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Equipment Hold-Time for Cleaning Validation

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Regulatory agencies expect companies to establish and monitor clean equipment- and dirty equipment-hold times for manufacturing equipment as part of their cleaning-validation program.

The concepts of "clean-hold time" and "dirty-hold time" have been part of cleaning validation since its inception. Clean-hold time is generally considered to be the time between the completion of cleaning and the initiation of the subsequent manufacturing operation. Dirty-hold time can begin when the clean equipment is initially soiled, but more often is defined as the time between the end of manufacturing and the beginning of the cleaning process. Intuitively, it makes sense to be concerned about both hold times. Dirty equipment is harder to clean the longer the hold time, and clean equipment has a greater chance of becoming soiled as hold time increases.

Background

In its *Guide to Inspection of Validation of Cleaning Processes*, the US Food and Drug Administration considers identifying and controlling the length of time between the end of processing and each cleaning step to be critical elements of the cleaning processes (1). FDA also expects pharmaceutical companies to demonstrate that routine cleaning and storage of equipment does not allow for microbial proliferation. The European Union expects companies to provide a validation master plan with clearly defined and documented validation program elements (2). Health Canada looks for companies to describe the interval between the end of production and the beginning of the cleaning procedures as well time-frames and conditions for the storage of clean equipment that do not allow for microbial proliferation (3). Finally, the Pharmaceutical Inspection Co-operation Scheme (PIC/S) guideline looks for documentation of both dirty- and clean-hold times (4). The general practice among industry is to routinely document and track equipment-hold times to ensure ongoing compliance.

Although regulatory agencies expect manufacturers to document and address hold times, they do not describe a process for establishing hold times. In this validation study, a dirty-hold time was established but ongoing implications were not examined (5). Several articles define both clean- and dirty-hold times and how to establish them but do not mention a strategy to guide the experiments (6, 7). A more recent article, which referred to hold-time studies as a "the last parameter for cleaning validation," explored several issues associated with hold-time studies (8). Issues included storage conditions, test locations, testing methodology, and the length of hold-time studies.

The concern with clean-hold times is that clean equipment will not stay clean indefinitely despite using appropriate storage conditions. Holding soiled equipment makes it more difficult to remove pharmaceutical soil and allows biological contamination to proliferate. To address these concerns, the author extended clean-hold time testing for more than 2 yrs and extended dirty-hold time studies for up to 9 days. After identifying clean- and dirty-hold time, ongoing control of the hold times became difficult. Every time a piece of equipment is used, the operator needs to confirm and document that the actual clean-hold time does not exceed the established clean-hold time. And before washing a piece of equipment, the washer needs to confirm and document that the actual dirty-hold time does not exceed the established dirty-hold time.

This study suggests that if clean- and dirty-hold time issues are addressed during the validation study that the severity of exceeding the established hold times diminishes to a near-acceptable level.



Equipment Hold Time For Cleaning Validation

Didier Musso



Equipment Hold Time For Cleaning Validation:

Unveiling the Magic of Words: A Report on "**Equipment Hold Time For Cleaning Validation**"

In some sort of defined by information and interconnectivity, the enchanting power of words has acquired unparalleled significance. Their power to kindle emotions, provoke contemplation, and ignite transformative change is actually awe-inspiring. Enter the realm of "**Equipment Hold Time For Cleaning Validation**," a mesmerizing literary masterpiece penned by way of a distinguished author, guiding readers on a profound journey to unravel the secrets and potential hidden within every word. In this critique, we shall delve in to the book is central themes, examine its distinctive writing style, and assess its profound affect the souls of its readers.

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