**West** ♦
**Contract
Manufacturing**

# Integrated Solutions for Cold Chain Pharmaceuticals

## Helping to Make Cold Storage Less Complicated

Patient safety is of utmost concern in the pharmaceutical industry, with the FDA requiring drug manufacturers and their manufacturing partners to have strong quality management systems.

Temperature-sensitive drugs require storage solutions that not only meet the needs of the drug product, but also ensure compliance with regulatory guidelines in a properly monitored and sustained environment. Any deviation from the ideal environment can affect patient safety and jeopardize the drug's quality, resulting in loss of potency, efficacy or even the need to discard the product entirely.

Drug products such as biologics, vaccines, and products whose chemical and physio-chemical stability depends on temperature put an added emphasis on pharmaceutical manufacturers to ensure proper handling, storage, transportation and dispensing.

The West Contract Manufacturing team can support integrated device assembly solutions that meet regulatory and U.S. Food and Drug Administration guidance for temperature sensitive drug handling. This can help simplify the supply chain and reduce overall risk by improving production efficiencies.

### West offers:

**Clinical support**

- Scalable solutions that support commercialization

**Drug re-packaging**

- Infrastructure to accommodate low to mid volume applications
- Cold chain services for drug stability
- Experience and capability specific to high-volume applications

**Serialization/Track and Trace**

- UDI, sNDC, Custom Serialization
- Aggregation
- MES infrastructure
- Work cell history and analytics

As one of the largest custom manufacturers of reusable pens and auto injectors, the West Contract Manufacturing team can provide proper cold chain solutions – helping to ensure that temperature sensitive drugs are delivered to the patients who need them without compromising the integrity, efficacy, safety or security of the drug.

For more information visit **www.westpharma.com**