Summary - Cold Chain Management of Biopharmaceutical Materials

Biopharmaceuticals, like other drugs, are used for the treatment, prevention or cure of disease inhumans. Biopharmaceuticals are of large molecular size and structural complexity and may include proteins, monoclonal antibodies, glycosaminoglycans, hormones, vaccines, oligonucleotides and PEGylated molecules.

Biopharmaceutical products are often defined by their manufacturing processes. Changes in the manufacturing process, equipment or facilities could result in changes to the biological product itself and potentially require additional clinical studies to demonstrate the product's safety, identity, purity and potency. Biopharmaceuticals are further characterized by their high susceptibility to irreversible degradation and exceptionally high financial value per unit.

Temperature, agitation and exposure to light are among the conditions known to degrade protein and oligonucleotide based materials.

A risk assessment should be conducted that examine potential conditions under which the integrity of each biopharmaceutical materials is known to be compromised. Among the points to consider:

During transport by air, each take-off and landing may result in pressure changes that could potentially impact container integrity through expansion and contraction, as well as accelerated coolant loss due to increased pressure.

To a lesser degree, pressure changes must also be considered for ground transportation in specific geographical locations.

Photo stability studies conducted on some biopharmaceutical products have shown that aggregate formation is possible on exposure to light. Transparent packaging, especially for refrigerated materials, should be avoided due to potential light exposure in walk-in cold rooms.

The shipping and distribution processes for drug substances and drug products should be qualified for commercial products, a summary of which is required for regulatory marketing applications of biopharmaceuticals. It should be noted that transport temperature ranges may be wider than the labelled storage temperature range for any given product, however, data to cover the anticipated transport process (mode, duration, container) and qualification testing of the product after transport is expected.

Transport vehicles themselves may function as an active system (i.e. temperature controlled trailers). Proper setting of the temperature set point and loading of materials in a container or trailer is required to ensure that the temperature is properly controlled. Unless otherwise qualified, loads should not be placed against the walls of the transport vehicle to allow for proper air circulation within the cargo area and to ensure ambient outside temperature does not transfer directly to the load. Temperature is typically controlled by air circulation; as such air vents must not be blocked by the shipment materials.

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