focusing on the micro issues, for example, modes of transportation, surcharges and accessorial, tracking and tracing, cold chain management, secure facilities, customs clearance, and a host of other disparate details. Narrow focus on single issues is not what drives effective supply chains.

As Stanford University professor Hau Lee observed, “Great supply chains are agile. They react speedily to sudden changes in demand or supply. Second, they adapt over time as market structures and strategies evolve. Third, they align the interests of all the firms in the supply network so that companies optimize the chain’s performance when they maximize their interests. Only supply chains that are agile, adaptable and aligned provide companies with sustainable competitive advantage.”⁴



Companies should begin by aligning the supply chain to the strategic vision of the organization—first the vision and then, and only then, supply chain alignment. Supply chains support corporate strategies. Sustainable business growth requires that supply chain tactics be aligned closely with a company’s strategic vision.

World-class supply chain management is fundamentally about the uninterrupted, seamless flow of materials and data. Integration of these elements is the foundation for an agile supply chain. But achieving this cohesion can be a challenge for many companies. A number of leading global healthcare corporations have found that the most effective, timely and efficient means of achieving supply chain integration is to work with a global logistics integrator. Strategic logistics partners provide turnkey, scalable solutions for end-to-end supply chain management, from upstream supplier to ultimate customer.

Establishing strategic partnerships requires the commitment and active engagement of senior management. If senior executives do not align to embrace partnerships, then not everyone in the enterprise will be able to effectively manage the transition. It all starts with executives with global vision and perspective. For a global supply chain to function at world-class peak efficiency and better serve the needs of its customers, including care providers and ultimately patients, integration, collaboration and long-term relationship management is required between the organization and its logistics partner.

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Not surprisingly, healthcare companies have unique needs that make the choice of a logistics partner more complex than simply looking for a provider of integrated shipping solutions. The following are key attributes to consider when evaluating logistics partners:



- Proven healthcare-optimized national and international transportation and distribution infrastructure
- Global information management portfolio, including healthcare-compliant, validated systems
- Consultative expertise in global network design and management
- Global visibility, specialized healthcare storage and transportation, business continuity and security, and regulatory and trade compliance infrastructure
- Track record of sustained long-term investments in expertise and capabilities specific to the healthcare industry
- Ability to adapt to changing market conditions with flexible multimodal and multichannel business solutions
- International support in areas of public affairs, and trade compliance
- The partner of choice should also provide quantified case examples of how it and its healthcare clients have implemented strategic supply chain solutions
- Relevant examples of partnership experience and culture

These elements together provide clear confirmation of a potential strategic logistics partner’s healthcare focus and are an essential foundation for an agile, adaptable, aligned global supply chain.

Pay particularly close attention to the case examples showing how the logistics provider has worked successfully with similarly situated healthcare clients. These case examples should clearly demonstrate how the provider and client work together with shared commitments, collaboration, and shared dependencies.

Part One: Getting started

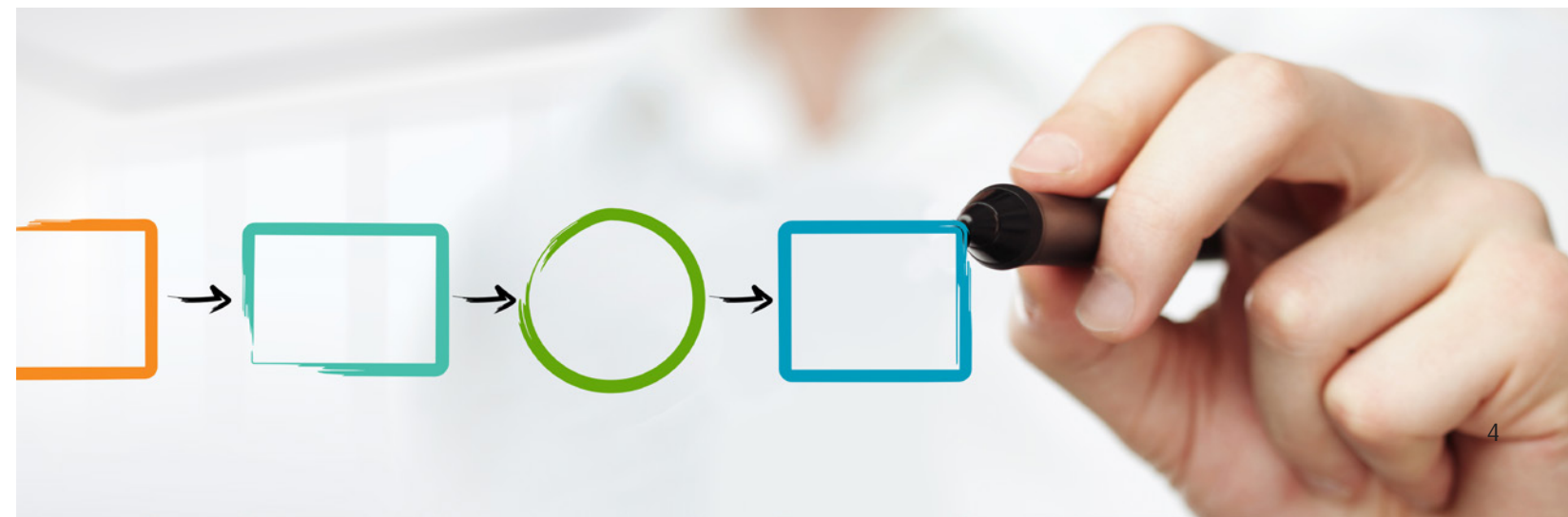
Determine where the logistics process is today. The optimum first step in the development of a global logistics supply chain for pharmaceuticals or medical devices is to ensure that all stakeholders have a clear and consistent understanding of the existing market situation, key business requirements, growth objectives, and strategic vision. The best method to achieve this is to hold a fact-finding/strategy alignment session with senior management, internal subject matter experts and with the logistics partner. These “white-boarding” sessions begin with statements by senior managers on the strategic vision of the organization for the next three to five years.

Key elements of the strategic vision include:

- Corporate strategy
- Competitive differentiators—both existing and needed
- Growth market conditions
- External issues the organization faces
- Challenges customers and suppliers contend with
- Longer-term product portfolio evolution

The strategic vision ensures that everyone from the top down asks the same question: “What supply chain capabilities are required, how must they fit together, and does each logistics component align with the guiding vision of the organization?”

The second part of the white-boarding process is to diagram the current supply chain from end to end, not simply the transportation of goods, but the flow of materials and data within the organization, both upstream from its suppliers and downstream to its customers, all the way to care providers and their patients. Almost without exception, this part of the white-boarding session uncovers logistics processes that are based on the organization’s history rather than its current reality or its strategic vision.



Part Two: Best Practices in the Global Supply Chain



This history-versus-strategy gap reveals a host of processes ripe for improvement in terms of greater agility, improved capabilities to adapt to market conditions, and closer alignment to the organization's vision for growth. Subsequently, in the third part of the white-boarding process, the partners begin to identify where short- and long-term changes can be made to inbound and outbound logistics in order to accomplish significant business improvements, which may include:

Overall

- Reduction of supply chain expenditures (inventory, transportation, warehousing)
- Regulatory compliance
- Reduction of product spoilage and perishable loss
- Improvement of asset utilization

Outbound

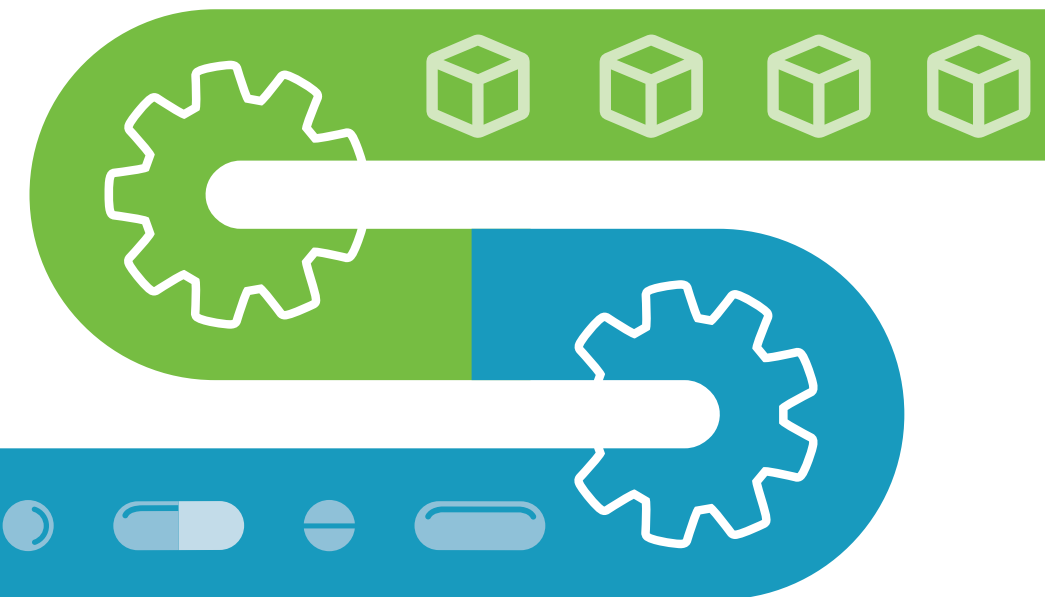
- Expansion of the width and depth of distribution within the company's home market and beyond its borders
- Growth of sales outside of the home market
- Improvement of customer service
- Improvement of on-time delivery
- Reduction of order-to-delivery cycle time, ultimately speeding up cash flow
- Reduction of lead time
- Reduction and rationalization of supplier base
- Improvement of the customer experience
- Maintenance of global branding consistency

Inbound

- Sourcing of materials and components with maximum efficiency
- Leveraging actionable supply chain data to help the inbound flow feed optimal production rates, preventing costly downtime or over production
- Effective management of inventory within the global network

What are some of the positive changes that must take place as the partners begin the alignment process in terms of the global supply chain? The following are examples of global supply chain best practices in the healthcare industry. Focus in these areas will maximize effective importing and exporting to drive improved top-line growth.

It should be noted that, while most of the best practices discussed are fundamental to import and export, many of the principles apply to the domestic supply chain as well. These focus areas also demonstrate why the selection of an experienced logistics partner with the right global resources is so important.



Managing suppliers

Importing quality, yet low-cost, components and products can reduce costs, but requires an active risk management focus. The potential for business disruption increases as a supply chain lengthens, and relying on outside parties for material mandates collaborative processes. The logistics partner can help manage these risks. The first best practice to adopt is using the provider's systems and tools to assess and manage foreign suppliers. Leading supply chain integrators have sophisticated tools to determine whether a potential supplier individual, company, or country is on the U.S. government denied-party list and therefore off limits. Denied-party screening requires real-time access to continually updated data from the U.S. Department of Commerce's Bureau of Industry and Security. Denied-party screening must also be performed when exporting.

Leading supply chain integrators have invested in import/export systems and tools that perform denied-party screening and a host of other validations and confirmations.

Utilizing these turnkey resources, many of which are provided at no additional charge, is a fundamental practice that helps to save time, resources, money, and potential legal entanglements.



Denied-party screening is just the start of trade-management solutions that a supply-chain integrator should be able to provide. The logistics partner may also help to appropriately classify products under the Harmonized Commodity Description and Coding System (HS)—the World Customs Organization standardized system for classifying traded products—for the most accurate tariff fees. Once the supplier has been screened and approved, and the products classified according to the HS guidelines, the company will need a system for ensuring appropriate labeling and documentation. For healthcare products where a typographical error or other non-conformance can hold up a shipment, proper labeling, documentation and reporting is vital.

The logistics partner may also be able to provide a solution for flagging over, short and damaged deliveries from suppliers before they ship internationally, to help ensure what was supposed to arrive is indeed shipped and labeled properly. This level of supplier management and oversight requires in-country distribution infrastructure. Some logistics companies lack their own integrated global networks, instead relying on an assortment of vendors and sub-contractors. It is important to understand where a logistics partner is utilizing its own network and where it is relying on outside parties. The optimum degree of control is to use distribution centers owned and operated directly by the logistics partner, thereby maximizing control over operations and integral compliance. It is worth noting that some logistics service providers don't even own or operate the healthcare distribution centers they market in the United States, much less internationally!

The right logistics partner can provide unique tools and resources to develop optimum packaging that both ensure product integrity (including thermal protection) while meeting the sustainability objective of a high product-to-package ratio. Ideally the package will consume minimum packaging material yet still protect the product. An effective logistics partner will also work to select the most effective and economical load per container or trailer. This means the highest density of product, safely packed, per available space. All of these steps will reduce costs in the supply chain.

Regulatory issues

Effective supply chain management demands active management of regulatory compliance when crossing borders. A study conducted by the United States Census Bureau found that about 37 percent of data records captured from paper customs entry forms and about eight percent of automated records contained errors.⁵ This exposes companies to both potential supply chain disruption and possible governmental penalties. The logistics partner should verify that the export license from the supplier is in compliance, and that all labeling is correct. Furthermore, before the shipment leaves the country the logistics partner must confirm that information required for import clearance is available to be appropriately filed with the destination country's authorities as specified by continually changing and evolving regulations, mandates, and laws.

Regulations are not static but in a constant state of flux. It is incumbent upon the logistics partner to stay at the forefront of the changing regulatory landscape in order to help to avoid surprises for a shipment. In the years following the terrorist attacks on 9/11, the U.S. issued at least four major pieces of legislation affecting import security, from the Homeland Security Act of 2002 to the Implementing Recommendations of the 9/11 Commission Act of 2007. Each of these, and the regulations that followed them, require precise understanding and compliance.⁶ Staying ahead of regulatory international trade compliance mandates is a major endeavor and parallels the requirement to stay ahead of healthcare-specific mandates. Companies need to comply with both of these distinct categories of oversight. By way of example, UPS operates the largest customs brokerage and trade management team in the third-party logistics (3PL) industry to ensure international trade compliance, while the UPS regulatory affairs quality assurance (RA/QA) team manages hundreds of geographically specific healthcare licenses and registrations. Both disciplines should be managed cohesively to support effective international healthcare operations.

This relationship is the cornerstone for a reliable conduit, in which shipments cross borders seamlessly and arrive intact where and when expected for the best patient outcome, also delivering maximum operational efficiencies and, most importantly, a supply chain that fulfills a defined business strategy.

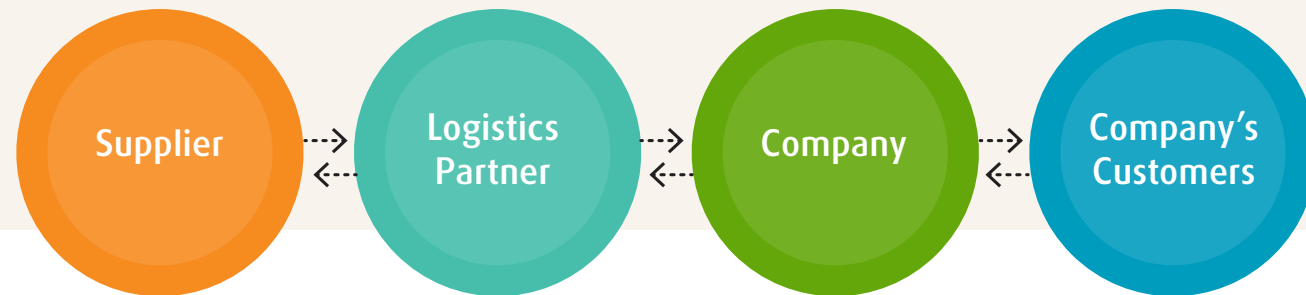
9 percent of electronically filed customs import forms have at least one regulatory compliance error.



The proper flow of information is essential

White-boarding sessions should not focus narrowly on the movement of physical goods—but should also encompass the flow of information, both inside and outside the enterprise.

Effective information flow requires tight integration and collaborative data-sharing by all parties associated with the supply chain:



Furthermore, detailed and verified data communication is a growing requirement with such governmental organizations as the U.S. Department of Homeland Security, U.S. Customs and Border Protection, FDA, DEA, and their international equivalents.

The benefits of inclusive, cohesive information management are profound, including greater agility in the disposition of inventory, faster reaction to changing market conditions, improvement to customer care through detailed product availability and status information, ready access to regulatory and quality assurance documentation, and improved cash flow through faster billing and invoicing.

Both import and export operations require focused information management in the following areas:



- Denied-party screening
- Harmonized code management
- Export license management
- Landed cost calculation
- Trade documents and forms
- Shipment management
- Purchase order and supplier management
- Import compliance filings
- Product quality assurance documentation
- Regulatory compliance records
- Shipment visibility
- Inventory management
- Order processing, fulfillment, and payment reconciliation

Discrete systems must share data for maximum visibility into the supply chain.

Information should be managed electronically to reduce re-keying errors and provide ubiquitous availability to all stakeholders as needed. Only then will agility and the capability to adapt to up-to-the-minute conditions be possible. Furthermore, in all international transactions, the ability to get paid directly depends on the ability to exchange information in an accurate and timely way. Companies are increasingly being required to file invoice and reimbursement information electronically.



Going international—start with Free Trade countries

By Joey C. Rosenberg, U.S. International Marketing Analyst, UPS

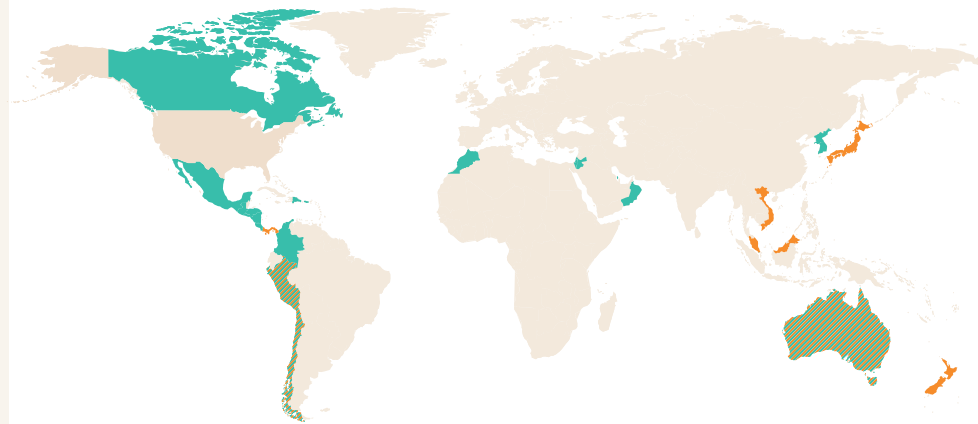
In 2012, the U.S.-South Korea agreement (KORUS) went into effect, as the first Free Trade Agreement (FTA) between the United States and a major Asian trading partner. Korea ranks seventh in overall trade with the U.S.

KORUS will eliminate 95 percent of tariffs within five years* and the U.S. International Trade Commission estimates that more than \$10 billion annually in new U.S. goods will be exported. KORUS will also open Korea's \$580 billion services market to highly competitive American companies in sectors ranging from delivery and telecommunications services to education and healthcare.

Korea is only one of 19 FTA countries available for import and export. Additional countries are on the docket for inclusion. For pharmaceutical and medical device manufacturers that want to spur top-line growth through import and export, FTA countries can be excellent places to begin developing expertise in international trade. If a company has already started the international journey, then these countries form a pool of markets in which to expand.

Fundamentally, FTAs make it easier and lower costs and risk to do business with a partnering country. These benefits include:

- The reduction or elimination of tariffs—saving the company money and positioning it for improved competitiveness
- The reduction or elimination of sales quotas for improved growth potential
- Intellectual property rights protection
- Increased transparency in the legal system
- The removal of barriers for service providers
- Improved customs experience



Current free trade countries:

- Australia
- Bahrain
- Canada
- Chile
- Colombia
- Costa Rica
- Dominican Republic
- El Salvador
- Guatemala
- Honduras
- Israel
- Jordan
- Korea
- Mexico
- Morocco
- Nicaragua
- Oman
- Panama
- Peru
- Singapore

FTA in progress:

Trans-Pacific Partnership (TPP) Agreement includes:

- Australia
- Brunei Darussalam
- Chile
- Japan
- Malaysia
- New Zealand
- Peru
- Singapore
- Vietnam

UPS offers a wealth of informational and consultative services for pharmaceutical and medical device manufacturers considering trade with FTA countries.

Go to global.ups.com to request more information. Visitors to this website will find vital information on navigating the complexities of global trade, including online tools for tracking, visibility, and automated shipment processing. It also contains a resource library and information on the joint effort between UPS and U.S. Commercial Service, an agency of the U.S. Department of Commerce that helps companies grow export sales.

Product control

Industry estimates indicate that, by 2016, eight out of ten of the top pharmaceuticals sold globally are going to require temperature-control management.⁷ Furthermore, the rapid growth in temperature-sensitive products within medical device portfolios will continue. For some classes of biological products, a two-degree Celsius variation in temperature can mean an entire lot will have to be discarded—a costly outcome in terms of inventory management, documentation, and customer experience, with the potential to adversely impact patient treatment. Warehouses, trucks, aircraft, and cargo containers are all locations where exact and best-in-class product control are demanded. Add the complications inherent in cross-border operations, and the complexity of product control grows exponentially. Best-in-class performance demands unparalleled monitoring, control and intervention infrastructure on the part of the logistics partner to protect expensive pharmaceuticals and devices, ensuring they are as potent when they are administered to a patient as they were when they were produced.

Supply chain disruptions can arise from myriad natural and man-made calamities. From volcanic eruptions to floods, hurricanes, snowstorms, power outages and civil unrest, the logistics partner must be agile in terms of overcoming the unforeseen. The key to counter such disruptions is to actually plan for them. Failure to plan equates to a plan to fail, and this is undoubtedly true in global supply chain management. But planning is half the battle; the other half can't be neglected either—the infrastructure and agility to respond to forces of nature or man-made events must not only be maintained to be called upon at a moment's notice, but also must continually be enhanced and improved through ongoing investment. It is important to know when to trigger business continuity plans, while there is still time to act. The only way to do that is to have real-time knowledge of where the shipment is—its disposition and status. Critically important, the logistics partner should have the demonstrated ability and resources to intervene and redirect the shipment according to the contingency plan. For more complete analysis of the issues in product control, download the current Healthcare Supply Chain Serialization Playbook by *Healthcare Packaging* magazine. www.healthcarepackaging.com/playbook/supplychain

Industry estimates indicate that, by 2016, eight of the top ten global best-selling drugs will require cold-chain handling.⁷



*United States International Trade Commission Congressional Research Services: The U.S.-South Korea Free Trade Agreement (KORUS FTA): Provisions and Implications



Best practice outcomes in the supply chain

The supply chain management fundamentals outlined in this white paper can lead to significant business growth and margin performance. These practices and methodologies give pharmaceutical and medical device manufacturers tactics to utilize in penetrating new markets. This can result in new top-line revenue in high-opportunity, high-growth developing economies. Effective international sourcing can also improve the organization's bottom line through operational efficiency, better economies of scale and cost-containment improvements. Medical materials and data will flow much more effectively by implementing improvements targeted during consultative white-boarding sessions. Through the application of best practices in the global supply chain, the organization becomes more agile and adaptable than ever before, while the entire supply chain is focused on achieving corporate strategic objectives. Pharmaceutical and medical-device manufacturers' products will be protected and profitably delivered to expanding middle classes around the world. Top-line growth creates the wherewithal to invest in the future. And it all starts with vision and the realization that global end-to-end supply chains are strategic for the healthcare industry.

We look forward to continuing this conversation on better ways to protect product integrity. In the meantime, you can visit ups.com/healthcare to learn more about our products or contact us to discuss how UPS can help design distribution, transportation, packaging, and monitoring and intervention solutions to protect your temperature-sensitive products.

Citations

- 1: "U.S. Merchandise Trade Statistics, A Quality Profile": Methods Research & Quality Assurance Branch, Foreign Trade Division, Bureau of the Census
- 2: Congressional Research Service: U.S. Customs and Border Protection: Trade Facilitation, Enforcement, and Security. (2013)
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- 7: Biopharma Cold Chain Sourcebook, 2014

About the author

Scott Szwest is a 24-year veteran in the global logistics industry and currently serves as a marketing director for UPS's South Atlantic District, which encompasses Georgia, North Carolina, and South Carolina.

Szwest directs a team responsible for marketing UPS's portfolio of best-in-class logistics and transportation solutions to serve the unique needs of customers in specific market segments. He is focused on leveraging UPS networks, facilities, technology, and expertise in regulatory compliance to enable customer growth.

Since joining UPS in 2000 as an e-commerce product manager, Szwest has shifted to industry-specific marketing emphasis for retail and consumer goods, high-tech, industrial manufacturing and automotive and government segments. His knowledge and differentiation of sector needs has contributed to UPS strategy for configured solutions that leverage UPS package and freight transportation expertise with value-added services and distribution facility infrastructure.

Prior to his segment marketing role, Szwest worked to position UPS international freight forwarding portfolio of services, directing a team aligning global enterprise resources for ocean freight, brokerage and a suite of global supplier management services for end-to-end alignment of order management through production scheduling, consolidation, export, transportation and expedited customs clearance for delivery.

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by Scott Szwest

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