

U.S. Pharmaceutical and Medical Device Manufacturer Supply Chain Efficiencies

Trends and Opportunities

It's an interesting time for U.S. manufacturers of pharmaceuticals and medical devices. Several significant trends have caused manufacturers to retool supply chain practices to reflect an industry that has become global in nature, more regulated than ever, and more responsive to changing customer preferences.

- **Regulatory Issues:** New and ever-changing regulatory and legislative mandates are the top supply chain concern for most healthcare executives. Manufacturers that ship to Canada face regulatory requirements from a multitude of sources. The U.S. Food and Drug Administration, U.S. Customs Border Protection, and the U.S. Census Bureau, along with Health Canada and the Canada Border Services Agency, are just some of the agencies with jurisdiction over the cross-border process. Manufacturers must obtain proper permits, meet labeling requirements, pay all appropriate duties and taxes, file all necessary paperwork, and meet stringent supply chain security standards.
- **Demographic Factors:** According to research published in the International Journal of Epidemiology, the number of Americans aged 85 or over, the group most likely to need long-term healthcare services, is expected to increase by 350 percent during the 2000-2050 period. The surge in demand has led to a fundamental change in the manner in which patients receive services in all venues – private homes, community centers, retirement homes, retail stores, mobile clinics, urgent care clinics, and physicians' offices. The aging of the population has increased demand worldwide for pharmaceuticals and medical devices.
- **Increased Product Lines:** Increasingly complex products and diverse consumer preferences have resulted in a typical plant handling double the amount of SKUs it processed 10 years ago. There has also been a dramatic increase in the number of medicines requiring refrigeration and associated special handling. Spending on "cold chain" logistics – the distribution necessary to transport biologically originating drugs – will increase to \$9.3 billion by 2017, a 20 percent increase over 2013 levels.
- **Surge in Generic Drugs:** During 2012, generic drugs accounted for roughly 84 percent of the world's prescription drugs. This has been primarily the result of a "patent cliff" that has taken hold in the pharmaceutical world, marked by the expiration of patents for some of the world's best-selling, and most profitable medicines. The trend is expected to continue through 2018.
- **Supply Chain Security:** Although medicines and medical devices are among the most regulated products in the world, they are top targets for counterfeiters. This is because fake products can be produced at a relatively low cost and because lax standards in many developing countries allow relatively easy entry to many consumer markets. Counterfeit drugs are a \$35-\$40 billion per year industry and can be found worldwide. Counterfeits pose a tremendous risk to public safety, and eliminating counterfeiting risk from the supply chain is a top priority for manufacturers, regulators, and law enforcement officials worldwide.



In a recent survey, North American healthcare executives cited regulatory compliance, managing costs, and product security as top supply chain issues.

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- **Product Returns:** Pharmaceutical returns must follow a very careful reverse logistics course, usually ending in product destruction. During 2013, the FDA issued a record 1,225 product recalls and was on track to surpass that number during 2014. Manufacturers must contend with as much as \$4.2 billion annually in expired products that must be collected and properly disposed of.

Supply Chain Solutions

Choosing the right logistics provider is critically important and requires a fair amount of research. Among the top things to consider is selecting a logistics provider that can handle the unique needs of pharmaceutical/medical device products. Other considerations include the following:

- Experience
 - Flexibility
 - Employee Training
 - Customer Service
 - Customs Experience
 - Scope of Service
 - Specialized Equipment
 - Canadian Distribution Network
 - Familiarity with Canadian Market
- **Processing and Distribution Efficiency:** Processing, warehousing, and distribution of healthcare products naturally trigger very specific – and often mandated – requirements that demand specialization, a highly trained workforce, and a technology component that links all parts and ensures efficiency.
 - **Warehousing.** Any warehouse that services pharmaceuticals and/or medical devices needs the capabilities required for managing temperature-dependent, time-critical, highly regulated products.
 - **Security:** State-of-the-art warehouses include vaults with motion detector alarms or electronic security systems that require employees to swipe an identification card to gain access to areas where narcotics or expensive devices are stored.
 - **Temperature Control.** Warehouses – and trucks – are now equipped with technology-controlled refrigeration systems that continually monitor product temperature and trigger alarms should fluctuation occur.

Transportation Solutions

- **Expedited Services:** Since few shipments require the care and attention – or regulatory control – inherent to pharmaceuticals, it's not surprising then that expedited service is an increasingly preferred logistics option. Expedited services, while more costly, offer premium levels of processing and customer service, along with care for temperature-sensitive products, high levels of security, guaranteed delivery times, and high-quality last-mile service.
- **Consolidation is King:** Shipments that may not need the "Rolls-Royce touch" inherent to expedited service can benefit from a more efficient LTL experience, namely, through consolidation.
- **Route Optimization:** Among the many positive contributions technology has made to the freight/logistics industry, the concept of route optimization has been among the most beneficial. Route optimization software helps companies better manage their distribution networks through the use of advanced algorithms. The process calculates the most efficient service option, maps out direct routes, and matches available trucks and drivers to make the delivery.

To learn more about these and other supply chain innovations, visit www.purolatorinternational.com/whitepapers to download Purolator International's white paper: *U.S. Pharmaceutical and Medical Device Manufacturers: Supply Chain Trends and Canadian Cross-Border Efficiencies*.