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Critical Cleaning Forum: Invitation To Participate

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Critical Cleaning Forum (CCF) is a new IVT feature that will provide readers an opportunity to discuss information about cleaning and related topics. Critical cleaning -- cleaning to an appropriate quantitative level of cleanliness -- is a fundamental expectation in regulated industries. Cleaning is a process with a final “product” delivered by the process. Any effort to increase the understanding and application of cleaning in daily work performance will be useful to readers.

WE NEED THIS FEATURE

The idea for an ongoing cleaning feature in the IVT journals came from multiple sources. Validation and Quality Managers have repeatedly requested that cleaning be addressed in the IVT journals; they heartily agree on the need to discuss the many individual topics associated with cleaning. Cleaning topics are not adequately addressed at technical professional meetings. Critical cleaning involves many types of products. In turn it involves multiple disciplines at a manufacturing site – the technical scope of critical cleaning is broad and diverse. Virtual meetings have only hurt our ability to network and interact on these topics; discussion of cleaning topics is needed more than ever at this time.

CRITICAL CLEANING SCOPE AND CONTENT

The potential scope of*CCF* content is extensive; applications in validation and QA activities are numerous. Pharma, medical device, and related industry professionals design experiments, evaluate process data, monitor ongoing cleaning performance within their function responsibilities – all of which add confidence and credibility to the performance of cleaning. Successful cleaning requires personnel with appropriate expertise; industry personnel with related technical expertise are part of all significant cleaning activities. Cleaning processes should involve a lifecycle approach. Validation and QA personnel must have reasonable understanding of critical cleaning concepts to effectively interact with the respective professionals and functions involved in cleaning.

Our goal in*CCF* is to provide basic understanding of critical cleaning concepts. We intend to identify concepts applicable to cleaning and demonstrate their use in examples. Readers have opined their preference for case studies describing practical applications of theory; we intend to emphasize fundamental theory and problem-solving. Our objectives are modest; it is unrealistic to expect readers to become cleaning SMEs based on reading content in*CCF.* Cleaning personnel sometimes speak with terminology unknown to non-experts, i.e., dirty hold time, NOEL, clean hold time, TOC, non-specific methods, campaign length, BATHOCARD, and so on; we intend to overcome these language barriers in*CCF* content. If we are able to provide a fundamental understanding of basic concepts to facilitate meaningful communication between validation, QA and related

cleaning professionals in the daily work environment,*CCF* will be a success.

Discussion Topics. The first topics to be discussed will provide a baseline understanding of relevant topics across several applications. Cleaning pharma products, both small molecule and biologic products, is fundamental. Cleaning of medical device products will also be addressed. We invite discussions of related cleaning such as cosmetic products, blood products, implants, tissues, and other applications to contribute to*CCF* content. Cleaning professionals can learn from cleaning applications in other industries. Discussion of the above is planned to include relevant examples.

WE NEED YOUR HELP

The title*Critical Cleaning Forum* was selected to emphasize our desire for reader involvement in this feature. We invite participation and contributions from industry professionals with cleaning-related expertise to help in*CCF.* We envision manuscripts with brief discussions of individual cleaning topics followed by example applications – brief, clear, and simple. Joint submissions from project groups with cleaning involvement are most welcome.

Communication Methods. The multiple communication methods available through IVT will be utilized in*CCF.* Journal submissions for publication in the*Journal of Validation Technology* and*Journal of GXP Compliance* are invited. Blog discussions posted on the IVT Network are more informal and are also welcome. IVT*"Voices in Validation"* podcasts provide visual and verbal discussion by individuals and groups; information sharing through IVT podcasts has been very well received and very successful. Coupling written and podcast discussions have been effective methods of transmitting content and provide multiple preferred adult learning methods. The IVT Network is currently experiencing tremendous growth in each of our communication vehicles; applying their outreach will contribute to general website value as well as providing contributing individuals with global visibility and recognition. Please join us;*CCF* will be most successful when technical, validation, quality, engineering, and analytical communities participate in this endeavor. Please respond in the comments section below with ideas, suggestions, or topics for discussion. We look forward to working with you on cleaning.

REFERENCES

1. FDA**.** Guidance for Industry. Process Validation: General Principles and Practices. January 2011. https://www.fda.gov/media/71021/download. Accessed 10-25-21.
