



*Accelerate Development
Reduce Time to Product
Automate Critical Tasks*

White Paper:

Build Better Software: Optimize Outsourced Validation for Medical Applications

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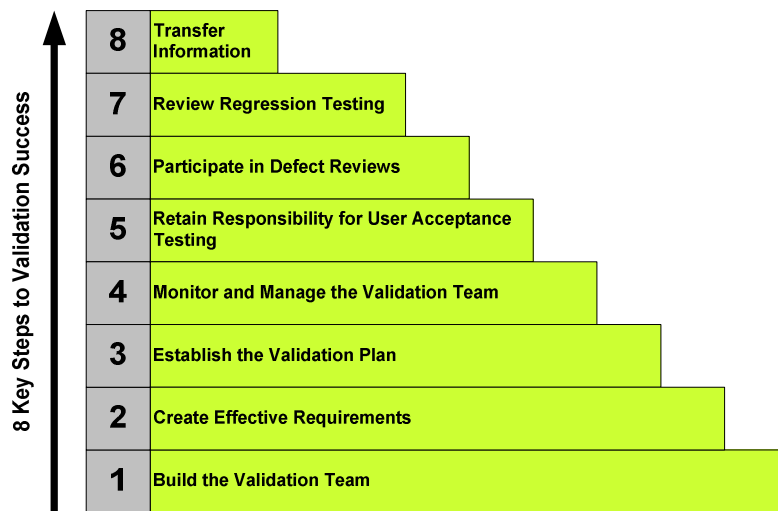
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INTRODUCTION

Validation is the most critical phase of the software development lifecycle for clinical and medical systems. The FDA dictates strict guidelines for validation of systems that establish, manage, manipulate and store medical data (FDA: General Principles of Software Validation; Final Guidance for Industry and FDA Staff). In many organizations the primary focus is on creating the software and unfortunately, the testing follows at the end of the lifecycle as an afterthought. Unless an organization has the luxury of having a pool of trained and experienced validation experts available, it may be more cost-effective and efficient to hire a professional validation consulting firm to assist in test execution, documentation and oversight. Outsourcing the validation of the medical system offers tangible benefits. These include:

- Independent and objective assessment of the software to increase performance confidence
- Availability of experienced resources trained in validation per FDA guidelines
- Dedicated, focused attention without internal distractions to support rapid implementation strategies

An experienced professional validation consultant backed by an organization of testing expertise has access to the skills necessary to support the core validation disciplines that ensure project and organizational success. Once the decision to outsource the validation has been made by an organization, steps can be taken to CONTROL and OPTIMIZE the process to insure success. This paper details **eight key steps** along with **success tips** to manage the outsourced validation resources and assure regulatory compliance to achieve better software.



BUILD THE VALIDATION TEAM

The Validation Team incorporates multi-functional participation and depending on the complexity of the validation effort may include:

- Software Developers and Systems Engineers
- Validation Consultants including Software QA and Testers
- Project Leaders

- Marketing/Product Managers and Subject Matter Experts

The Validation Team is responsible for defining, planning, assessing risk, evaluating intended use, executing, documenting, reviewing and approving the validation efforts. The Validation Team should have a combination of skill sets for effective results. This will include individuals who are experienced with regulations, validation approaches, systems, processes and intended uses associated with the validation effort. A diligent validation consulting firm will furnish the necessary resources to assist in effectively controlling the project. The consultant's job is to manage the entire process including:

- Optimizing testing plans and scheduling
- Verifying functionality and performance
- Providing documentation and summary reports
- Identifying, controlling, and minimizing risk; and monitoring cost
- Completing traceability to specifications
- Training qualified testers

Client organizations must critically review the consultant's recommended skill levels and resources they intend to provide to support the validation effort. And the client organization must look at their own internal resources they are providing to manage and support the Validation Team to assure adequate experience and skill level.

CREATE EFFECTIVE REQUIREMENTS: THE KEY TO VALIDATION SUCCESS

Identification of Requirements is the most important element of a successful software project. The FDA stipulates that design validation conform to defined user needs and intended use which includes testing of production ready software under actual or simulated use conditions. The client organization must know what they are creating in order to successfully test the application. This knowledge needs to be communicated to all members of the validation team. Communication involves fully documenting, reviewing, and clarifying the product requirements. Creating a detailed software requirements specification (SRS) is the foundation of the validation process.

Requirements gathering usually starts with customer or marketing requirements and flows through the system engineering and regulatory process to fully define how the product will look, feel, and perform once it is complete. However, the process is iterative as tradeoffs are made between features and functions, and the inherent safety, regulatory, and implementation overhead incurred to implement these features. The end product emerges as a comprehensive product requirements specification. It is the responsibility of the client organization to make certain the product requirements are complete, thoroughly documented in a formal and verifiable manner, updated to include all modifications and placed under configuration management before the validation effort begins.

ESTABLISH THE VALIDATION PLAN

Several approaches to software validation exist and may be appropriate for the specific project. The scope of any validation effort depends upon a number of factors, including the size and complexity of the software, the origin of the software (custom vs. off-the-shelf) and whether the functions are critical

or non-critical in nature. By effectively planning the process, validation time and resources can be reduced while meeting regulatory requirements. Client organization must assure that systems are in compliance with applicable regulations; however, many clients rely too heavily upon consultant-supplied information and test data to support their system validation. The client organization must work closely with the consultant's validation team to establish the Validation Plan and approach to validation.

A well thought out Validation Plan will cover all the key elements of the Validation Lifecycle, along with complete detail regarding deliverables and responsibilities from both the client organization and the consulting validation team. Both the client and the consultant must agree on the components of the plan including:

- A. Entry Criteria Inputs**
- B. Exit Criteria Outputs**
- C. Roles of the Client**
- D. Roles of the Consultant**
- E. Deliverables and Documentation**
- F. Approval Criteria**
- G. Project Tasks / Schedule**
- H. Key Measures**

MONITOR AND MANAGE THE VALIDATION TEAM

Outsourced validation may be the best approach for the software development project but the client organization does not surrender the project without caution since the client is ultimately responsible for the outcome. The management of the outsourced Validation Team must be assigned and accountable to the person or functional area from the client who is responsible for the implementation/development of the software. Challenges in managing outsourced validation include issues management, change management, communication and effective building of the joint team that includes client and consultant. The following **Success Tips** are offered to help effectively mitigate the challenges:

❖ **Success Tip #1:** Create the Right Expectations

The validation consultant is a separate company with its own goals, motivations and agendas. The onus for the success of the validation effort still rests with client. It is the client's responsibility to make certain that the requirements are well defined and that appropriate project corrections are made early-on in the validation's lifespan. Blaming the consultant is easy, but making the whole exercise successful can only happen if the right expectations are in place from the beginning of the project. Legal documents, agreements, and contracts formally communicate expectations. However, legal documents cannot capture all expectations from the project team. These should be established at the beginning of the project and periodically reviewed.

❖ **Success Tip #2:** Build Effective Communication

Systematic and planned communication between all members of the project team is essential throughout the validation. The project leader on the client side is responsible for the success and effort of the communication and may need to use every communication mechanism to communicate freely and often with team members. Project review conference calls /web sharing meetings, status update

emails, instant messaging (IM), formal project reports and face to face meetings are some examples of communication mechanisms.

❖ **Success Tip #3:** Routinely Monitor Progress and Deliverables

A project schedule is the roadmap to completing the validation effort. Periodic review of the schedule assures the project is on track. Ensure that the schedule identifies specific milestones that can be used to quickly assess the status of the project. Include a risk analysis with each review of the project.

❖ **Success Tip #4:** Trust but Verify

Outsourced validation teams can be trusted but it is still the responsibility of the client to make certain the results are in compliance with regulations and the progress is real. During the validation process, the client should plan to audit the efforts at critical milestones such as auditing test protocols for completeness, auditing configuration management processes and auditing test documentation.

❖ **Success Tip #5:** Understand and Adjust Project Plans

Plans have to be flexible and reflect the actual efforts for the project. As the project progresses, plans should be re-evaluated to assure compliance.

RETAIN RESPONSIBILITY FOR USER ACCEPTANCE TESTING

User Acceptance Testing (UAT) is a process to obtain confirmation by a Subject Matter Expert (SME), preferably the client organization or client customers to test, through trial or review, that the application meets mutually agreed-upon requirements. In software development, UAT is one of the final stages of a project and often occurs before a client organization accepts the new system. Users of the system perform these tests, which are derived from the requirements specification. Test designers draw up formal tests and devise a range of severity levels. It is preferable that the designer of the user acceptance tests come from the client organization and NOT be the creator of the formal integration and system test cases for the same system (these tests are typically written by the consultant). UAT acts as a final verification of the required business functions and proper functioning of the system, emulating real-world usage conditions on behalf of the client organization. If the software works as intended and without issues during UAT, one can reasonably infer the same level of stability when implemented. The results of UAT give confidence to the client organization as to how the system will perform. They may also be a legal or contractual requirement for acceptance of the system.

USE A TEAM APPROACH TO ADDRESS DEFECTS

It is critically important to the success of the project that the client organization participate in routine defect review meetings that are on-going throughout the validation effort. Defect tracking is an important task necessary to understand the risks, issues and potential delays with that may impact the project. Clients must not wait until the end of the validation to review the results. When defects aren't effectively managed, they often get miscategorized, misprioritized, and may even fall completely through the cracks. When this happens, projects are delivered late or not at all. At best, it causes the implementation team increased work as code is reworked or bugs are discovered late in the development cycle. Many defect tracking tools are readily available and the validation consultant should use one that can be easily accessed and monitored by the client organization. The client must assure that each defect is completely and comprehensively recorded, assigned priority and severity, assigned responsibility for closure and reviewed periodically to support the project schedule.

When defect management is handled ad hoc, developers are often left to decide which issues are addressed. While a developer may mean well, unforeseen changes to code introduced by unmanaged source code check-ins can wreak havoc on project schedules and software quality. Therefore, it is important the client organization verify that the defect is adequately described, documented, assigned, addressed and tested.

CAREFULLY REVIEW REGRESSION TESTING

Regression testing is defined as selective retesting of a system or component to verify that modifications have not caused unintended effects and that the system still complies with its specified requirements. Typically regression testing means rerunning test protocols from existing test suites to build confidence that software changes have no unintended side-effects. The “ideal” process would be to create an extensive test suite and run it after each and every change. Unfortunately, for many projects this is not possible because test suites are often too large, changes come in too fast, or because testing must be done on many different hardware and OS platforms. Software validation experts have tried to make regression testing more effective and efficient by developing regression test selection (RTS) techniques, but many problems remain, such as (1) Unpredictable performance- RTS techniques may save time and money, but they sometimes select most or all of the original test cases, and (2) Incompatible process assumptions -testing time is often limited. RTS techniques do not consider such constraints and, therefore, may select more test cases than can be run in the allocated time period. Or they run too few tests to fully cover the impact of the change.

The level of regression testing to be completed will depend on the overall risks associated with the change in the code. During the validation effort, both client and consulting organization must agree on the level of regression testing required to complete the validation effort. Client organizations must play the primary role in assessing the amount of regression testing to be performed.

TRANSFER ALL THE INFORMATION

The last key element in an outsourced validation project is identification of the information transfer requirements. The information transfer requirements describe who needs which deliverables at the end of the project and, more specifically, the format and form that these deliverables must assume to seamlessly integrate into the destination systems. Whether it is executed testing protocols or a database of closed defects, clear definition of how the recipient must receive the project outputs in order to quickly and efficiently finish the product development project pays huge dividends at the end of the successful validation effort.

A final Validation Report that is reviewed and approved by both the consultant and client organization will summarize the outcome of the validation but the FDA looks for evidence the validation has been successfully executed. Therefore, it is important to adequately list and obtain all sources of information gathered in the validation process by the validation team. The basics include: approved Validation Plans, all executed testing protocols, traceability matrix and defect tracking data. The items frequently overlooked that are also important include: a complete list of the names/signatures/initials of the

validation team, training records for the validation team, screen captures that provide evidence of protocol execution, automated test scripts, system topology and description of the testing environment.

CONCLUSION

Organizations face ever stronger demands to bring software products to market quickly, safely and compliantly. Outsourcing can provide organizations with the additional professional skilled resources needed to augment their project teams and provide an un-biased third party assessment of the application. Putting together a well trained, comprehensive Validation Team is the first step in the process to control and optimize outsourced validation resources. The Validation Team is a combination of client and consultant resources. Comprehensive, complete and “testable” requirements documentation is critical for any Medical Application to assure thorough and compliant validation. The Validation Plan outlines the approach to validation, entry/exit criteria, roles/responsibilities of all team members, project deliverables, approval criteria and key project measures. During the validation execution, follow the **5 Success Tips** provided to monitor and manage the Team.

User Acceptance Testing occurs once the application has been proven stable enough to move to the hands of end-users. The client organization is the ultimate authority on the Medical Application and should therefore; retain responsibility for the User Acceptance Testing. In order to assure schedule compliance, quality and effective use of resources, both client and consultant should work together to review, manage and track defects. And finally, the Validation Consultant must transfer all the necessary information back to the client organization to support the validation test effort and product release. Companies can build better software by following the eight key steps recommended to control and therefore optimize the outsourced validation process.

ABOUT THE ASHVINS GROUP

The Ashvins Group Inc. is a team of IT consultants who design, develop, test and implement custom software and data management projects. The Ashvins Group is a Florida corporation since 2000 and classified as a Women Owned Small Business. We offer Full Life Cycle Application Development and Validation services with a specialty in healthcare, medical and clinical data management applications. Our expertise includes FDA and HIPAA compliant applications development.

The Ashvins Group applies disciplined application development industry standards combined with our unique Rapid Development Methodology (RDM) and project management practice to achieve client goals. As Development Accelerators, the Ashvins Group will enable clients to meet their critical objectives effectively while reducing time to implement and managing expenses. We utilize controlled processes and apply rigid documentation practices commensurate with healthcare industry compliance requirements and regulations. For additional information see our website at www.ashvinsgroup.com and contact us at info@ashvinsgroup.com.