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19-20 October 2022

U.S.-PH Cold Chain Standards and Innovation Virtual Workshop

Current State of Standards and Regulations in the Philippines and the Global Trends

The Pharmaceutical Cold Chain Process

The Critical Purpose of Cold Chain Logistics in the Pharmaceutical Industry:

- **Ensure proper handling of environment-controlled products safely and securely in the healthcare supply chain**

- Determine how to protect your pharmaceutical shipments from temperature excursions and other environmental conditions

- Knowing the key criteria for storage and later for distribution

Healthcare Cold Chain Standards and Innovation

Environmental and Storage Influence on Stability, Quality and Efficacy of Healthcare Products

The proper storage is important right from the drug manufacturing facility to the pharmacy stores and until it reaches the consumers.

Storage and Transit Controls are therefore one of the most important aspects of the TOTAL DRUG CONTROL SYSTEM which will result to loss of potency if mismanaged and which could adversely influence the efficacy and safety of the pharmaceutical products.

Healthcare Cold Chain Standards and Innovation

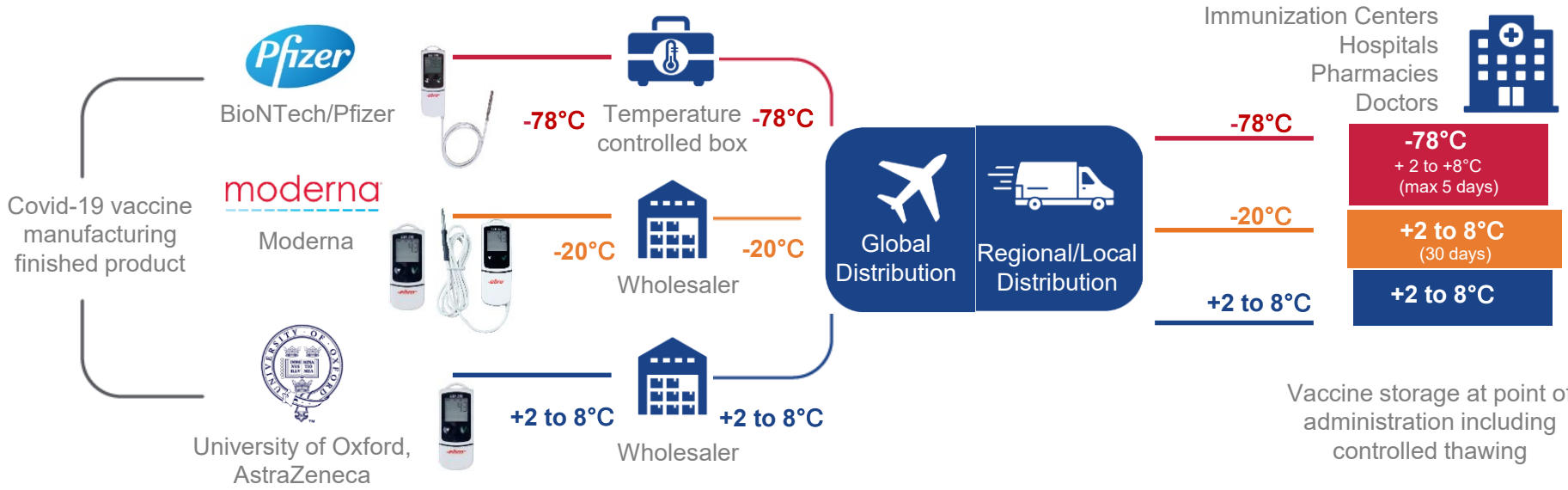
Environmental and Storage Influence on Stability, Quality and Efficacy of Healthcare Products

Proper Environmental Control should include:

- Suitable but Adequate Lighting in the facility
- Correct Storage Temperature
- Acceptable Humidity/ %RH Levels
- Conditions of Sanitation
- Air Flow and Ventilation
- Segregation

Healthcare Cold Chain Standards and Innovation

Vaccine distribution as an example:



The Applicable Standards/Norms and Regulations

- *USP, GMP, cGMP, GDP and the Norms/Standards*

http://www.who.int/medicines/areas/quality_safety/quality_assurance/GuideGoodStoragePracticesTRS908Annex9.pdf

World Health Organization; WHO Technical Report Series, # 908, 2003:

Guide to Good Storage Practices for Pharmaceuticals

Storage in dry, well-ventilated premises at temperatures of 15–25°C or, depending on climatic conditions, up to 30°C. Extraneous odours, other indications of contamination, intense light must be excluded. Drug products that must be stored under defined conditions require appropriate storage instructions.

IFP – *International Pharmaceutical Federation*

..."The Guidelines are applicable not only to Manufacturers of Medicinal Products but also to Pharmaceutical Importers, contractors and wholesalers and hospital & community Pharmacies..."

Qualification / Validation in the Pharma Cold Chain Process

Thermal Mapping as a key requirement:

Good manufacturing practice (GMP) regulators have sharpened their focus on warehouse storage and distribution practices. Driving this trend is a shift in regulatory thinking from quality-by-test to quality-by-design systems with emphasis on level of risk to product quality and consumer safety.

Other drivers include greater demand for storage facilities due to globalization of manufacturing, increase in temperature-sensitive products, and changes in technology.

Thermal Mapping – Pharmaceutical

Supplement 7

Qualification of temperature-controlled storage areas

Technical supplement to WHO Technical Report Series, No. 961, 2011

Annex 9: Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products

applicable areas, as well as a plan of action in the event of an unacceptable excursion.

TEMPERATURE MAPPING

The basis of any temperature mapping in a temperature controlled space (e.g., facility, vehicle, shipping containers, refrigerator, freezer) is the identification and documentation of a sound rationale used for a given mapping procedure. The temperature variability associated with mapped locations and the level of thermal risk to the product should be defined, unless another process has been put in place to ensure environmental control.

A temperature mapping study should be designed to assess temperature uniformity and stability over time and across a three-dimensional space. Completing a three-dimensional temperature profile should be achieved by measuring points at not less than three dimensional planes in each direction/axis—top-to-bottom, left-to-right, front-to-back, where product will be present.

When temperature mapping is necessary, it should begin

usp®

USP 36

General

⟨1079⟩ GOOD STORAGE AND DISTRIBUTION PRACTICES FOR DRUG PRODUCTS

VALIDATION AND THERMAL PERFORMANCE QUALIFICATION FOR TRANSPORT SYSTEMS

Drug product transport systems should be continuously monitored by calibrated monitoring systems, (continuous verification), or shipping systems should be qualified and based on historical data relative to the process. However, it may be acceptable to use product stability data and supply chain risk assessment to justify shipping without either continuous monitoring or qualification of the shipping system.

Operational and performance shipping studies should on a generic level be part of a formal qualification protocol that may use controlled environments or actual field testing, depending on the projected transport channel. These studies should reflect actual load configurations, conditions, and expected environmental extremes. Testing should be performed on both active and passive thermal packaging systems.

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Thank you for your attention!

Feel free to contact us

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