Agaram TECHNOLOGIES

How Logilab SDMS helped a leading Biopharmaceuticals Organization who was an early innovator of vaccines for COVID-19, achieve Data Integrity, Compliance & Automation

Case Study

V. Raghavan

Agaram Technologies Private Limited

Dec - 2021

Logilab SDMS

TABLE OF CONTENTS

INTRODUCTION

WHATS' UP WITH VACCINE DEVELOPMENT

A leading Biopharmaceuticals organization who are an early innovator of COVID-19 vaccine wanted to achieve automated process for achieving data integrity and compliance for their manufacturing plant QC and research laboratories. They were looking for a computerised system which is capable of handling the following complex compliance requirements along with reliable infrastructure support;

Technical Requirements

- ✓ Able to work on cloud infrastructure
- ✓ Able to work with database running as Relation Database as Service
- ✓ Can store data in cloud

Core Functional requirements

- ✓ Support GMP requirements for quality control
- ✓ 21 CFR Part 11 compliance for instrument data
- ✓ Building a single source of truth
- ✓ Data Integrity
- ✓ Sharing data with other systems like LIMS

Solution from Agaram Technologies:

Implementation of Logilab SDMS with CFR Gateway to ensure data integrity compliance.

Q: What can you achieve using a computerised system like SDMS for collecting and storing the instrument data

A: Logilab SDMS has been designed mainly to

- ✓ Capture, Catalogue, and Archive instrument raw data,
- ✓ Store metadata along with machine and human readable data

- ✓ Tag data in a manner such that, the data can be indexed and archived for long term purposes.

"Logilab SDMS introduced a very high level of data integrity and compliance. Implementation resulted in positive outcomes. We won the best digitisation award in the pharmaceutical space "

– Director of GxP Digital Systems of leading Biopharmaceuticals

GET THE PICTURE

Before Logilab SDMS was implemented, the company was using the traditional IT systems for manually storing data captured from various instruments and other disparate systems. There were multiple manual processes that were completely dependent on the personnel involved in the GxP environment with less control and traceability.

There was no "Single source of truth" along with metadata for all the data being recorded. Hence a system that can fully automate the data capture, storage, controlled access, versioning of data from instruments with proper regulatory compliance was much needed.

AUTOMATED DATA CAPTURE WITH DATA INTEGRITY

Logilab SDMS from Agaram Technologies ensures automated data capture and data integrity as below:

- Logilab SDMS instrument data schedulers monitor instrument data folders or ports and capture data generated in real-time and will store the data "as-is" in a central repository
- Logilab SDMS also stores the metadata about the data i.e. which instrument generated the data, who generated, date/time along with standard attributes like file name, type, size, modified date.
- Additional user defined metadata called as tags can be added to view the data in a meaningful manner based on metadata hierarchy e.g., Project>Test>Instrument or Product>Batch>Test>Instrument

- Logilab SDMS "CFR Gateway Module" was introduced for all desktop and laptops in the GxP environment, this ensured
  a. Controlled access to any software application that a person is authorised to use
  b. Data generated by the instruments are also securely stored in central repository.
  c. CFR Gateway will eliminate the need for hardening of Windows for GxP environment. e.g., the system will control copy/paste, renaming, deleting, right-click of files in the PC.
  d. Software that do not have 21 CFR Part 11 features like user authentication, audit trail, versioning of data and meta etc can be made fully compliant when "CFR Gateway" is used

IMPLEMENTATION PROCESS

PHASE-I IMPLEMENTATION: Logilab SDMS

Initially a pilot system was setup to evaluate the customer's key requirements

Pilot Instruments configured:

- ✓ Wyatt DynaPro NanoStar - Dynamics V7 software
- ✓ Advanced Analytical Fragment Analyzer - OpenLAB CDS Chemstation edition c.01.07
- ✓ SpectraMax M5 Molecular Devices Microplate Reader - Softmax pro 6.4
- ✓ Balance - Mettler Toledo via TCP/IP
- ✓ CFR Gateway installed in their instrument PCs

Phase 1 of project was planned to add every piece of instrument and PCs in the GxP environment

Phase 1 - SDMS key requirements

- ✓ Push and Pull Mechanism of Logilab SDMS
- ✓ Data capture from RS232 or TCP/IP standalone instruments
- ✓ "CFR Gateway" module for data integrity and 21 CFR Part 11 compliance
- ✓ Tagging of data before data capture using mobile and desktop apps
- ✓ Fully operation with AWS cloud infrastructure

Scaled up for entire QC lab

- ✓ All GMP related instruments connected to SDMS
- ✓ Single source of truth built
- ✓ IQ & OQ done along with configuration.
- ✓ PQ done by customer
- ✓ Electronic review of data

Phase – I Outcome

All instrument PCs were installed with CFR gateway to achieve

- ✓ 100% data integrity
- ✓ 21 CFR Part 11 compliance
- ✓ Also audited by US FDA with very positive comments about data integrity due to CFR Gateway

PHASE-II IMPLEMENTATION: CDS INTEGRATION

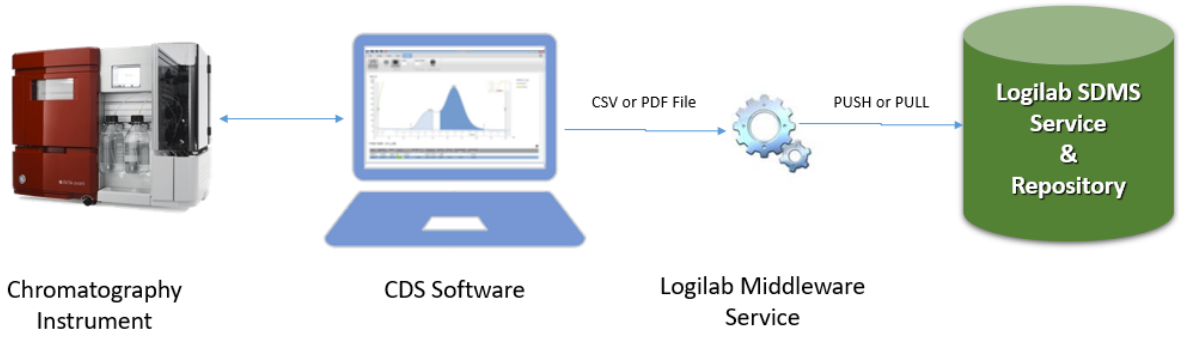
Key Requirements for Phase II:

Integrate the Chromeleon chromatography Data System (CDS)

- ✓ Options for integration
- ✓ SDK based integration
- ✓ PDF file-based integration

Logilab SDMS Integration with CDS & LIMS

- ✓ Logilab middleware service was introduced & Integrated with Chromeleon SDK
- ✓ Run files that were reviewed and approved were processed and sent to LIMS
- ✓ The links to raw data were also shared with LIMS



PHASE-III IMPLEMENTATION: LIMS INTEGRATION

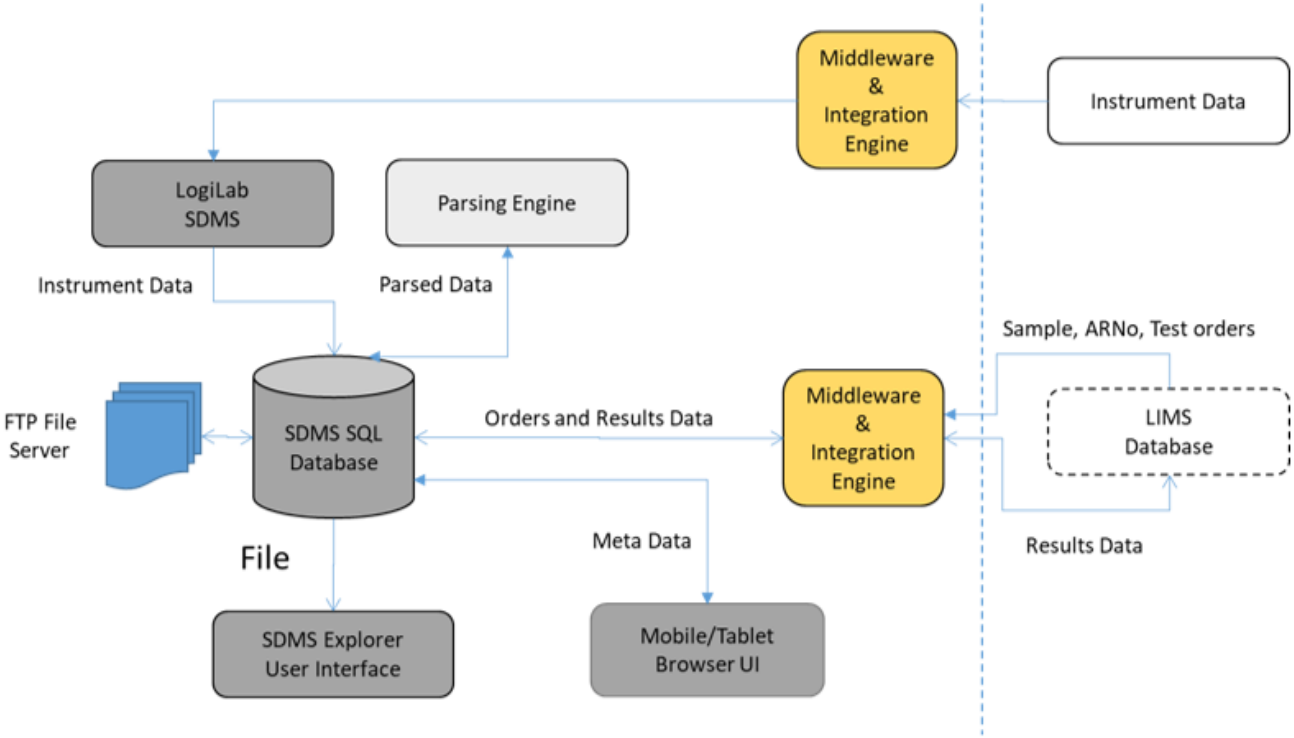
Key Requirements for Phase 3

- ✓ Several non-chromatographic instruments had to be integrated with LIMS
- ✓ Bi-directional Integration of Logilab SDMS with Laboratory Information Management System (LIMS)

Logilab SDMS Integration with Instrument and LIMS

- ✓ Our parsing tool was used to interface the instruments. The parser could handle the following output from instruments
  - Pdf files
  - CSV & excel files
  - ASCII files

- ✓ Interfacer middleware was configured to handle
  - Receive XML orders from the LIMS containing samples and tests
  - Instrument output was parsed and stored in SDMS
- ✓ Middleware will prepare an XML file with results and send it to LIMS by making a REST service call



PROJECT OUTCOME

- ✓ Logilab SDMS is found to be an easy to deploy and implement solution
- ✓ It covers all instruments in lab including standalone (RS232, TCP/IP, PC-based)
- ✓ Compliance to GLP, 21 CFR Part 11, EudraLex Vol. 4 Annex 11
- ✓ Controlled access to data has been achieved
- ✓ Version control for data has been achieved
- ✓ CFR Gateway is perfect for data integrity controls
- ✓ SDMS investment also covered automation of integration with LIMS
- ✓ Total automation by integrating CDS via SDK
- ✓ Quick to implement & fully validated
- ✓ Cloud ready-made scalability and maintainability has been achieved easily
- ✓ Automation increased throughput and accuracy and reduced errors
- ✓ Digitization made data available for analytics.

CONCLUSION

This leading Biopharmaceutical organization achieved their following primary objectives by using Logilab SDMS:

- ✓ Paperless automation in processes combined with regulatory compliance and data integrity guidelines.
- ✓ Achieve integration with Chromeleon Chromatography Data system (CDS)
- ✓ Seamless integration with LIMS.

They have been able to achieve the following additional benefits through the implementation of Logilab SDMS.

- ✓ Simple and Easy to use application interface – Better user experience & confidence
- ✓ Time savings in terms of implementation and operational perspective
- ✓ Cost Savings in terms of paperless automated transactions
- ✓ Low cost of ownership due to standard technology architecture
- ✓ Low cost of compliance due to adherence to Regulatory and Industry standards and data integrity principles.
- ✓ Minimal or No error due to automated processes of sending results to LIMS

Note: All brand, product names belong to respective owners.