



Agaram
TECHNOLOGIES

How Logilab SDMS helps Laboratories to enable GLP Compliance

White Paper

Part 3

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GLP Principles During Project Implementation Phase of Logilab SDMS

Validation

Logilab SDMS has been designed and demonstrated to be fit for purpose in a GLP environment and introduced in a pre-planned manner. The system's operational validation process during its original product development as well as any project implementation stage includes requirement specification, design documentation, industry coding standards, unit and system testing processes with test documents and reports. Typically, Installation Qualification (IQ) and Operational Qualification (OQ) documents are prepared by Implementation Project Team. While carrying out validation process the complexity and intended use of a system with adequate risk management are considered.

Change Control

GLP principles require laboratories to follow change control process during Computerized system implementation. Change control is the formal approval and documentation of any change to the computerized system during the operational life of the system. It is needed when a change may affect the computerized system's validation status. Change control procedures must be effective during the project implementation phase as well as after system go-live.

The requirement of proper Support mechanism to be in place is being carefully considered to ensure that the Logilab SDMS has been used correctly by the end users. The implementation team as well as Agaram's Quality Assurance (QA) team work in collaboration with Product Development to resolve any issues encountered during implementation stage. The implemented changes are system tested by QA team and testing procedure as well as results are documented in test cases.

System Description

A System architecture detailing the physical and logical arrangements, data flows, interfaces with other systems or processes, any hardware and software prerequisites and security measures are identified, documented and communicated to the customer well in advance. An up-to-date system description is also maintained throughout the product life cycle as well as implementation in Installation guide.

User Requirement Specification

User requirement specifications are of paramount importance for all validation activities and should be generated for all GLP-relevant computerized systems. Hence Agaram 's Logilab SDMS Development team considered all aspects of Laboratory best business processes and the detailed functional requirements during the software design and development. Customer specific functional requirements are also considered during the Project implementation. An initial validation risk assessment is based upon an understanding of the business processes, user requirement specifications and regulatory requirements.

User requirement specifications is documented covering all GLP-relevant functions of a system and is be used in the risk assessment to identify critical functions and appropriate testing activities. This requirement specification and functional design in conjunction play a vital role in software design, development, configuration and testing.

Quality Management system and support procedures

According to GLP Principle, both the development of a computerized system as well as the validation process should be governed by a quality management system. In Agaram Product Development, Project Implementation team works with Quality Assurance team during the validation process. This as per Agaram' s Software Development as well as Implementation Process developed for ISO 9001: 2015 Quality Management System for which Agaram is certified by TUV.

Customized Systems

Logilab SDMS can be implemented by the Laboratories without any customization in the functionalities. It is fully configurable by the Administration Users of Laboratories. However, during the implementation stage, any custom reports or workflows or any laboratory-specific or customer-specific custom extensions are developed, it goes through software development life cycle with adequate processes like requirements gathering, functional design documentation, Technical Design documentation, Test case documents during QA testing and UAT acceptance.

Testing

In Agaram, testing activities related to Logilab SDMS (e.g. installation testing, System Integration Testing and user acceptance testing) are carried out to ensure that a system meets predefined requirements. Test documents are prepared by QA team describing how tests are conducted and the test results are recorded. The project Implementation team also prepares Installation Qualification (IQ) and Operational Qualification (OQ) documents with screenshots as evidences.

When testing leads to system changes in codes or configuration or any custom extension, these should be managed via change control.

Data Migration

Data migration may be required during the project implementation. This data may be configuration data, meta data or transactional data. Where electronic data are transferred from one system to another, the details including what data needs to be migrated, the reason for migration (for example, new application implementation, upgrade from one version to another, etc.), migration technical details (namely database tables, codes, procedure, to which format, etc.) are documented in Technical Design Document. Necessary precautions and efforts are taken so that migrated data should remain usable and should retain its content and meaning. The value and/or meaning of and links between a system audit trail and electronic signatures are also ensured in a migration process.

Exchange of Data

Logilab SDMS has the capability to automatically capture data from wide-range of instruments and Computer systems. The instruments with RS232 and TCP/IP protocols are serviced by SDMS without issues. It supports files of any format. It supports even the non-standard non-compliant instruments and those in which SDMS application client cannot be installed (using Pull method).

The core functionality of Logilab SDMS is Scheduler. The Scheduler can capture data generated by instruments automatically. Scheduler can be configured with respect to time. Live-capture module is used as and when data is generated being used by any other software.

Logilab SDMS can also be integrated to external systems like LIMS, ELN and ERP. It has appropriate SDKs, APIs and Restful services available so that it external systems can be integrated along with Logilab SDMS.

In **Part 1**, we have understood the fundamental concepts of GLP and its principles as applicable to Computerized systems

In **Part 2**, we have understood the overview of Logilab SDMS and its importance in GLP principles as applicable to Computerized systems

In **Part 3**, we have understood how GLP principles can be applied during the Project Implementation phase of Logilab SDMS.

In **Part 4**, we shall look into how GLP principles can be applied during the Operational phase of Logilab SDMS.

(To be continued and concluded in Part – 4)