Agaram Technologies

LogiLAB SDMS Web Installation Qualification

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1 Purpose

The objective of this protocol is to verify the installation of the LogiLAB SDMS program and to verify that it performs its intended function in a consistent and reproducible manner. Specific test objectives and acceptance criteria are defined.

1.1 Installation Qualification

The Installation Qualification consists of tests to ensure that the components of the LogiLAB SDMS program have been properly installed. Specific test objectives and acceptance criteria are defined.

2 Scope

This protocol specifies the Installation Qualification tests that are to be applied to the LogiLAB SDMS program, which will be used in a cGMP environment, for the purpose of verifying proper installation. The LogiLAB SDMS program was installed to capture, store raw-data, meta-data, files and transfer necessary data over the LAN to a database. Within the scope of this protocol are the activities and tasks that must be performed throughout the qualification process.

Changes made to the software and/or computer systems after validation is completed must be conducted under the appropriate system change control procedure. Parts of the protocol may be used for reconfirmation or revalidation, if necessary.

3 Validation Methodology

Tests within this protocol have been designed to verify that all-important elements of the LogiLAB SDMS program installation adhere to the requirements set forth by the manufacturer, when successfully completed. For each installation test in this protocol, a cover sheet is provided to define the test objective, procedure, and acceptance criteria. Following each cover sheet are the data sheets. These data sheets outline the information that must be verified and/or documented, as well as provide space for recording additional information. The information recorded on the test data sheets combined with referenced supporting test documentation provides a method whereby adherence to the test acceptance criteria can be verified.

Any deviation from the specified acceptance criteria/expected results must be recorded on a deviation report.

4 Acronyms

Acronym/Initials	Meaning
CFR	Code of Federal Regulations
FDA	Food & Drug Administration.
CGMP	Current Good Manufacturing Practice
FIELD	Meaningful data
HTML	Hypertext Markup Language
LAN	Local Area Network
IQ	Installation qualification
IIS	Internet Information Server
N/A	Not applicable
N/AV	Not available
N/S	Not specified

OQ	Operational qualification
PC	Personal Computer
PDF	Portable Data File
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedure
UPS	Uninterruptible Power Supply
LIMS	Laboratory Information Management System
BLOB	Binary Large Objects
DSN	Domain Source Name
TCP/IP	Transmission control Protocol / Internet Protocol
ASCII	American Standard Code for Information Interchange
SDMS	Scientific Data Management System
FTP	File Transfer Protocol
DB	Database

5 System Description

5.1 Introduction

LogiLAB SDMS is generic software designed to handle the scientific instrument data from any analytical instruments and can facilitate data management with access control. System will perform periodic data backup and facilitate restore the same. The data collected would be stored as flat files in a FTP server in a non readable format. Data access view is controlled through user rights providing data security. The data entered by the user is sent to a centralized database server and a FTP server. All data generated from instrument or any other source in laboratory operations is captured and store centrally. Secured storage with version control of all the SOPs, Instruction manuals and MSDS can be achieved with SDMS and secured access to data as required enables availability of any required data to users. Strong search facility ensures availability of required data instantaneously.

5.2 Work Flow

LogiLAB SDMS will collect the Laboratory Data generated from Instrument PCs and store centrally on FTP / DB servers. Data collection will be scheduled based on each client/instrument requirement to automate the storage process. Storage structure of Archival data being maintained as is including Directory structure as per Client setup ensures easy search on LogiLAB SDMS view panels as well as restoration of data back on client as and when required. Modified files are stored with version controls and maintaining number of versions can be defined to reduce the unwanted data storage. Data on client machine can be automatically removed periodically upon backup reducing load on client machines.

5.3 21 CFR Part 11 Compliance Management

LogiLAB SDMS 21 CFR Part 11 component has a security module which covers the security needs, user rights allocation, CFR policy settings like password length, ageing, auto log-off timer, audit trail, reason resource creation and electronic signature support.

Audit trail viewer will support export of audit trail into human readable format. All audit trail data is stored inside the database, is accessible and can be traced back to the actual user, date/time stamped, action performed and reason for the action.

6 Responsibilities

The LogiLAB SDMS Customer has the following responsibilities:

1. Overall supervision for carrying out this qualification protocol.
2. All regulatory matters within its facilities.
3. Reviewing and approving all qualification documentation (protocol, executed protocol, and final report).
4. Providing trained users, specialists, and technical support, as required for the preparation, review, and carrying out this qualification protocol.
5. Carrying out this qualification protocol, the actual performance of this study, the collection of all test data, and the review and sign-off of verification/test data sheets.
6. Preparing a final report that summarizes the protocol execution.

7 Test Plan

The test plan includes IQ protocols of the LogiLAB SDMS program. The testing is detailed in the following sub-sections:

The IQ tests to ensure the components of the LogiLAB SDMS program are installed properly, including:

1. Prerequisites review
2. Verifying Computer system specifications and Power Supply
3. Software review
4. Installing LogiLAB SDMS
5. Verifying components of the LogiLAB SDMS software after Installation

7.1 Prerequisite Review

Computer Type: Application Server

Record the server name: _____
Attach evidence for all components.

Components	Actual Result	Pass / Fail	Verified Date	Reviewed Date
1. OS: Windows Server 2012 or above		☐ Pass ☐ Fail		
2. IIS installed		☐ Pass ☐ Fail		
3. FTP installed		☐ Pass ☐ Fail		
4. .Net 3.5 framework installed		☐ Pass ☐ Fail		
5. Tomcat v8.0 Configuration		☐ Pass ☐ Fail		
6. JRE8		☐ Pass ☐ Fail		
7. Chrome Web Browser installed		☐ Pass ☐ Fail		

Verified By	Reviewed By

Link to access Validation Environment: http://appsvr:8080/SDMS_Web/Login.html

Computer Type: Database Server

Record the server name: _____

Attach evidence for all components.

Components	Pass / Fail	Verified Date	Reviewed Date
1. SQL Server 2014 or higher installed	☐ Pass ☐ Fail		
2. SQL Server Management Studio installed	☐ Pass ☐ Fail		

Verified By	Reviewed By

7.2 Verifying Computer Specifications

Computer Type: Client Computers

Computer Name: Refer Annexure-A for the clients list.

Components	Pass / Fail	Verified Date	Reviewed Date
1. Web Browser	Pass		

Verified By	Reviewed By

7.3 Verifying Installation of LogiLAB SDMS

Objectives

Verify that the LogiLAB SDMS installation was performed successfully.

Procedures

Perform an inspection of the LogiLAB SDMS software installation and document any discrepancies from the installation guide.

Record all results, as required, in the appropriate location on the data sheets. If more than one data sheet will be required, record the results on photocopies of the applicable original data sheet.

Acceptance Criteria

The LogiLAB SDMS software is installed correctly.

Computer Type: Application Server

Record the computer name: _____

Attach evidence for all steps.

Step	Specified Action	Expected Result	Actual Result	Pass/Fail	Verified Date	Reviewed Date
1	Verify the LogiLAB SDMS folder exists in **D:\Agarm Technologies\SDMS Programs\SDMS Services**, having all the required files	LogiLAB SDMS folder will exists in the specified path with all the required files		☐Pass ☐ Fail		
2	Verify the version of LogiLAB SDMS Web installed	5.1 beta		☐Pass ☐ Fail		
Verified By			Reviewed By			

Computer Type: Application Client

Record the computer name: _____

Step	Specified Action	Expected Result	Actual Result	Pass/Fail	Verified Date	Reviewed Date
1	Verify the LogiLAB SDMS folder exists in C:\Program Files, having all the required files	LogiLAB SDMS folder will exists in the specified path with all the required files		☐Pass ☐ Fail		
2	Verify whether services related to LogiLAB SDMS are started and running by going to Control Panel -> Services.	Robotic File Upload Robotic File Watcher Robotic File Monitor services will be exists in Services. msc		☐Pass ☐ Fail		
4	Verify Chrome Web Browser Installed	Google Chrome web browser is available in system		☐Pass ☐ Fail		

Verified By	Reviewed By

8 Qualification Support Data

Att. No.	Description	No. Of Pages	Document Name
1.	Screenshot of IQ report from Application Server, DB Server and Client		LogiLAB SDMS Installation Qualification Attachment v5.1
2.	Annexure document for all the client PCs list		Annexure-A

9 Discrepancy Log

In the following Discrepancy Log, record the discrepancy numbers for any discrepancy reports.
Include a brief description of the issue. When the discrepancy is resolved and approved, write the date resolved.

Deficiency number	Brief description	Date resolved