Considering Digitizing Your Cleaning Validation? Five Common Questions Answered.

Thinking about fully digitizing your cleaning validation? Need targeted tips to inform the next transition discussion with your team? Here's what you need to know.

1 What paper-based cleaning validation pain points will digitization help to mitigate?

- **Lack of Manageability:** Paper is hard to manage, often resulting in an absence of a pre-approved validation plan or strategy. Digitization offers a consistent way to carry out cleaning validation lifecycle activities.
- **Inconsistency:** Consistency is very important in cleaning validation, and paper documentation leads to human error. Properly configured digitized cleaning validation ensures consistent output, including:
  - Worst-case product and equipment identification
  - Product assessment
  - Product family
  - Equipment grouping
  - Dirty and clean hold times
  - Calculation of surface area matrices
  - MACO calculations
- **Vague Analytical Methods:** How do you make sure that, when you establish your acceptance criteria, your analytical methods are quantifiable? Digitization simplifies and clarifies this process, ensuring that procedures and SOPs are rooted in scientific evidence.
- **Time-consuming Cleanability Impact Assessments:** Anytime anything in your cleaning validation process changes, digitization gives you the ability to perform the cleanability impact assessment through a one-time framework setup that automatically walks you through every required consideration, streamlining this process.

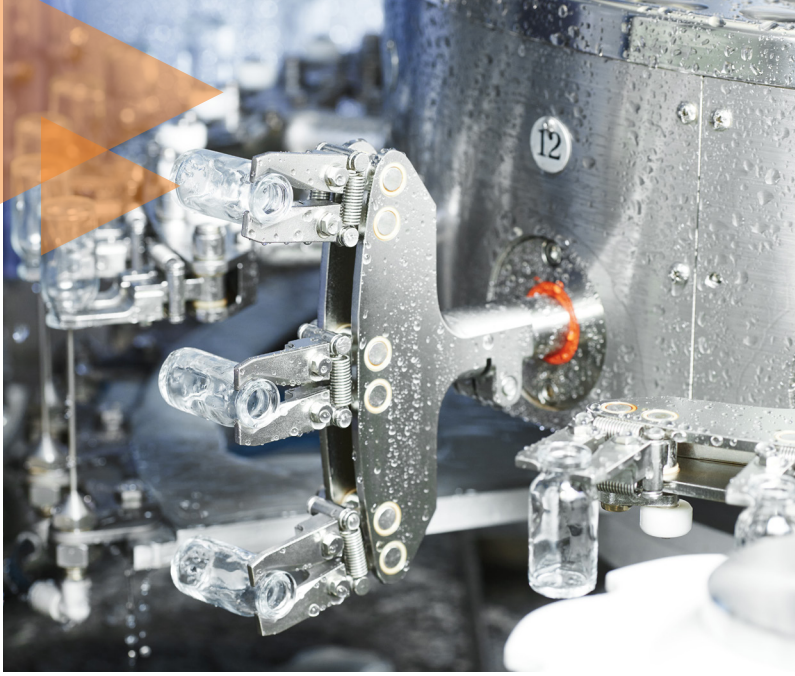
2 We have an optimized cleaning validation lifecycle process in place on paper. Will we need to reconfigure it in order to digitize?

No. Digitization can replicate exactly what you do currently while subtracting the human error factor implicit in paper-based methods. It provides the improved consistency and reliability you need while allowing you to continue configuring your unique process the way you want to.

3 How does digitization help with risk management?

Digitization allows risk management to exist as living documentation, regardless of how many cleaning processes you have. It supports you with:

- How you control your risk
- How you identify failure
- How you track failures
- Audit trails for every stage
- Alignment with ICH-Q9 principles



4 We need the flexibility to incorporate additional data into our cleaning validation process and configure as we go. Paper allows that. Does digitization include such flexibility?

Yes. Any information that is mandatory for international regulatory bodies will be denoted as mandatory within the program. Then you'll have the option to configure additional data entry fields to meet your specific needs.

5 What happens when we need to add a new piece of equipment or a new product to the process? How easily does the digitized system account for this?

Your digitized cleaning validation lifecycle will seamlessly be able to accommodate new products and equipment as needed. It's a one-time, point-and-click configuration option optimized for your unique process.

Ready to digitize? Contact ValGenesis today to discuss digitization of your cleaning validation lifecycle.

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