













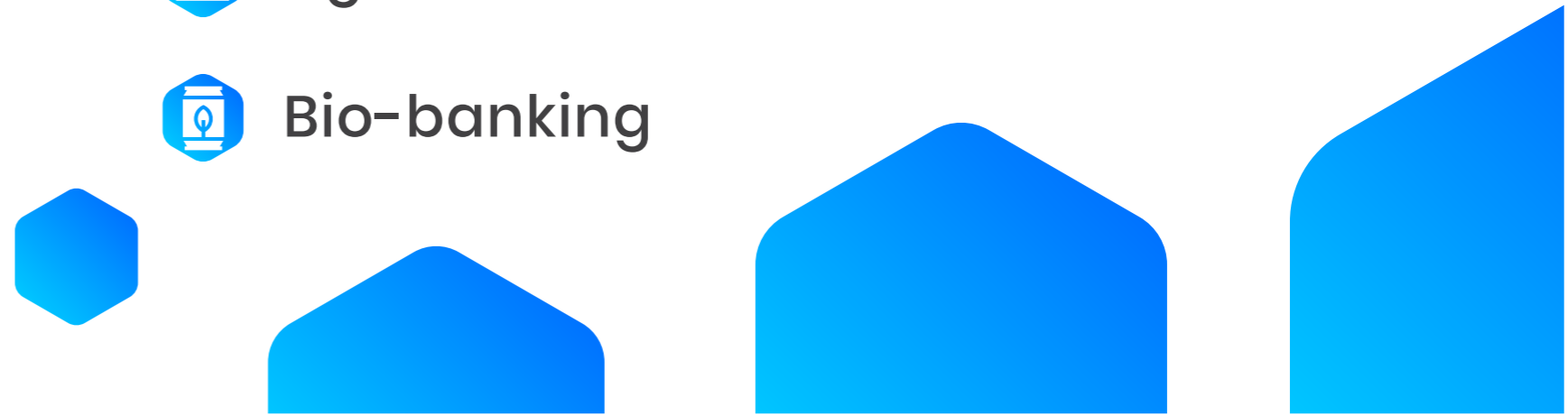


# Scientific Data Management System for Quality & Research Laboratories

Capture, Catalog, Retrieve, Search, Share, Archive & Integrate

## INDUSTRIES

-  Pharmaceuticals
-  Life Sciences
-  Biopharmaceuticals
-  Drug Discovery
-  Clinical Research
-  Contract Research Organization
-  Healthcare and Diagnostics
-  Oil and Gas
-  Dairy, Food & Beverages
-  Chemicals
-  Agriculture
-  Bio-banking



# Regulated Industry Requirements for Data Integrity and Compliance



**Regulated industries** are mandated to properly store raw & meta data generated by instruments.



**Logilab SDMS** can be deployed and scaled from single site to multiple global sites. Logilab SDMS can be deployed on on-premise or cloud for global access.



**Data used for cGMP decisions** or by GLP facilities should be available in a controlled environment and should be auditable by internal and external regulatory bodies.



**A single source of truth** as recommended by ALCOA principles for data integrity should be maintained.



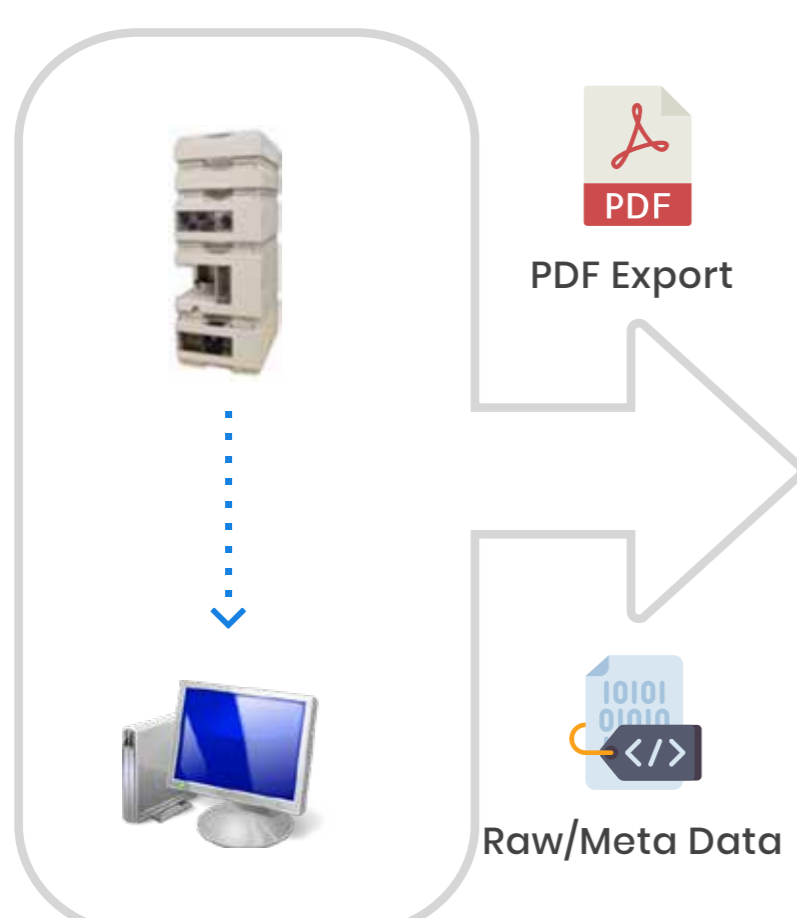
**For cGMP facilities** 21 CFR Part 11 and EudraLex Annex 11 compliances are mandated



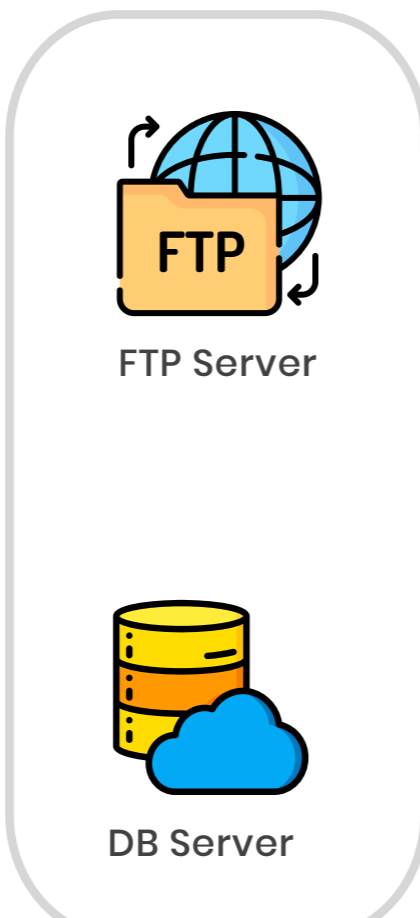
**A controlled secure environment** for such data to be available, data should be versioned if modified, should be a true copy of the original data, human readable & metadata should also be available, restoring and archival for long term storage until the life of the data.

## Logilab SDMS Architecture

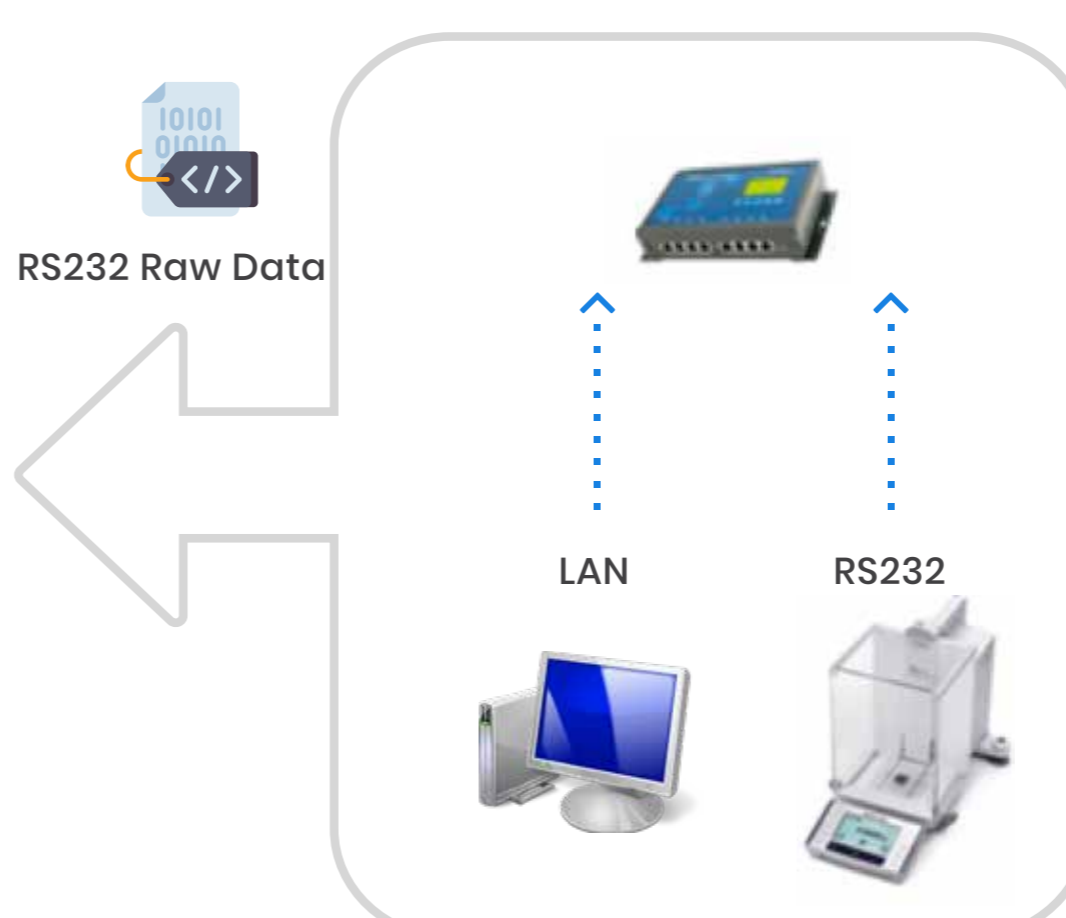
### PC Based Instrument



### Site Data Center



### RS232 TO TCP/IP



# Logilab SDMS for Data Integrity (ALCOA) and Regulatory Standards Compliance











Logilab SDMS is the world's leading Scientific Data Management System that will enable the Industries and Laboratories to meet 100% of ALCOA Data Integrity principles and 21 CFR Part 11 and Eudralex Annex 11 requirements.

It is a generic enterprise class data management solution designed to capture scientific instrument data from any analytical instrument (PC-software based and standalone instruments with ports like RS232, TCP/IP, Analog), irrespective of instrument type, make and manufacturer and store in a central secure server. It has the capabilities to schedule data capture, catalog, link meta data, extract metadata, search, archive, restore, extract data of interest and integrate with external systems like ELN, LIMS or ERP.

Data access and viewing are controlled through user rights ensuring data security. The metadata like data instrument/user source, date/time, file size, checksum and user-entered tags along with the parsed and extracted data is stored in the central database repository. Full text indexing allows strong search facility and ensures the availability of required data instantaneously.



# Logilab SDMS Core Product Capabilities

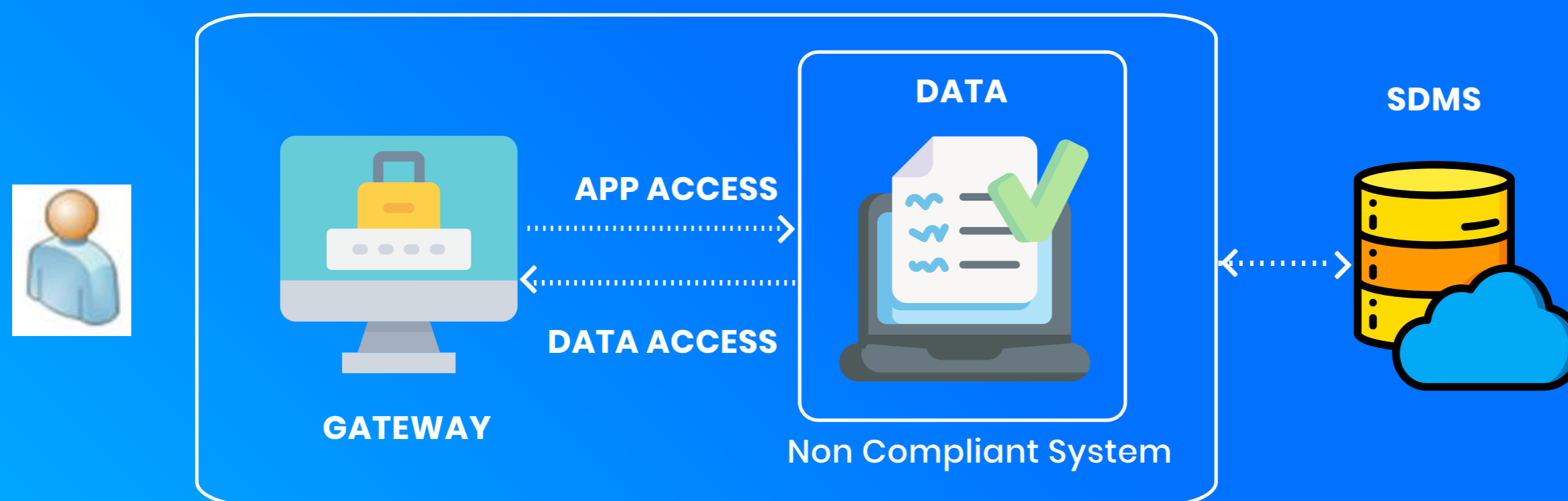
-  Versatile Data Capture – Any instrument data of any format including PC-Based, RS232, TCP/IP & analog output.
-  User defined logical separation of data like QC, Research, QA etc.
-  Fully automated secure file handling by SDMS Scheduler with file version control
-  Better Tracking, Easy Troubleshooting – By Audit Trail
-  Easy Navigation, Secure, Faster & Wider search by Data Explorer
-  Easy extraction of data of interest – By Parsing Engine
-  Human Readable Data for 21 CFR Part 11 compliance – By PDF & Print Functionality
-  Complete Access Control of all applications including non-complaint ones – By CFR Gateway
-  Better organization, categorization and standardization of data – By Tagging & Templates
-  Mobile usability to contemporaneously record data – By SDMS Mobile application
-  Better security and control of operations – By User & Password Management
-  Electronic data and electronic signature – 21 CFR Part 11 Compliance
-  Controlled sharing of data with colleagues and partners
-  Integration capabilities with other ELN, LIMS and ERP systems.



## Logilab SDMS – Purchase and Deployment Options

Logilab SDMS is licensed based on number and type of instruments

	On-Premise	Customer owned Cloud	Agaram Hosted Cloud & Managed
<b>1</b> Perpetual License	✓✓	✓✓	✓✓
<b>2</b> SaaS Subscription			✓✓



CFR Gateway was designed for provide 100% data integrity and compliance for instrument software applications and standard desktop applications like Microsoft.

Upon Operating System boot, CFR gateway will be loaded at startup for users to login into the gateway to access applications that the user is authorized to use.

Any data created or modified by the user is fully tracked and sent to server repository automatically. Even popular applications like Excel can be used with high level of data integrity and version control.



## Key Benefits of implementing Logilab SDMS



Improved reliability, consistency in operations and low cost of compliance due to 100% automated adherence to data integrity, 21 CFR Part 11 and EudraLex Annex 11



Error-free results due to automated Data capture from instruments & user systems.



Simple and easy-to-use User application interface – Better user experience & confidence



Globally accessible, scalable to multi-sites increases ease and time of implementation



Time savings from operational perspective due to automation of tasks



Cost Savings in terms of paperless transactions



Low cost of ownership due to standard technology architecture

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