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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

**S Ashworth**



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The Top Books of the Year Equipment Hold Time For Cleaning Validation The year 2023 has witnessed a noteworthy surge in literary brilliance, with numerous captivating novels enthralling the hearts of readers worldwide. Lets delve into the realm of popular books, exploring the captivating narratives that have charmed audiences this year. The Must-Read : Colleen Hoover "It Ends with Us" This poignant tale of love, loss, and resilience has gripped readers with its raw and emotional exploration of domestic abuse. Hoover masterfully weaves a story of hope and healing, reminding us that even in the darkest of times, the human spirit can triumph. Equipment Hold Time For Cleaning Validation : Taylor Jenkins Reids "The Seven Husbands of Evelyn Hugo" This intriguing historical fiction novel unravels the life of Evelyn Hugo, a Hollywood icon who defies expectations and societal norms to pursue her dreams. Reids compelling storytelling and compelling characters transport readers to a bygone era, immersing them in a world of glamour, ambition, and self-discovery. Discover the Magic : Delia Owens "Where the Crawdads Sing" This evocative coming-of-age story follows Kya Clark, a young woman who grows up alone in the marshes of North Carolina. Owens spins a tale of resilience, survival, and the transformative power of nature, entrancing readers with its evocative prose and mesmerizing setting. These popular novels represent just a fraction of the literary treasures that have emerged in 2023. Whether you seek tales of romance, adventure, or personal growth, the world of literature offers an abundance of captivating stories waiting to be discovered. The novel begins with Richard Pape, a bright but troubled young man, arriving at Hampden College. Richard is immediately drawn to the group of students who call themselves the Classics Club. The club is led by Henry Winter, a brilliant and charismatic young man. Henry is obsessed with Greek mythology and philosophy, and he quickly draws Richard into his world. The other members of the Classics Club are equally as fascinating. Bunny Corcoran is a wealthy and spoiled young man who is always looking for a good time. Charles Tavis is a quiet and reserved young man who is deeply in love with Henry. Camilla Macaulay is a beautiful and intelligent young woman who is drawn to the power and danger of the Classics Club. The students are all deeply in love with Morrow, and they are willing to do anything to please him. Morrow is a complex and mysterious figure, and he seems to be manipulating the students for his own purposes. As the students become more involved with Morrow, they begin to commit increasingly dangerous acts. The Secret History is a brilliant and gripping novel that will keep you speculating until the very end. The novel is a cautionary tale about the dangers of obsession and the power of evil.

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