White Paper

MasterControl

8 Best Practices for Compliant and Quick Software Validation in the Cloud

By Erin Wright [1]

Software validation can be a huge burden on regulated companies that may not have the manpower, time or experience to perform the necessary validation activities.

If you are responsible for software validation, navigating the regulations, industry standards, and validation requirements can be a daunting task, especially when you have other responsibilities on top of implementing new software. If you think four months spent on validation implementation after upgrading every few years is tough, think again. Multiply that effort four times for a new software release every quarter for most cloud applications, and it can be an overwhelming process.

In this white paper, I will offer insights based on my experience working closely with quality, IT, and validation professionals from hundreds of regulated companies. I will share some lessons and observations from my experience leading MasterControl's development of an innovative validation tool.

Key Best Practices

We at MasterControl have honed a set of best practices resulting from over two decades of experience working with regulated companies. Let's discuss eight key best practices you can adopt to ensure a quick, and most importantly, compliant software validation in cloud environments. At the end of each best practice, you will see the relevant passage from either the GAMP Good Practice Guide[2] or the U.S. Food and Drug Administration's (FDA) General Principles of Software Validation.[3]

1. Assess and accept your software supplier's documentation and templates.

Most software as a service (SaaS) companies of commercial off-the-shelf (COTS) systems provide extensive internally generated validation documentation for clients to leverage. If you are using SaaS, this will save you a significant amount of time when it comes to onboarding or upgrading software; you won't have to reinvent the wheel. The FDA recommends the least burdensome approach to software validation, which can mean assessing and accepting supplier validation documentation as part of the client validation package. Who better to write and test the system requirements than the team that designed the software? Even industry guidance on validation, such as GAMP, recommends leveraging as much of the supplier documentation as possible to minimize your testing and document re-creation.

Likewise, we recommend that our clients make use of our extensive testing documentation. To reduce the validation document-creation burden further, MasterControl provides User Requirements Specifications templates for our clients to use as a guidance for typical user requirements. I worked with clients a few years ago who wrote their own User Requirements based on their understanding of the software that didn't line up with the actual functionality of the MasterControl Quality Management System (QMS) platform. They didn't

realize this until they were writing their usage testing protocols and couldn't test some of their requirements because the system simply didn't work the way they wrote into their usage requirements. This meant going back and rewriting the requirements, submitting them to MasterControl experts for review, and delaying several of their validation activities and go-live. For our clients, using our templates is the best way to streamline validation activities and to avoid this kind of mishap.

"Regulated companies should seek to maximize supplier involvement throughout the system life cycle in order to leverage knowledge, experience, and documentation, subject to satisfactory supplier assessment." GAMP Good Practice Guide: A risk-based approach to testing of GxP Systems, 2nd edition, 2012.

2. Include your supplier's usage testing in your validation package.

When moving to the cloud environment and automatic upgrades, you need to be able to leverage as much validation documentation as you can so you don't spend all your time validating the next release.

At MasterControl, we provide fully executed functional testing and recommended usage testing for every release of our software. We include a full validation package for each release so clients can trace the requirements to the executed testing and review a final summary report of any deviations we found internally.

Using our new automated testing tools, MasterControl performs full regression testing throughout the life cycle of our software to ensure we release the cleanest code possible. One of the many advantages of our automated testing is that we can validate changes on a daily and weekly basis. Because of how thorough our functional testing is, clients don't have to perform any functional-level testing for their instance of MasterControl. We recently introduced the inclusion of usage testing as part of our internal validation package for most of our standard modules. By performing usage testing internally, we are helping clients reduce the amount of usage testing they need to do. We execute new usage testing protocols prior to every software release to keep up to date with new features and enhancements.

We've had clients reject our internal functional testing and write their own because of their internal procedures and requirements. Because writing functional test scripts requires an in-depth knowledge of expected software functionality, clients spend weeks or months just learning the ins and outs of MasterControl to understand what tests to even write, let alone executing the protocols. It's common for these clients to take our exact functional test scripts and run the same testing we have already performed. This just adds time to the validation effort without adding any value.

"The regulated organization should be seeking to leverage supplier documentation and testing. Where the system has been appropriately tested, there is no value in the regulated organization repeating those tests. The need for additional testing

should be based on the regulated organization applying a documented quality risk management process to ensure the supplier is adopting good quality practices toward testing." GAMP Good Practice Guide: A risk-based approach to testing of GxP Systems, 2nd edition, 2012.

3. Follow the best-practice configurations outlined by your supplier.

While the extreme flexibility and customizable configuration options of a COTS software can be appealing, it can lead to option paralysis and an overly complicated configuration of the system. Most SaaS suppliers have a best practice set up for their software that is designed for ease of use and scalability as your company grows. Staying as close as possible to the recommended best-practice configurations will save you a lot of time and effort on your software implementation and validation, and streamline your production usage of the software.

It is very common for clients to want a configuration that better matches their paper process than one that works best in MasterControl. I worked with a client who created elaborate approval routes for documents and intricate user permissions that required individual roles for each person in the company. After one year of maintaining this approach in the production environment, the client came back and asked to fully reconfigure the site to simplify the roles and routes based on MasterControl best practices. To facilitate client adoption of our best practices, we provide a formal documentation of our Best Practice Configuration Specifications that can be downloaded from our customer website.

Following your provider's best practices for your configuration will ensure that you are using the tried-and-true methodology that is scalable, easy to use, and easy to maintain. Not to mention that this will drastically reduce your implementation time as you aren't reinventing the wheel for your configuration. Using your supplier's recommended configuration shortens your timeline, which is critical for cloud implementations with scheduled upgrades.

"The regulated organization can minimize the volume and rigor of testing required by: Avoiding unnecessary customization, e.g., by modifying the business process, if this is practical, to match an off-the-shelf application." GAMP Good Practice Guide: A risk-based approach to testing of GxP Systems, 2nd edition, 2012.

4. Assess your specific configuration and usage for risk-based validation.

Often we see clients who want to validate features and functionalities that aren't part of their production usage of the software. This is wasteful validation effort. The FDA recommends that risk-based validation is performed based on the intended usage of the software, and not just the software functionality risk to the client as detailed in the "Pharmaceutical cGMPs for the 21st Century – A Risk-Based Approach Final Report."

This means taking a deep dive into your actual configuration to see what aspects of the software you are using and how you are using them. This can be the most difficult aspect of the cloud validation as you may not be intimately familiar with the best practices recommended by the supplier and what variations you have in your configuration. Not only that, but it requires a deep knowledge of the regulations that apply to your company and industry. How you use the software impacts the risk more so than the inherent software functionality. As pointed out in GAMP, accepting the boilerplate internal testing of a software alone has risks. Clients must be the ones to call out the critical aspects and processes of their usage of the system. There is no default risk of software usage, as your usage could increase the risk tremendously from your supplier's assessment.

"The regulated organization should be wary of relying upon any risk assessment of the level of testing required carried out by the supplier in isolation. It is unlikely that the supplier will fully understand all the regulated organization's processes and all the critical aspects of the system." GAMP Good Practice Guide: A risk-based approach to testing of GxP Systems, 2nd edition, 2012.

5. Focus on validating your critical business processes (CBPs).

For years MasterControl allowed clients to decide which CBPs to validate in addition to a handful of other standard usage scenarios. It was a massive undertaking for clients with neither the experience nor expertise in documenting and communicating their intended usage. This caused a lot of unnecessary testing and validation work for functions and features that weren't critical. This bloat of validation effort with every module added weeks to the validation period. It was normal for a new client implementation to take up to four months.

While experience may be the best teacher for those clients, it wasn't enough. The question was: Would they be able to perform software validation easily and successfully not just once, but throughout the life cycle of their system? We at MasterControl wanted to streamline the validation process for a more sustainable approach over the long haul.

In 2017, we developed the MasterControl Validation Excellence (Vx) methodology and tool in response to the challenges our clients have experienced over the years. We have quantified and streamlined the risk-based validation approach to document the configuration variations from our best practices, the regulatory sensitivity of client usage, and how well client configurations are covered by our internal testing. Our Vx approach follows the risk-based principle advocated by the FDA.

"The selection of validation activities, tasks, and work items should be commensurate with the complexity of the software design and the risk associated with the use of the software for the specified intended use." General Principles of Software Validation; Final Guidance for Industry and FDA Staff, 2002.

6. Follow a risk-based approach in software validation.

It's critically important to let your risk assessment guide your software validation. Too often we see clients rate everything, from audit trails to email notification text, as "high risk" worthy of validation. An improper risk assessment such as this does nothing to enhance your validation. It calls into question the soundness of your risk-based methodology. To paraphrase Disney's animated superhero movie, "The Incredibles," if everything is high risk, then nothing is.

Once you have established what the true risks are to your company, it's important to perform risk-based validation on the elements of the system that are considered high risk. If your cloud supplier has performed adequate internal functional and usage testing and your usage is identical to the best-practice configurations, you may be able to leverage the supplier's internal documentation.

If you have performed a proper risk assessment, you will be able to focus your company-specific usage testing on the critical areas of the software, often the regulatory software requirements such as audit trail and electronic signatures, and your critical business processes. What's important with risk-based validation testing is that it focuses on your usage and your configuration.

At MasterControl, we provide usage testing protocol templates that are customized to a client's specific usage and risks. These customized risk-based protocols are driven through the Risk Assessment feature of the patented (U.S. Pat. 10,324,830) MasterControl Validation Excellence Tool (VxT)™. Our validation consultants have decades of experience in tailoring our protocols to best match CBPs. As the use of our revolutionary VxT expands, MasterControl will perform tracking and trending of the high-risk areas identified for our clients and will update the usage protocol templates to better address the client usage risks, streamlining the validation effort even further.

"The selection of validation activities, tasks, and work items should be commensurate with the complexity of the software design and the risk associated with the use of the software for the specified intended use." General Principles of Software Validation; Final Guidance for Industry and FDA Staff, 2002.

7. Use a change control methodology for upgrades.

Too often we see clients perform a full revalidation for minor upgrades, including creating new validation plans, user requirements specifications, and a whole slew of documents to support the upgrade. This is unnecessary. By creating all of these validation documents, you are adding time to the upgrade validation by routing minimal changes to the full validation documents through your approval process. Instead, clients should use a change control form to capture the pertinent validation information with each of the upgrades. By consolidating the documentation for a single approval, you will streamline the approval process, as well as make the overall change control implementation viewable at once.

Previously, MasterControl required the creation of a full validation package with every upgrade, no matter how minor the changes were. This meant a new validation plan, new user requirements, full new risk assessment, protocols for every module, and full summary reports for the usage testing and overall validation package. It was a lot of documentation for a minor enhancement implementation. This approach easily took two months in document creation and approval alone, not even counting configuration changes. We found that this approach just wasn't sustainable, particularly as we moved to the cloud environment when the time frame for validation is reduced to 30 days for quarterly upgrades. By consolidating the validation documentation information into a single Change Control Form, we have brought down the number of documents needed to two documents in total. And as the Change Control Form is exported from the Validation Excellence Tool, it will be even easier to manage the change documentation with each upgrade.

An important aspect of risk assessment is to ensure that you are adequately evaluating the risk of each software change. The breadth and depth of the validation effort for a software change should be commensurate to the risks imposed by the software change. Based on the scope of the changes, it may be beneficial to do a full system risk assessment, but most often, only new features and high and critical defects need to be assessed for risk.

The VxT's Change Control portion assesses how new features and defect resolutions impact your usage of the MasterControl system. By narrowing the scope of what needs to be reviewed for each release, it allows for a quick and simple validation process for the upgrade. If the new enhancements aren't critical to a client's usage, the client may be able to fully leverage the MasterControl internal functional and usage testing. Once your assessment is done, the risk assessment and pertinent validation documentation are exported into a customized change control form.

"Change management should provide a dependable mechanism for prompt implementation of technically sound improvements following the approach to specification, design, and verification. The rigor of the approach, including extent of documentation and verification, should be based on the risk and complexity of the change." GAMP 5 Guide: A Risk-Based Approach to Compliant GxP Computerized Systems, 2008.

8. Upgrade frequently to keep current on latest bug fixes and features.

While it seems to be counter-intuitive, frequently upgrading in the cloud environment actually reduces the validation overhead over time. One of the reasons clients don't upgrade on a regular basis is the time and effort it takes to revalidate the system. Following an old-school, full revalidation methodology will cost your business far more than multiple small validations. Clients who take over six months to upgrade and validate their software have told us the lengthy process is due to the onerous and burdensome documentation creation and approval paths required by their company validation procedures. If you can streamline the validation approach

into a smaller, targeted validation, you will be able to shorten the validation time frame from months to days, possibly hours.

By upgrading on a regular basis and implementing new features as soon as they are released, you will be able to keep your validation requirements and overhead in small, manageable bite-sized portions. Frequent upgrades minimize the documentation needed with each release. As we noted above with the use of the Change Control documentation, the validation documentation overhead is minimal and with the use of the VxT risk assessment for new enhancements, MasterControl provides the ability to laser focus validation efforts on the critical areas and changes that impact the client.

A director of quality I've worked with has bemoaned how difficult it can be to get bug fixes installed on her premise site because her instance of MasterControl is several releases behind. Like most software companies, MasterControl provides full product support for two years after a software release. So, after that period, the only way to get defect fixes would be to upgrade. For clients who are several releases behind, upgrading becomes a big project that requires a lot of resources and significant money to ensure successful validation.

As MasterControl CEO Jon Beckstrand pointed out during a recent speech, this causes a vicious cycle of release sitting.[4] By moving to a more frequent validation approach, you can ensure that you have the latest bug fixes in your system and that your software version is fully supported by your supplier.

Conclusion

While software validation historically has been difficult and time intensive, you can ensure a speedy, and most importantly, compliant validation package for your regulated software by following best practices. By leveraging the supplier documentation, sticking to the supplier best practices, assessing your usage and regulatory requirements, leveraging change control methodology, and upgrading frequently, you can—and you will—significantly lighten the validation load for your system.

References

(1) Erin Wright, MasterControl's validation product manager, spearheads the efforts pertaining to the development of the company's groundbreaking Validation Excellence Tool (VxT), which streamlines the risk-assessment process and greatly reduces validation time. She created and implemented the configuration-based testing that drives the VxT and developed the formalized risk-based approach at the heart of MasterControl's Validation Excellence methodology.

She joined MasterControl in 2013 as a professional services consultant and worked closely with hundreds of regulated companies, including the FDA's Center for Drug Evaluation and Research (CDER), Ancestry.com, Abbott Point of Care, Institute for Transfusion Medicine (ITxM), and the University of Utah, in conducting

custom validation implementations. Her extensive experience in quality, validation, and regulatory compliance includes working for an automated-testing software company and several clinical-trial software providers. Wright graduated summa cum laude from West Chester University with a degree in psychology.

(2) The International Society for Pharmaceutical Engineering (ISPE) developed the GAMP guidelines. GAMP stands for Good Automated Manufacturing Practice.

(3) General Principles of Software Validation; Final Guidance for Industry and FDA Staff.

(4) In a plenary presentation at the 2017 Masters Summit, MasterControl CEO Jon Beckstrand cited a company survey of about 3,500 quality professionals indicating the average cost of upgrading a quality management software is about $50,000. The high cost leads to "release sitting," which refers to staying on an old software version and just waiting to upgrade. The Masters Summit is the premier educational conference for MasterControl users.

About MasterControl

MasterControl Inc. creates software solutions that enable life science and other regulated companies to deliver life-improving products to more people sooner. MasterControl's integrated solutions accelerate ROI and increase efficiencies by automating and securely managing critical business processes throughout the entire product lifecycle. More than 1,000 companies worldwide, ranging in size from five employees to tens of thousands, rely on MasterControl cloud solutions to automate processes for new product development, clinical, regulatory, quality management, supplier management, manufacturing and postmarket surveillance. MasterControl solutions are well-known for being scalable, easy to implement, easy to validate and easy to use. For more information, visit www.mastercontrol.com.

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