Managing the Validation and Migration from SAS® 9.13 to 9.2 on a New Server

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ABSTRACT

Managing the validation and migration from SAS ® version 9.1.3 to 9.2 on a new server presents many challenges. In May, 2010, such a project was completed. The manager of such a project should take the following into account: (1) purchasing hardware and software, (2) following company validation standards, (3) regular meetings with IT, Quality and other personnel, (4) the time required to write and execute validation documents, (5) file migration from the old to the new server, (6) start-up of the new SAS system, and (7) hiring personnel with validation experience, if needed. The successful manager should not underestimate the amount of time and resources to accomplish this type of project.

INTRODUCTION

Validation of a SAS system most commonly occurs during an upgrade from an older version of SAS or moving to a new platform. The example used in this paper include:

- Migrating from SAS 9.1.3 to SAS 9.2
- Moving from a legacy server (Windows) and operating system to a newer windows platform

It is recommended that you first acquire a global view of the system and identify the architecture. Only after gaining this perspective would it be useful to then zoom in and focus on individual components. This allows you to access the scope and interconnectedness of each component so that your validation efforts are balanced and thorough. Once the architecture is clearly understood, the requirements and functional specifications of each component are documented. These functional specifications then drive the validation testing.

It is important to follow these steps in a systematic and orderly fashion since they are interdependent. Documentation of each step in the validation process is also essential in capturing and proving that the validation effort was done properly. Besides documenting each step, it is also important to capture the traceability of each validation task. For each test case that is performed, there is an associated functional specification which then is connected to the requirements for a particular component of the system as a whole. The map or traceability matrix that ties all these validation components together is pivotal to an auditor. Proper documentation will make the difference between a successful validation audit and a complete failure.

The main goal of the validation effort is to ensure that the installation and implementation of the SAS system and its associated tools function as intended by the vendor (SAS Institute) and your organization. The validation will ensure this success. In addition to this goal, the documentation of your validation effort will also ensure the integrity of your computing environment and be in compliance with regulatory requirements such as the CFR Part 11 within the biotechnology and pharmaceutical industry.

Detailed information on the following items have been published elsewhere (Truong, Smoak 2010):

- SAS Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ)
- File migration and the use of checksums to verify that the files were migrated properly
- Incorporating third-party software
- Technical issues

THE PROJECT

A project to upgrade from an old Windows server to a new Windows server and an upgrade from SAS 9.1.3 to SAS 9.2 was undertaken in 2009 and completed in May, 2010. Third-party software was also installed on the new server. Thus the project involved both a hardware and software upgrade. All files from the old server were migrated to the new server.

The project involved validating (according to company standards) SAS and the third-party software on the server. The file migration involved the use of checksums to verify that the files migrated properly. A final check of the software and the migrated files was performed prior to putting the server into production.

MANAGEMENT PERSPECTIVE

Managers of SAS programming are busy people and they often wear multiple hats. Dedicating the proper amount of time and resources to the task of upgrading to a new version of SAS and validating SAS on a new server is important. Do not underestimate the amount of time and resources required.

Specific tasks which the manager should oversee include:

- Purchasing hardware and software
- Follow company validation standards
- Meeting with IT, Quality and other personnel on a regular basis
- Writing and execution of validation documents, such as:
    - Validation plan
    - User requirements and specifications
    - Change management
    - Traceability matrix
    - Test scripts
    - Validation Protocol (IQ/OQ/PQ)
    - Validation reports (IQ/OQ/PQ)
- File migration
- Start-up of the new SAS system
- Hiring personnel with validation experience, if needed

PURCHASING HARDWARE AND SOFTWARE

Your IT department should assist you with the purchase of the hardware and software needed for this project. The SAS website (www.sas.com) should provide you with the necessary information to get started. Personnel at the SAS Institute should also be available to assist matching your hardware and SAS software needs.

FOLLOWING COMPANY VALIDATION STANDARDS

It is vitally important to contact your company's Quality and IT departments from the beginning. Their input on the process of validating the hardware and software and the migration from the old server to the new one is essential. Spend as much time as needed to understand your company's requirements for computer software validation and migration of files from an old server to a new one. Failure to understand your company's standards may result in delays in completing the project of upgrading and validating SAS software on a new server.

REGULAR MEETINGS

One vital component to completing this task is to meet regularly with the relevant stakeholders. In particular, regular meetings with IT and Quality are highly recommended. The purpose of these meetings is to keep the project moving and to ensure that all of the necessary tasks are completed on time.

WRITING AND EXECUTING VALIDATION DOCUMENTS

Writing validation documents is a laborious task which requires time and attention to detail. Details like writing proper validation test scripts requires that the test scripts are tested and the documents updated as needed based upon the test runs. Final execution of the validation test scripts should be verified by an independent reviewer per company standards.

FILE MIGRATION

Migration of all the files from the old server to the new one takes considerable time. It is recommended that checksums be used to verify that the files were correctly migrated.

START-UP OF THE NEW SYSTEM

Start-up of the new system requires approval from IT. The end-users also need to be educated and trained on the use of the new server and the new software.

PERSONNEL WITH VALIDATION EXPERIENCE

A hardware and software upgrade, validation and migration project is challenging and time consuming. Therefore, if the manager does not have validation experience and/or personnel with validation experience then hiring someone with validation experience is recommended. A knowledgeable and experienced person should be sought out to assist with this type of project.

LESSONS LEARNED

There are multiple factors that create challenges when performing testing and validating the SAS system. The software mixed with third party vendor software combined with variations in the PQ test scripts create an infinite number of possible issues that you can run into in performing a testing. It is important to have a clearly defined test

plan and protocol, but you must also be flexible in the event that there are technical issues that require changes to the protocol.

Anticipate that unexpected deviations will occur. Have a clear and efficient method for managing deviations and their resolutions. Effective communication between team members from different departments is essential. This can be accomplished by having clearly defined meetings with all the key team members.

Good version control of all validation documents (MS Word, Excel and PDF) is recommended for the entire team. The use of a share-point site can be useful for accessing and controlling the versions of the validation documents. Many of these challenges and methods are not unique to validating SAS, but are issues involved in any complex technical endeavor that involves team effort. If there are existing processes, tools and procedures that you already use to tackle complex projects with many moving parts, use what has worked before for your validation project.

CONCLUSION

Validating a SAS system and migrating to a new version and a new server is challenging due to the many dependent components relating to hardware, software and people. For the manager of this type of project it is important to not underestimate the time and resources need to complete all of the various tasks. The validation requires multidisciplinary set of skills that involves a collaborative effort from many team members ranging from IT, Quality, project managers, SAS programmers and statisticians. This paper gives practical advice for the manager of project in which there is upgrading, validating and migrating of hardware and software. Although this type of project requires resources and investment in time, the result is worthwhile resulting in a system which will function with integrity and meet regulatory standards.

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