Cold Chain and vaccine handling

The Center for Disease Control (CDC) has published two documents in the past seven years aimed at vaccine storage and handling (*Vaccine Storage & Handling Toolkit, 2012* which replaced *Vaccine Management: Recommendations for Storage and Handling of Selected Biologicals*, *November 2007*). The *Vaccine Storage & Handling Toolkit* provides best practices and guidance as the approved standard of care for all public and private sector providers; therefore, the focus of the content is for healthcare providers. The process for cold chain packaging, storage and handling of refrigerated pharmaceuticals that Cardinal Health utilizes either meets or exceeds the guidelines set forth by the CDC for vaccines.

1. Cardinal Health only uses commercial refrigeration units that are temperature mapped, alarmed and monitored with National Institute of Standards and Technology (NIST) calibrated devices.

2. Cardinal Health utilizes a qualified refrigerated tote delivery system to maintain refrigerated pharmaceuticals at the labeled storage range of 2-8°C (36-46°F). This cold chain packaging maintains a 2-8°C environment regardless of the season or geography and regardless of the amount of product shipped, from a single vial to a full tote. Redundant environmental laboratory testing was conducted following industry acknowledged and accepted engineering test standards utilizing industry recognized winter and summer temperature profiles.

3. The Cardinal Health qualified refrigerated tote delivery system utilizes phase change material as opposed to the industry standard frozen, water-based gel-packs. This phase change system was design specifically to maintain a 2-8°C environment regardless of the season or geography and regardless of the amount of product shipped, from a single vial to a full tote. Redundant environmental laboratory testing was conducted following industry acknowledged and accepted engineering test standards utilizing industry recognized winter and summer temperature profiles.

   The phase change material used by Cardinal Health is safe and non-toxic, bio-friendly, biodegradable, made of 100 percent renewable resources (plant-based oils and fatty acids) and approved by the U.S. Department of Agriculture (USDA) as a bio-preferred product.

4. Phase change material is ideal to protect product from freezing since the phase change material next to the product freezes at 4°C (39°F), thus protecting the product from going below 2°C (36°F). Freezing, which is a risk with traditional frozen, water-based gel-packs, may reduce efficacy, potency or expiry, especially with vaccines.

5. Cardinal Health does not utilize portable temperature indicators in the cold chain totes or other coolers because the cold chain packaging system is qualified. Therefore, temperature indicators are not necessary. Portable monitoring devices can be problematic due to inaccuracies involving the type of monitoring device / temperature indicators, calibration, and placement. Additionally, typical temperature indicators used for vaccine shipments do not indicate excursions outside of 2-8°C (36-46°F), rather excursions below 1°C (34°F) or above 15°C (59°F) for a defined time period, which is helpful for non-qualified packaging; however, unnecessary for qualified packaging.

Leading the industry in refrigerated pharmaceutical packaging

Cardinal Health has been recognized by the Healthcare Distribution Management Association (HDMA) with the 2012 HDMA Distribution Management Award and was honored by the Council of Supply Chain Management Professionals (CSCMP) with the 2012 Supply Chain Innovation Award (2nd Place) for innovative cold chain packaging system for refrigerated pharmaceuticals.

Cardinal Health was also a contributing author on the Parenteral Drug Association's task force for PDA's Technical Report 46 *Last Mile: Guidance for Good Distribution Practices for Pharmaceutical Products to the End User* (2009).

Cardinal Health is subject to laws, rules and standards and provides training, internal auditing, and receives routine federal FDA, state board of pharmacy and drug manufacturer audits reviewing compliance to include cold chain. Cardinal Health is regulated by the FDA - 21 CFR Part 203, Prescription Drug Marketing Act (PDMA) and Part 205, Guideline for

State Licensing of Wholesale Prescription Drug Distributors; state drug wholesale licensing entities (e.g., state boards of pharmacy). Cardinal Health reviews industry guidance for testing and qualification of cold chain systems related to refrigerated storage and packaging. Some of these guidelines include, but are not limited to: USP (United States Pharmacopeia) - General Guidance Chapter 1079, Good Storage and Shipping Practices, American Society for Testing and Materials, ASTM D 3103-99 Standard Test Method for Thermal Insulation Performance of Distribution Packages, and the International Safe Transit Association.

For more information about Cardinal Health cold chain, including an informative video about the cold chain tote with phase change material as well documents on refrigerated tote qualification and limitation of spot testing, please go to cardinalhealth.com/ColdChain

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