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Active Temperature-Controlled Systems: Qualification Guidance

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1.0 Introduction

1.1 Purpose and Scope

Fundamental to any temperature-controlled process is the expectation that materials that are stored and shipped within a controlled environment are maintained within a defined temperature range. Typically, this temperature range is within the recommended product storage requirements derived from stability data. The temperature within a temperature-controlled vehicle; temperature-controlled ocean container; active unit load device (ULD); or walk-in, temperature-controlled stores (e.g., a cold room, refrigerator, freezer, or standalone unit) is expected to be maintained:

- Reliably and consistently through the period in which the product is stored within the controlled environment (i.e., over time)
- In compliance with the product requirements for temperature at all locations in which the product might be stored (i.e., temperature and location or storage boundary)

The qualification process proves that the transportation system can consistently meet product temperature requirements. Strategies for conducting qualification studies should be based on the product's temperature and stability requirements as well as the transportation and storage process for that product.

Qualification is part of a validation program with a validation master plan (VMP) for the transportation system in question that defines the design qualification (DQ), installation qualification (IQ), operational qualification (OQ) and performance qualification (PQ) requirements. The VMP is discussed in more detail in **Section 4.0.**

This guidance discusses the process of qualifying actively controlled spaces that are designed to maintain a stable and uniform temperature around the cargo for the duration of transportation or storage at any temperature range. Specifically, this guidance addresses best practices for qualifying temperature-controlled trucks or trailers (hereafter referred to simply as "trucks"), temperature-controlled ocean containers, active ULDs, and walk-in temperature-controlled stores that are used to quarantine, hold, or store raw materials, intermediates, or products. It provides details on selected temperature-controlled units and their qualification testing, and it identifies best practices for performing and documenting the qualification activities, including temperature mapping studies, that are part of an overall validation program, whether that program is conducted by the pharmaceutical shipper or a service provider.

1.2 Aircraft Cargo Compartments

The environment of packages or freight in aircraft cargo compartments can be influenced by the transportation process. Transportation processes can be combined with other temperature-controlled packaging processes (active or passive) to help reduce the extremes of temperature for commodities during transit. In marketing their aircraft equipment and procedural controls, some air carriers are claiming that the aircraft cargo hold can serve as an active temperature-controlled system for cargo that is less sensitive to temperature variations (e.g., for products that are stable in a controlled room temperature range of 15°C to 25°C with allowable excursions). Although the temperature inside many current aircraft compartments can be regulated, aircraft themselves are not designed as temperature control systems. Thus, they are not discussed as such in this guidance.

Pharmaceutical shippers with cargo that is sufficiently stable to withstand the rigors of air travel without additional protection by an active container or passive packaging system should perform shipping temperature studies to ensure that process controls are sufficient to protect the product within the air planes used. Such studies are outside the scope of this guidance.