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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.



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Table of Contents Equipment Hold Time For Cleaning Validation

1. Understanding the eBook Equipment Hold Time For Cleaning Validation
 - The Rise of Digital Reading Equipment Hold Time For Cleaning Validation
 - Advantages of eBooks Over Traditional Books
2. Identifying Equipment Hold Time For Cleaning Validation
 - Exploring Different Genres
 - Considering Fiction vs. Non-Fiction
 - Determining Your Reading Goals
3. Choosing the Right eBook Platform
 - Popular eBook Platforms
 - Features to Look for in an Equipment Hold Time For Cleaning Validation
 - User-Friendly Interface
4. Exploring eBook Recommendations from Equipment Hold Time For Cleaning Validation
 - Personalized Recommendations
 - Equipment Hold Time For Cleaning Validation User Reviews and Ratings
 - Equipment Hold Time For Cleaning Validation and Bestseller Lists
5. Accessing Equipment Hold Time For Cleaning Validation Free and Paid eBooks

- Equipment Hold Time For Cleaning Validation Public Domain eBooks
 - Equipment Hold Time For Cleaning Validation eBook Subscription Services
 - Equipment Hold Time For Cleaning Validation Budget-Friendly Options
6. Navigating Equipment Hold Time For Cleaning Validation eBook Formats
 - ePub, PDF, MOBI, and More
 - Equipment Hold Time For Cleaning Validation Compatibility with Devices
 - Equipment Hold Time For Cleaning Validation Enhanced eBook Features
 7. Enhancing Your Reading Experience
 - Adjustable Fonts and Text Sizes of Equipment Hold Time For Cleaning Validation
 - Highlighting and Note-Taking Equipment Hold Time For Cleaning Validation
 - Interactive Elements Equipment Hold Time For Cleaning Validation
 8. Staying Engaged with Equipment Hold Time For Cleaning Validation
 - Joining Online Reading Communities
 - Participating in Virtual Book Clubs
 - Following Authors and Publishers Equipment Hold Time For Cleaning Validation
 9. Balancing eBooks and Physical Books Equipment Hold Time For Cleaning Validation
 - Benefits of a Digital Library
 - Creating a Diverse Reading Collection Equipment Hold Time For Cleaning Validation
 10. Overcoming Reading Challenges
 - Dealing with Digital Eye Strain
 - Minimizing Distractions
 - Managing Screen Time
 11. Cultivating a Reading Routine Equipment Hold Time For Cleaning Validation
 - Setting Reading Goals Equipment Hold Time For Cleaning Validation
 - Carving Out Dedicated Reading Time
 12. Sourcing Reliable Information of Equipment Hold Time For Cleaning Validation
 - Fact-Checking eBook Content of Equipment Hold Time For Cleaning Validation
 - Distinguishing Credible Sources
 13. Promoting Lifelong Learning
 - Utilizing eBooks for Skill Development

- Exploring Educational eBooks
14. Embracing eBook Trends
- Integration of Multimedia Elements
 - Interactive and Gamified eBooks

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