Agaram TECHNOLOGIES

How Logilab SDMS helps Laboratories to enable 21 CFR Part 11 Compliance

White Paper

Part 2

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12 – Dec - 2020

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Overview of Logilab SDMS

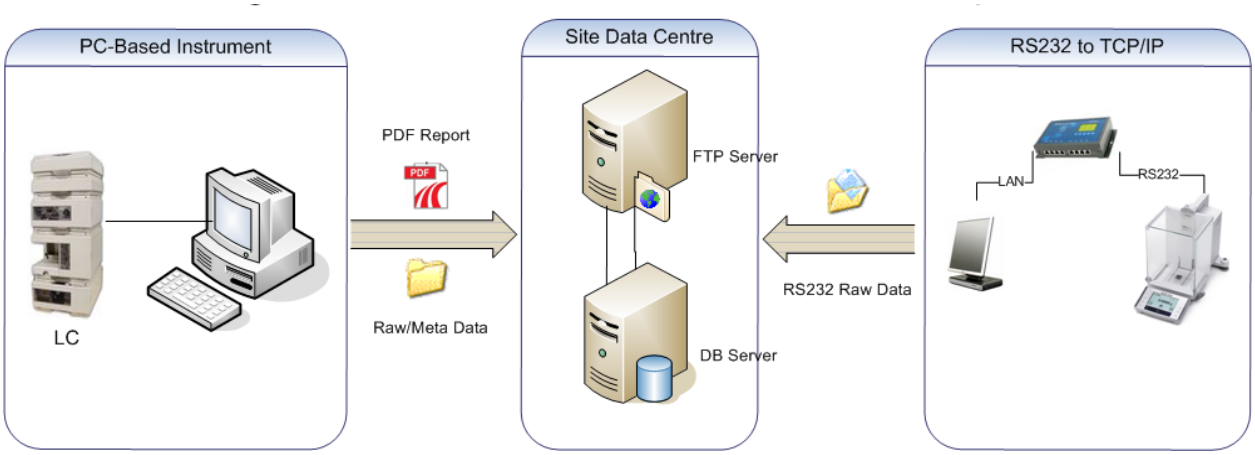
Agaram Technologies' Logilab SDMS is a generic software application designed to handle scientific instrument data from any analytical instrument and can facilitate data management with access control. Logilab SDMS will perform scheduled data capture, cataloguing, archival and facilitate restoring data and has capabilities to extract data of interest from instrument output to be pushed to external systems like Electronic Note Book (ELN), Laboratory Information Management System (LIMS) and Enterprise Resources Planning (ERP).

The data files captured are stored as flat files in a secure FTP file server as an encrypted file name. Data access and viewing is controlled through user rights providing data security. The meta-data like data source, date/time, file size, checksum and user entered tags along with parsed and extracted data is stored in the database.

Full text indexing allows strong search facility and ensures availability of required data instantaneously. Built-in integration tools allow the users to integrate external systems as well.

Logilab SDMS helps laboratories to capture and organise data in a central repository. Laboratory instruments generate raw and meta data which is a mandatory to be maintained in a controlled environment. Logilab SDMS is independent of the instrument manufacturer and model. Instruments could be a standalone with RS232 or LAN port or pc-controlled instrument. Apart from the instrument output laboratories prepare and maintain a whole lot of documents.

All the information can be stored and accessed from a central server-based repository by implementing Logilab SDMS.



Logilab SDMS Product Capabilities

- ✓ Versatile Data Capture – Any instrument data of any format including PC-Based, RS232 and TCP/IP.
- ✓ Fully automated secure file handling by SDMS Scheduler
- ✓ Easy Navigation, Secure, Faster & Wider search by Data Explorer
- ✓ Human Readable Data for 21 CFR Part 11 compliance – By PDF & Print Functionality
- ✓ Better organization, categorization and standardization of data – By Tagging & Templates
- ✓ Better security and control of operations – By User & Password Management
- ✓ Better Tracking, Easy Troubleshooting – By Audit Trail
- ✓ Easy extraction of data of interest – By Parsing Engine
- ✓ Complete Access Control of all applications including non-complaint ones – By CFR Gateway
- ✓ Mobile usability to contemporaneously record data – By SDMS Mobile application
- ✓ Electronic data and electronic signature using workflow as well as for all the changes/edit of system parameters - 21 CFR Part 11 Compliance
- ✓ Integration capabilities with ELN, LIMS and ERP systems.

Importance of 21 CFR Part 11 requirements in computerized systems and Logilab SDMS

According to 21 CFR Part 11, all computerized systems used for the generation, measurement or assessment of data intended for regulatory submission should be developed, validated, operated and maintained in ways which are compliant with the regulatory requirements. Logilab SDMS is one such a system designed, developed, validated, operated and maintained in the manner mentioned above.

Any laboratory looking forward to implementing a computerized system, during the planning, conduct and reporting of studies there may be several points to be considered to fulfil various purposes. Such purposes might include the direct or indirect capture of data from automated instruments, operation/control of automated equipment and the processing, reporting and storage of data.

For these different activities, computerized systems can vary from a programmable analytical instrument, or a personal computer to any laboratory information management system (LIMS) - with multiple functions. Whatever the scale of computer involvement, the 21 CFR Part 11 requirements should be applied. This is exactly where Agaram' s Logilab SDMS proves to be an ideal choice.

21 CFR Part 11 have been considered during the product development phase of Logilab SDMS. In the subsequent product enhancements during its lifecycle, 21 CFR Part 11 requirements and other regulatory compliances have been and are being considered to ensure continuous quality, integrity and security of research data stored in the electronic archive facilities.

One need to consider that fact that compliant adherence to 21 CFR Part 11 s not exclusively based on the software system only but also depends on procedural controls (such as Standard Operating Procedures, well trained personnel, physical conditions of research facilities) within a laboratory or other research organizations using electronic management systems for research purposes.

A software application or system cannot be officially certified to be compliant (and any software vendor officially claiming 21 CFR Part 11-compliance is incorrect! It may help laboratories to enable compliance). However, software vendors can offer a system which meets the technical requirements for Laboratory data management software systems and the management of electronic records set by the US FDA in a compliant set-up.

In this white paper, we focus our attention only towards the application of the 21 CFR Part 11 requirements to the Computerized system (in this particular case, it is Logilab SDMS).

In **Part 1**, we have understood the fundamental concepts of 21 CFR Part 11 and its principles as applicable to Computerized systems

In **Part 2**, we have understood the overview of Logilab SDMS and its importance in 21 CFR Part 11 as applicable to Computerized systems

In **Part 3**, we shall look into how Logilab SDMS fulfils the requirements of 21 CFR Part 11

(To be continued in Part – 3)