

Implementing SAS using Microsoft Windows Server and Remote Desktop

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ABSTRACT

DataCeutics provides SAS-based clinical and statistical reporting services to multiple pharmaceutical and biotechnology clients. This requires us to maintain a Microsoft Windows SAS programming environment that is easily and cost effectively managed by our systems administrators, supports multiple versions of SAS, supports related programming tools, supports electronic submission tools, allows our staff to work at the office or remotely, and provides our programming staff with a regulatory compliant environment.

In this paper we discuss the advantages of using a Windows Server platform with user access via Remote Desktop vs. distributed Windows installations. We describe the Microsoft Windows software required to support the platform; the tools that are needed to support the SAS-based programming/electronic submission environment, and outline the qualification of this environment to meet industry systems compliance standards.

INTRODUCTION

DataCeutics provides SAS-based clinical and statistical reporting services to multiple pharmaceutical and biotechnology clients. We need to support SAS programming environments on both the UNIX and Windows platforms. This presents several challenges to DataCeutics.

- Clients require specific versions of SAS. We are required to support both v8 and v9 of SAS. This includes different test releases or service packs. This can lead to supporting up to six instances of SAS.
- Many of our employees have the flexibility to work at the office or remotely. This requires us to provide a consistent SAS programming environment to our staff independent of their physical location.
- The pharmaceutical industry is highly regulated. This requires us to provide a SAS programming environment that can comply with FDA regulations such as 21 CFR Part 11 and our clients needs to meet their internal systems compliance standards. The effort required to meet these requirements can be time consuming and costly.

In this paper we will discuss the implementation of the Windows Server based SAS programming environment utilizing Remote Desktop. In the following sections we will focus in several topics.

- The advantages of using a Windows Server platform with Remote Desktop compared to using Windows Workstations.
- Present the Microsoft Windows software required to support the Windows Server platform.
- Discuss the tools that are needed to support the SAS-based programming and electronic submission environment.
- Review the qualification of SAS-based programming environment to meet industry systems compliance standards.

WINDOWS SERVER VS WINDOWS WORKSTATION

This section reviews the advantages of using a Windows Server platform with Remote Desktop compared to using Windows Workstations as a SAS programming and electronic submission platform. In the model we describe a single, centralized server is configured to support all SAS programmers. All SAS programs are run on this server, replacing the installation and maintenance of SAS on each user's Workstation.

First, we will give an overview of Remote Desktop. Using the Remote Desktop to connect to Windows 2003 Server, users can remotely logon to the server from any networked computer: from another office, from home, or while traveling. Each user authorized to access the server is given a desktop-like session that functions as though working directly on the server. This allows users access all applications and network resources that are on the server, regardless of location.

By configuring a complete SAS programming environment on the server including SAS software, programming tools, utilities, code management systems, electronic submission tools, etc. a standard, controlled environment can be efficiently maintained and assured for all users. This single instance replaces distributed installation and maintenance of SAS programming software on each user's workstation and minimizes effort required to maintain a fully qualified statistical programming environment.

Some of the advantages of using Remote Desktop include:

- Without utilizing automated PC management utility, the management and maintenance of multiple SAS software installations on multiple workstations can be time consuming and costly. Maintaining all required instances of the SAS software and related programming applications on one server greatly reduces the management and maintenance costs.
- There can be network performance issues when running SAS on a workstation to access files on a shared network drive. This can easily increase network load and affect performance and response time for all network users. Additionally, when working from a remote site, utilizing DSL or a cable modem, the performance can be slow as data, logs and output are transferred across the wide area network. Utilizing a server and Remote Desktop, you can always expect optimum performance, especially when the network drive is directly attached to the server.
- Using a server-based environment assures that all users are using the same qualified SAS programming environment and that the users only have access to the SAS versions/instances and applications that are to be used for their specific projects. The Remote Desktop software allows the system administrator to give users access to only the applications they need. This can be done on a user or user group level.
- Remote Desktop allows users work from almost any location. The Remote Desktop client software is built into Windows XP and can easily be installed on Windows 2000. The user can use their home PC to access Remote Desktop or they can use a loaner laptop to access Remote Desktop when traveling.
- Using a server-based environment you can easily add applications to the SAS programming environment. The system administrator can install and qualify a new instance of SAS software or a utility application in less than a day. Rolling out the application to the users is then a matter of giving the users access.
- Using a server-based environment you can quickly scale-up the computing power the server. Additional processors, memory and disk space can be added to the server as staff or computing needs increase.

The advantages listed above have led to less cost on maintaining our SAS programming environment and have led to greater productivity. The productivity increases are primarily due to increased system performance and a greater availability of the SAS software and the clinical reporting environment.

WINDOWS SOFTWARE

This section provides an overview of the installation and configuration required to implement Microsoft Remote Desktop on a Windows 2003 server. The Microsoft required products highlighted in bold.

Microsoft Terminal Server: The first part of the base Terminal Server install only requires a standard installation. The standard install will allow for up to two administrative group members to connect to the terminal server remotely via a LAN connection or VPN into the local LAN. This method can be used if only two people will be accessing the server for remote SAS development. If more the two people will be accessing the Remote Terminal Machine, then the licensing service for Microsoft Terminal Server is required. This service is called Terminal Service Licensing.

Microsoft Terminal Server Licensing: After the Terminal Service Licensing service is installed, the network administrator will be required to install MS Terminal Server licenses. The licenses can be purchased per five users and range from \$65 to \$75 per user. The license should be installed as a per-connection and not a per-user or per-client. The per-user or per-client connection has a habit of locking up the license even when a user closes SAS and exits the Terminal Service session. The per-connection method will allow for the user to exit SAS and logout without locking up the license.

After Terminal Server has been configured, users will need to be assigned to the Remote Desktop Users Group (RDUG). The RDUG has the permissions predefined to allow for user connection via the workstation client using Remote Desktop Connection. When the Terminal Server Licensing is installed, only the users assigned to the RDUG will be allowed to access the server via Terminal Service. When users are added to the RDUG, the administrator can configure access the user's remote session. This configuration can allow for an administrator to take control of a remote session, or to simply watch a remote session in progress.

Remote Desktop Connection Client: The Remote Desktop Connection client needs to be installed on the user's workstation. The software is included in Windows XP operating system. It needs to be installed on the Windows 2000 operating system. The client install is located on the Server 2003 installation media. This service can be configured for one user per client machine or for all users on a client machine.

The user connects to the Remote Terminal Server by entering the Server name. The Remote Desktop Connection can be customized to work over multiple network (LAN) configurations and including a VPN connection or even a dial-up connection.

Routing and Remote Access: The Routing and Remote Access service is used to provide for a quick and easy VPN setup. Routing and Remote Access can be setup as a per user connection. There is no special Client Access License (CAL) needed other than the standard CAL for normal server access. Routing and Remote Access allows for multi-

point VPN for site to site (between two or more offices) or for a point to point VPN (from client to office). Routing and Remote Access also allows a remote VPN client to surf the web via the companies Internet lines when properly configured. This will also allow for the user to use a company's internal Intranet and shared work space portals.

SAS PROGRAMMING AND ELECTRONIC SUBMISSION ENVIRONMENT

In this section we discuss the tools that can be used to support the SAS-based programming and electronic submission environment (SAS Environment). If you currently use PC SAS on a work station then these tools can be the same tools you use now. Additionally, the SAS environment may utilize various server-related tools.

In your production environment you will most likely need to support both **SAS v8** and **SAS v9**.

A **standard folder structure** should be used to organize and store the project information and deliverables. When designing the structure you should focus on what the programming environment is delivering. Depending on your company workflow, the SAS environment may be delivering individual files to be published or completed sections of the published electronic submission or eCTD.

The SAS environment will require **utility tools** to facilitate the development and execution of SAS programs. These tools may include editors, file viewers, printing applications, file conversion applications, file comparison applications and batch submission applications.

A **code management application** is a must for the SAS environment. There are several applications that provide security, check-in, check-out and versioning. At the minimum, they should be used to manage program files. Some of the applications allow you to manage data files, log files and output files.

There are several types of **productivity tools** that can be used in the SAS environment. The SAS Enterprise ETL Server can be used to extract, transform and load data from across the enterprise. SAS Enterprise BI Server includes both a suite of business intelligence tools and a powerful, integrated business intelligence platform to provide fast, simple access to consistent data. SAS Enterprise Guide can be used by less technical users to generate analysis and reports. SAS-based tools such as DataCeutics CR Toolkit™ can be used for the production of listings, tables and graphics that used in clinical reporting.

If you are responsible for delivering individual files or completed sections of the electronic submission then you will utilize **desktop publishing** tools and possibly **eCTD management** tools. Adobe Acrobat is a the basic tool for desktop publishing. May of the desktop publishing tools are Adobe Acrobat plug-ins. The desktop publishing tools assist in the creation, management and delivery of PDF-based documents. These documents may include scanned CRFs, Data Definition Document files and Output files. These tools can also assist in creating and managing your CRT data files that are delivered in V5 SAS Transport format. The eCTD tools can provide the capability to created, receive, validate, review and archive eCTD submissions. Two of the leading companies in this are Datafarm Inc. (www.datafarminc.com) and Image Solutions (www.imagesolutions.com).

A **user manual** should be provided to the SAS users as both a training reference and ongoing usage reference. It should document the processes and tools that are used when working in the SAS Environment. It does not need to be a detailed technical manual as most of the tools used in the SAS Environment will have online help or a user manual. It should focus on the work flow and how to produce the deliverables.

We do want to mention that there are several **work flow management** applications on the market that that can be surfaced to the user utilizing Remote desktop. These tools include DataCeutics Report Portal™ and SAS Drug Development. These tools provide many of the utility, code management and productivity tool functions that are described above. Additionally, they provide audit trail and report generation capabilities.

QUALIFICATION OF THE SAS PROGRAMMING ENVIRONMENT

In this section we discuss the qualification of SAS-based programming and electronic submission environment (SAS Environment) to meet industry systems compliance standards. The validation process for any company is typically described in a Systems Validation Standard Operating Procedure (SOP). Although the systems validation process varies from company to company, it should contain some basic common documents utilized in the validation process. These documents are described below.

The **Validation Plan** contains an overview of how the SAS Environment will be validated. The plan documents the scope of the validation effort, the personnel comprising the validation team and their responsibilities, the company business areas involved in the validation, and the personnel responsible for final acceptance and sign off. It describes all of the validation activities to be executed, all of the validation documents and the order in which the activities are executed and documents are accepted.

The **System Requirements** defines the system's technical aspects based upon the user requirements. The system requirements may include, but not be limited to, hardware, system interfaces, system configuration and input / output definition. The system requirements should be numbered to allow for traceability. An example of a system requirement for the SAS Environment is listed below.

2.2.1	User must be able to print the output using the application level printing for HTML, LST, PDF, SAS, LOG and RTF file types.
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The **System Specifications** details the hardware, software and tools that will be utilized in the SAS Environment. Additionally it should reference and processes or standards, such as standard directory structures, that will be utilized in the SAS Environment. It is based upon the system requirements. The system specifications should be numbered to allow for traceability.

The **Traceability Matrix** documents the relationship between the system requirements, the system specifications, and the test scripts that are contained in the operational qualification and the performance qualification documents. It is used to trace from requirement to specification to a test.

The **Installation Qualification (IQ)** of hardware or software provides documented evidence of proper installation and configuration. It assures adherence to the manufacturer specifications for installation and conformance to specified environmental conditions that are essential to the proper functioning of a computer system. There is usually one IQ for hardware and one IQ for each software application. The IQ usually contains or references the hardware or software provider's installation instructions. The IQ usually details the application configuration parameters and values.

The **Operational Qualification (OQ)** of software provides documented evidence that the software is operating properly and the software functions meet the system requirements. There is usually one OQ for each software application. The OQ contains test scripts to exercise the appropriate software functions that are detailed in the system requirements. The final OQ contains the results of the execution of the OQ.

The **Performance Qualification (PQ)** provides documented evidence that the system performs as intended throughout its operating range in the SAS Environment. There is usually one PQ for the SAS Environment. The PQ contains test scripts to exercise the appropriate system performance parameters that are detailed in the system requirements. The final PQ contains the results of the execution of the PQ.

The **Validation Summary Report (VSR)** documents the successful completion of the SAS Environment validation activities. The report summarizes the successful execution of the IQ, OQ and PQ activities. It summarizes and resolves those activities that resulted in a non-conformance. It should provide evidence that the SAS Environment was installed and configured as per the vendor's recommendations and that it operates correctly in accordance with system requirements and system specifications.

The **Change Control** process is the ongoing practice of testing and documenting changes to the SAS Environment after it is in production. In most cases it is not needed for routine activities that are covered by normal operational procedures, for example adding a new user to the SAS Environment. A change control may be used for upgrading SAS service pack or upgrading an editing package.

CONCLUSION

At DataCeutics we support both UNIX and Windows platforms. We have been successfully utilizing Windows Server with Remote Desktop for over a year. We are able to support multiple versions of both v8 and v9 of SAS on the same machine. We have realized both cost and time savings by migrating from many workstations to a single server.

By providing a SAS Environment that is independent of location, our employees have the flexibility to work at the office or remotely. This has increased our productivity.

By properly qualifying the SAS Environment we are confident that we have met regulatory and compliance needs of the Regulatory bodies such as the FDA and the compliance standard of our clients. Additionally, in the last year we have been audited by several clients and have passed all audits.

REFERENCES

Microsoft Windows Server 2003 Terminal Services and Remote Desktop information can be found at <http://www.microsoft.com/windowsserver2003/technologies/terminalservices/default.aspx> .

KEY WORDS

Windows Server, Remote Desktop, Programming Platform, Regulatory Compliance, Electronic Submission.

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