

Summary - Establishing and Extending Clean Equipment Hold Times

This guidance describes considerations and risks for determining if the establishment of clean equipment hold times (CEHT) for equipment producing drug product and Active Pharmaceutical Ingredients (API). This guidance does not apply to clean equipment after sterilization.

Grouping of equipment to establish CEHT is also explained.

The clean equipment hold time is defined as the time between the last step of the cleaning procedure

The risk of contamination of clean equipment with dust, etc due to exposure to the environment. For this risk, it is required that equipment either be held clean in a controlled clean environment or protected from the environment.

The following factors should be considered to determine the level of risk for clean equipment hold times.

Considerations for the risk of contamination of clean equipment with non-viable particulates (e.g. dust) due to exposure to the environment.

Conditions of equipment storage, such as protection from an uncontrolled unclean environment. Protecting equipment such as with plastic sheaths or bags, closing lids, storing in clean areas, etc. are methods of minimizing negative effects of storage with respect to potential non-viable particulate contamination.

If CEHT must be monitored (i.e. tracked) and/or validated, establishing or extending the clean equipment hold time for a group of equipment may be done by obtaining data for one representative item in the group.

For example, data generated for 1 of 5 coating pans, 1 of 4 tablet presses, or 1 of 4 centrifuges would apply to the other pieces in the group, if the pieces are documented to be equivalent with respect to cleanability.

Sampling locations may be designated as most likely to contain contamination upon storage. Locations may or may not necessarily be the same locations as those most likely to contain residual product residue.

A rationale for sampling locations for CEHT is suggested. If an established CEHT is exceeded the equipment should be cleaned or rinsed prior to next use. Additional sampling after the extended CEHT can also be considered.

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