IVT NETWORK
Published on *IVT Network* (http://www.ivtnetwork.com)

Paperless Cleaning Validation Lifecycle Management

By **Ivan Soto Dec 12, 2016 1:24 pm PST**

ABSTRACT

This discussion addresses the benefits of paperless cleaning validation. Potential inefficiencies with *paper-based* cleaning validation and corresponding benefits of *paperless* cleaning validation are discussed. Some of the specific benefits described include reduced cleaning validation cycle time, less cost, improved consistency, integrated lifecycle stages, and electronic protocol execution. Benefits of paperless cleaning validation are significant and should be considered in validation organizations.

INTRODUCTION

The cleaning validation lifecycle is managed in many organizations using paper-based documentation. While paper-based systems have been successfully used in validation for many years, new paperless approaches to validation offer significant advantages. This discussion describes advantages of paperless systems applied to cleaning validation. Comparable deficiencies of traditional paper-based cleaning validation are discussed.

CHALLENGES WITH TRADITIONAL CLEANING VALIDATION

The cleaning validation lifecycle has long been managed in many organizations using paper-based documentation systems. The following challenges are found in traditional paper-based cleaning validation:

- Silo approach in organizations -- Design and development are not integrated with validation execution and continued process verification
- Lengthy and inefficient cycle times
- Isolated islands of information in paper, databases, and file folders
- Lack of data visibility
- Unknown or difficultly determined cleaning validation status of equipment
- Delays in validation execution
- Errors in validation execution

Managing cleaning validation using paper creates the challenge that there is no integration between the different stages of the cleaning lifecycle. This creates a situation where design and development are managed as separate activities during the lifecycle instead of being integrated with other validation stages. The lack of integration between design / development, validation execution, and continued process verification provides no visibility of data and associated information to organizations involved with the different stages of the lifecycle. Access to data and information is not expeditious.

Traditional cleaning validation lifecycle management leads to a significant amount of data challenges such as islands of information found in paper, databases, and file folders. Islands of information provide no data integration during the different stages of the validation lifecycle. Situations in which data and information would be useful are not possible or require extended time to be accomplished. This lack of visibility during the lifecycle creates the challenges related to understanding the cleaning validation data and technical details buried in paper-based records. There also is inadequate visibility to the cleaning validation status of the equipment and related activities.

BENEFITS OF PAPERLESS CLEANING VALIDATION MANAGEMENT

Managing the cleaning validation lifecycle by a paperless electronic system provides significant benefits and efficiencies. The following benefits can be achieved:

- Design and development is integrated with validation execution and subsequent stages
- Paperless lifecycle management enables efficiency and cost reduction
- Data integration throughout the entire cleaning validation lifecycle
- Global visibility to data and cleaning validation status of equipment across multiple sites
- Paperless execution eliminates challenges created with paper based validation.

One of the key benefits of managing the cleaning validation lifecycle paperless is the ability to integrate the respective stages of the lifecycle including design / development, validation execution, and continued process verification. Managing the cleaning validation lifecycle by paperless systems provides the ability to have data and documentation related to cycle development, cleaning validation studies, and performance qualification of the cleaning procedures In a single repository. This provides significant advantages compared to multiple locations, multiple local organizations, and binders and paper documents that are not integrated in one single repository with universal access. The integration between the three stages of the cleaning validation lifecycle enables efficient issue resolution and investigations during cleaning failures during validation and commercial operations.

Managing the cleaning validation lifecycle by paperless systems enables a significant efficiency in shorter cycle times and cost reduction. Managing the cleaning validation lifecycle by paperless systems eliminates inefficiencies in routing documents, printing, scanning documents into file folders, manual protocol execution, and document storage.

Paperless validation systems fully automate the cleaning validation lifecycle by eliminating manual activities from the process. Paperless validation lifecycle management systems enable the ability to configure workflows that fully automate the cleaning validation lifecycle. Paperless validation lifecycle management systems enable electronic execution of cleaning validation protocols. Electronic execution of cleaning validation protocols reduces errors, costs, deviations, duplications and rework.

Paperless validation lifecycle management systems enable global visibility to critical data during the cleaning validation lifecycle across multiple sites. Paperless validation lifecycle management systems enable users to configure frameworks and decision trees that can be used to define the lifecycle activities needed to consider cleaning validation completed. This enables consistency and enforcement of procedure requirements during the cleaning validation lifecycle.

Paperless validation lifecycle management systems maintain the entire cleaning validation lifecycle electronically with built-in best practices. Paperless validation lifecycle management systems provide integrated functional modules to manage the entire cleaning validation lifecycle electronically. Paperless validation lifecycle management systems integrate functional modules as follows:

- Decision trees can be defined based on the cleaning validation standard operating procedures and policies
- Decision trees auto generates the cleaning validation protocols based on responses from the users
- Eliminates human errors, enforces the consistency in the cleaning validation process and significantly reduces regulatory risk
- Supports creation of cleaning validation frameworks to enforce the deliverable requirements and periodic review schedules

- Workflow based system manages the entire cleaning validation lifecycle along with required supporting data and documents
- Supports a risk based approach
- Decision trees, protocols, templates and processes can be shared across multiple sites globally
- Provides real-time cleaning validation status through a site dashboard.

SUMMARY

Paper-based cleaning validation is inadequate, inefficient and costly. Paperless validation lifecycle management systems provide full automation of the cleaning validation lifecycle process. Paperless cleaning validation lifecycle management provides a significant advantages and benefits such as the following:

- Reduces cleaning validation cycle times
- Cost reduction
- Improved consistency
- Fully integrates cleaning validation lifecycle management
- Eliminates non-value added activities while increasing compliance
- Approvals are tracked and alerts are sent through e-mail
- Requirements and cleaning specifications are managed individually
- Dynamic trace-matrix generation
- Electronic protocol execution
- Eliminates data integrity issues
- Integrations with risk management systems.

ABOUT THE AUTHOR

Ivan Soto is Director, Client Engagement and Product Strategy, ValGenesis, Fremont, CA 94539. He may be contacted at ivan.soto@valgenesis.com and at 401-262-5911 x-1026.

Source URL: http://www.ivtnetwork.com/article/paperless-cleaning-validation-lifecycle-management