

In-Source or Outsource?

Creating and Operating a Cold Storage and Logistics Facility

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Facing an increasingly competitive global marketplace, biopharmaceutical firms are under extreme pressure to get drugs to market faster as well as cost-effectively. In the quest to find greater business efficiencies, many compare the benefits of outsourcing or in-sourcing core functions such as storage and logistics. Building and operating a cold storage and logistics facility is a complex, high-risk proposition that warrants deeper reflection than is usually included in cost-benefit analysis alone.

As part of the decision-making process, organizations must assess associated expenditures, planning aspects, facility assets, staffing requirements, technologies, and quality systems needed to build, manage, and maintain a secure, fully validated facility that complies with applicable industry standards and regulations. Baseline requirements for designing, constructing, and operating a warehouse and logistics hub that is compliant and secure for temperature-sensitive biopharmaceutical products include both capital investments and site selection matters.

Upfront Capital Investments: Owning and operating a stable cold chain logistics center is a capital-intensive undertaking that requires significant upfront investments in advanced features such as high-level security, temperature-monitoring technologies and temperature-control systems, and back-up power generators to preserve and protect product integrity.

Initial expenses for building and outfitting such a specialized facility include buying land, designing and building a structure, and purchasing all indispensable depreciable equipment. Although property, materials, and labor values vary across the



globe, a company should be prepared to spend \$6,000,000--\$9,000,000 for a 50,000-ft² facility. Would those financial resources be better spent in the research and development, new business development initiatives, and/or establishing strategic alliances that drive revenue?

STRATEGIC SITE SELECTION

Geography plays a significant role in the success of any business—especially a biopharmaceutical storage and logistics center. To strategically select a site that can support your facility today and scale to meet tomorrow's demands, you should investigate several elements before choosing a location. These include transportation and utilities infrastructure; business climate and foreign trade zone (FTZ) status; and available personnel and expertise in such areas as validation, project management, and regulatory compliance.

Robust Transportation Infrastructure: Choosing a site within a well-developed transportation system is crucial to logistics. Companies can save time and reduce costs by select-

ing a site with many diverse modes of shipping and distribution. An ideal location includes easy access to an international airport, multiple interstates/highways, marine ports, and railroads as well as a diverse network of shipping providers such as ground transporters, freight forwarders, custom couriers, and integrated service providers such as FedEx (www.fedex.com), United Parcel Service (www.ups.com), and DHL International (www.dhl.com).

FTZ Designation: Free zones (foreign trade zones in the United States) are ports with relaxed jurisdiction regarding trade, where imported goods can be stored and processed duty-free. Facilities located in an official FTZ offer a number of inherent advantages to international companies doing business in the United States (Table 1). FTZ status can significantly reduce US customs duties, inventory taxes, and brokerage fees as well as shorten supply-chain wait times by eliminating delays that can occur during customs clearance. For example, international companies that use

FTZ methods to export to the United States can save up to 90% annually, depending on the frequency of shipments (1).

Reliable Utilities: It is important to determine whether local utilities provide reliable, clean power and are robust enough to support a large power user. Gauging the amount of energy required to sustain your facility in advance is wise, as is finding a location that pulls its energy from more than one power source. To protect against prolonged outages, buildings should be wired with back-up electricity from different power grids and linked to additional back-up power sources. Special agreements can be arranged with utility companies for peak and off-peak use, which could prove to be a significant source of savings.

Fervent Business Climate: A thorough evaluation of the local business climate is fundamental to the long-term viability of a biopharmaceutical logistics center. Is the area thriving or deteriorating economically? Are any tax incentives or economic development funds available to companies in the biotech/life-science industry? Understanding the local business environment can help forecast future business opportunities as well as predict potential economic declines.

Case in Point: Sentry Logistic Solutions selected its five-acre parcel of land in Indianapolis, IN, after thorough analysis of several factors. Centrally located in the heart of the midwest, the city is within a half day's drive of more than 20 major metropolitan markets. In fact, more national highways intersect Indianapolis than any other metropolis in the country. About 75% of the US and Canadian population can be reached within a one-day truck drive from the region (2). Another major reason we selected Indianapolis as our base of operations is its close proximity to the second largest FedEx hub in the United States as well as the Indianapolis International Airport, which transports more than a million cargo packages

Table 1: Benefits of foreign trade zone designation – savings of \$226,980 (custom fee = merchandise processing fee per shipment charged by US customs)

	Shipment Value	Customs Fee	Shipments/ Week	Total Cost/ Week	Annual Cost
No FTZ Access	\$230,000+	\$485	10	\$4,850	\$252,200
With FTZ Access	\$230,000+	\$485	1*	\$485	\$25,220

*No matter how many shipments per week, merchandise processing fee is charged only once.

every year. The airport also provides ideal distribution advantages to manufacturers and cargo and freight forwarders as well as companies with stringent shipping and receiving requirements.

Site Selection magazine recently ranked Indiana sixth among the nation's best business environments, moving up from tenth place in 2002 (3). Companies conducting business there benefit from lower than average state business taxes and the second lowest electricity costs in the United States (4).

SPECIAL EXPERTISE

Validation Processes: Once the right location has been identified and assets are purchased, all systems and equipment must be properly validated and maintained. These include advanced freezer and refrigeration systems, sophisticated temperature-monitoring systems, smoke detection and fire suppression systems, highly-redundant power and cooling systems, and on-site and off-site data back-up and data security systems in addition to the physical building security.

To sustain those critical assets, organizations must have the expertise and available resources to calibrate, validate, maintain, and test them routinely to make certain they are working properly even in the event of power loss, natural disaster, emergency situations, and/or security risk. Validation processes are intricate and can take months depending upon the complexity of the systems. Is your company prepared to dedicate qualified personnel, time, and financial investment to guarantee that its facility will consistently pass audits and inspections well into the future?

Planning and Project Management Expertise: Facility design and construction processes may take longer than planned due to delays in obtaining required permits, securing appropriate zoning, finding qualified contractors, sourcing supplies, and validating equipment. For example, to obtain the appropriate property insurance coverage, buildings must demonstrate superior construction and meet other specific requirements outlined by insurers. Does your organization have the necessary resources in place (employees, vendors, industry relationships, governmental connections) to secure timely and cost-effective completion of its facility?

Qualified Employees: Finding the right team with the appropriate experience, certifications and familiarity with current industry best practices can be an arduous task. Bear in mind the diverse functional expertise it takes to operate a 24-hours-a-day, seven-days-a-week global biopharmaceutical supply chain. This requires personnel with a solid background in cold chain storage and logistics, biopharmaceutical manufacturing, quality assurance, commissioning, qualification and validation, packaging and kitting development services. Does your current team meet these criteria? What is the quality of the potential workforce in the area? Do nearby universities and technical institutes offer strong degree programs, certifications, and continuing education that prepare prospective employees for the logistics and/or biopharmaceutical fields?

The caliber of the existing and future labor forces can help or hinder a company's growth and expansion. With intense pressure to launch new

drug products, you need employees who are well equipped to handle the nuances of pharmaceutical commercialization.

However, be prepared to pay a premium for those with the right qualifications. According to the Bureau of Labor and Statistics, companies will fight over the best and brightest candidates in the near future—based on projections that the biopharmaceutical industry will demand more workers than are currently enrolled in training programs. Additionally, over 60% of those working in biotechnology hold a bachelor, master, professional, or doctorate degree, twice the proportion for all other industries combined (5). Therefore, earnings for employees in the biopharmaceutical industry are much higher than other manufacturing industries. Can you afford to recruit and retain top talent to ensure your cold chain logistics center functions professionally and profitably, meets regulatory compliance requirements, and safeguards your products?

Case in Point: Life science jobs pay an average of \$65,775/year nationally, compared with \$39,003 in the overall private sector (6). The Indianapolis-area pharmaceutical industry employs nearly 15,000 people at an average salary of \$94,629, roughly three times the state's average wage of \$33,000 (7). Even if a company chooses to pay more for qualified employees, Indiana supports those companies' long-term business needs through its concentrated investment in life science incubators, a thriving life science business community, and university training programs.

TECHNOLOGY AND REGULATION

Building and operating a world-class biopharmaceutical storage and logistics center requires significant investment in technology. This includes buying and maintaining systems that regulate temperature-controlled materials and warehouse operations. Because of the temperature and time sensitivity of biologic products, "smart" inventory

control is necessary to capture information on the original source of the product, history of transactions, life-cycle ownerships, and certification of transaction authenticity — otherwise known as a drug's pedigree.

A hefty investment in technology is not only essential for inventory management and pedigree, but also for other aspects of regulatory compliance. Sophisticated logistics and product-tracking technologies such as enterprise resource planning (ERP) software, document management systems, and bar-coding are needed to provide a complete history of the handling, status, transfer, and overall management of biopharmaceutical products. Such systems must be evaluated, purchased, installed, maintained, and upgraded often to maintain compliance.

Currently, there is no single industry-standard software package that satisfies tracking requirements for storage of biopharmaceuticals. As a result, most companies use multiple software packages simultaneously to manage different aspects of their cold chain processes. Therefore, staff must be familiar with each system and create contingency plans in case of technological error or failure.

With mounting concerns about drug counterfeiting and brand security, pharmaceutical manufacturers are constantly looking for ways to improve inventory management, visibility, and control. RFID (radio frequency identification) is being tested to serve in this capacity, but its application for the biopharmaceutical industry is still mostly conceptual. Although many people anticipate its future proliferation, an industry standard has yet to emerge. Can your organization afford to invest in such technologies that function adequately today but may quickly become obsolete as new regulatory mandates are put in place?

Regulatory Compliance: Meeting the standards of a regulated industry adds numerous levels of operational complexities to building and managing a biopharmaceutical storage and

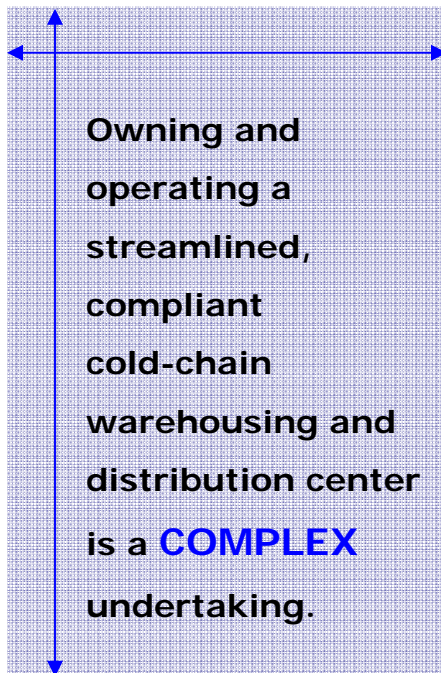
logistics center. Facilities, systems, and methodologies must be compliant with applicable industry regulations including 21 CFR Part 11 and good manufacturing practice (GMPs) as well as guidelines provided by the US Drug Enforcement Administration (DEA, www.usdoj.gov/dea) and Department of Health and Human Services (www.hhs.gov).

Establishing standard operating procedures (SOPs) in addition to training staff throughout the facility and across all functions ensures proper compliance with the way materials should be stored and shipped. This also means constantly being prepared for third-party audits and inspections. Keeping up with the various domestic regulations outlined by the FDA, DEA, and other US regulatory agencies can be a daunting task in itself. For companies doing business internationally, it is even more complex. Each country has its own body of rules and mandates that govern the shipping and handling procedures of pharmaceutical and biopharmaceutical products. Failing to observe these diverse regulations can result in customs delays and jeopardized product integrity, which could lead to financial loss. Does your organization have extensive international experience and an understanding of current worldwide cold-chain practices and guidelines to make sure products reach their intended destinations on time and in optimal condition?

DISASTER RECOVERY

Unforeseen crises that disrupt operations not only have grave financial consequences, but they can lead to widespread customer disappointment and brand erosion. Proactive contingency planning can go a long way toward mitigating risks and safeguarding the integrity of regulated products.

Planning for the unexpected requires myriad scales of redundancy across all functions of a biopharmaceutical storage and logistics center including power, cooling, equipment, data recovery, and security. To make



certain the facility can continue operating during an emergency situation, routine weekly tests of all back-up systems and periodic full-scale risk assessments are encouraged. A transition plan for moving stored products to a contingent facility is also highly recommended. Does your organization have the resources to design and test a recovery and business continuity plan to minimize the potential impact and eliminate the chances of a devastating loss in the event of an extended outage or other disaster situation?

Case in Point: Joining forces with another logistics or distribution center in your region can prove beneficial in the face of disaster. For example, our company and BioStorage Technologies (www.biostorage.com) – which is also located in Indianapolis and provides biomaterial sample and specimen storage, shipping, and logistics services – have a reciprocal agreement in case an unforeseen catastrophe plagues either one. Together, the two entities help protect each other's best interests and their clients' valuable assets from crisis.

A BIG DECISION

Companies across all industries grapple with the decision of whether to in-source or outsource an array of core business functions. For the biotechnology and pharmaceutical sectors, these choices are a matter of long-term survival.

Drug companies are experiencing more pressure than ever before: to launch new products frequently in a highly competitive marketplace, to meet the demands of an international customer base, to comply with stringent industry regulations, and to generate bottom-line results. A stable, efficient, and cost-effective supply chain is critical to addressing each of these challenges. So a pharmaceutical company's storage and logistics functions are prime targets for outsourcing.

Owning and operating a streamlined, compliant cold-chain warehousing and distribution center is a complex undertaking. It entails long-term financial resources, a strategic location, ongoing validation, expert management, a sustainable pool of qualified employees, investments in technology, an intimate understanding of worldwide industry regulations, and continuously updated contingency plans.

In-sourcing the cold-chain storage and logistics functions (and all associated infrastructure and personnel) may seem convenient and sound like a good investment over the short-term. But it may become an overwhelming, high-risk, and expensive burden in the long run. Choosing between in-sourcing and outsourcing is not exclusively a financial decision; it should be based on business priorities and functional expertise.

Ask yourself the following questions to help determine which option makes sense for your organization:

- Is our organization a qualified

expert in pharmaceutical and/or biotechnology product development or cold-chain logistics?

- Where are our resources (financial and human capital) best allocated: in creating new products or moving them through the supply chain?
- What risks would we incur by in-sourcing?
- What benefits could we gain by outsourcing?

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