



## Cold Comfort – In Short Supply, WDSrx Partners With Pharmaceutical Client To Create Cold-Chain Capacity



### Introduction

Companies manufacturing pharmaceutical products requiring cold-chain storage at refrigerated or frozen temperatures are facing a scarcity of regulatory-compliant capacity meeting industry standards.

### Challenge

The client, one of the world's largest solution providers in the design, development and manufacturing of

auto-injectors and pen injectors routinely supports pharmaceutical products with instructions for storage at temperatures between 2-8 degrees Celsius. A growing quantity of drugs must be stored and transported within specific temperature ranges to maintain ingredient integrity and potency. Failure to maintain appropriate conditions at any point in the supply chain can harm the efficacy of the drug resulting in the loss of a shipment that may put patients at risk.

When the client developed the project scope, an initial meeting was scheduled to outline expectations. The goal was to develop a solution with WDSrx for the new auto-injector product. According to WDSrx President Adam Runsdorf, “Communication at this preliminary stage was key to explore relevant options to be implemented within the desired timeline.”

## Solution

The guidelines established by the client included multiple objectives to determine program success. Among the desired outcomes were: the availability at reasonable cost of dedicated refrigerated capacity near the point of manufacture; licensing and authorizations from regulatory authorities to be active upon initial product delivery; a labor force with relevant training, skills and in sufficient supply for ongoing program management; flexibility to quickly scale operations to match demand.

It became apparent after initial review that the optimal solution would require additional refrigeration capacity that did not currently exist. A bold strategy was implemented that required both management teams to work closely together to achieve program goals.

As an experienced pharmaceutical logistics services provider, WDSrx utilized their industry expertise to plan, construct and operate a new refrigeration unit that would be constructed within one of their warehouse facilities close to the client’s operations. With active licenses to operate in all 50 states, current documentation satisfied regulatory requirements. The 2,500 square foot unit would be purpose-built for refrigerated cold-chain products stored at a temperature range between 2-8 degrees Celsius. With a capacity of approximately 240 pallet positions, the space would satisfy initial storage needs and anticipate future growth.

An innovative partnership was developed to accelerate the project. WDSrx agreed to finance the entire project and enable the client to contribute to total cost over an extended period of time. This arrangement was designed to address client budget constraints and develop a long-term relationship for cold-chain opportunities.

## Results

Early collaboration between client and logistics services provider resulted in an agreement that successfully addressed key project objectives.

A bold solution approved the construction of additional cold-chain capacity in a preferred location close to the client business. With initial construction costs paid by WDSrx, the client was relieved of a significant capital expenditure, build-out was able to begin immediately and the refrigeration unit was completed on schedule.

The initial product delivery from the client to WDSrx was received within six months of construction start.

In anticipation of increasing cold-chain demand from the client, WDSrx also arranged for priority storage privileges based on available space within the refrigeration unit.

## Conclusion

A large manufacturer of auto-injectors and pen injectors searching for a regulatory compliant refrigerated environment developed a solution with WDSrx to custom build a refrigeration unit to store temperature-sensitive medication.

The strategy achieved project objectives specified during initial leadership meetings:

According to the Director of the client company, “We work with partners who add expertise and value that help us deliver our products safely and efficiently to patients. WDSrx promotes a culture of collaboration and innovation with solutions that achieve our goals and exceed expectations.”

Adds WDSrx President Adam Runsdorf, “It is an important priority for WDSrx to establish end-to-end solutions with clients to streamline the supply chain between treatments and patients.”

## Expertise

The addition of refrigerated cold-chain storage space to meet the needs of a client with a new product requiring special handling within 2-8 degrees Celsius was made possible with multiple logistics services

provided by WDSrx:

**Project Management** – From thoughtful assessment of initial project scope to program development and ongoing implementation, WDSrx has vast practical expertise in multiple disciplines to assure client success.

**Financial Services** – In addition to order-to-cash management, WDSrx works with clients by recommending available financial options to support business objectives.

**Warehousing and Fulfillment** – Facilities in seven States are licensed by regulatory authorities for prescription pharmaceutical drug products, over-the-counter medications, dietary supplements, nutritional foods, animal health and personal care products and related categories.

**Transportation Services** – As an independent logistics services provider, WDSrx selects solutions from among several trusted transportation partners that address each client's specific requirements for safety, cost, mode and speed.

**Packaging and Labeling** – Dedicated production suites with trained technicians handle a variety of projects including medical device assembly, kitting, clinical trial randomization, solid and liquid dosage primary and secondary packaging.

**Regulatory Compliance** – WDSrx is authorized by the U.S. Drug Enforcement Agency (DEA) as an Importer and Exporter for handling of Controlled Substances (Schedules CII-CV) and all facilities are State licensed nationally to operate throughout the country and internationally. All facilities are DSCSA-compliant and follow guidelines for the distribution of pharmaceuticals established by the Federal Code of Regulations 21 CFR 210/211.

**Specialized Handling** – Additional regulations and procedures must be followed to assure the integrity of pharmaceutical drug products requiring temperature-regulated environments including refrigerated and chilled (2-8 degrees Celsius), frozen (-20 degrees Celsius) and deep frozen (-85 degrees Celsius) medications.

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Reference: