ACHIEVING DATA INTEGRITY THROUGH STARLIMS STANDALONE SCIENTIFIC DATA MANAGEMENT SYSTEM

Abbott Informatics is now offering a standalone version of STARLIMS Scientific Data Management System (SDMS) to help clients achieve compliance with the data integrity expectations of the Food and Drug Administration (FDA) as well as other regulatory authorities. The acronym "ALCOA", largely attributed to the FDA and later expanded to ALCOA+ by the European Medicines Agency, helps us remember the key concepts relevant to data integrity. The requirements are that data be attributable, legible, contemporaneous, original, accurate, complete, consistent, enduring, and available[1]. These concepts must not only be applied to a paper environment but also the electronic world.

Common data integrity issues include shared passwords, loosely controlled user privileges, lack of computer system controls, poorly defined processing methods, incomplete data, and missing audit trails[2]. More and more the FDA is issuing warning letters as a result of laboratories not following current Good Documentation Practices (GDP). Beyond the warning letters, a lack of data integrity can lead to facility shutdown, import bans, recalls, lawsuits, and a drop in brand value and market share.

The data below (see Figure 1) shows that when looking at warning letters issued by the FDA between 2013 and 2018, a significant number of them cite data integrity as a problem[3].

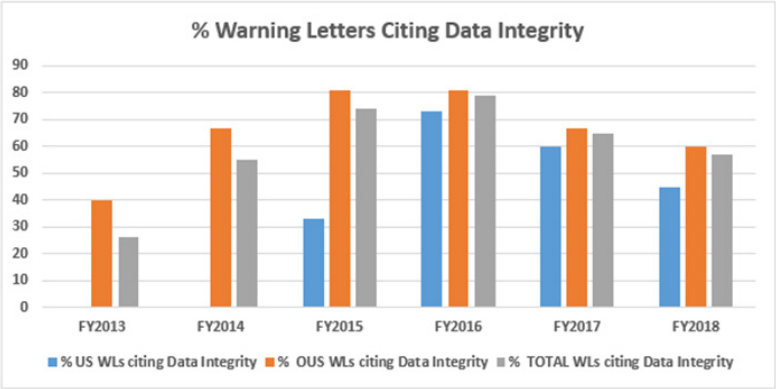


Figure 1:
Data Integrity Deficiencies in Warning Letters, Excluding Compounding Pharmacies

The issue is so prevalent that in December of 2018 the FDA issued the "Data Integrity and Compliance with Drug CGMP Questions and Answers Guide for Industry[v]. This document offers guidance on many topics including what constitutes data integrity and goes on to explain some of the 21 CFR requirements. For the purpose of the guidance document, data integrity was described consistent with the ALCOA acronym discussed above and information was provided on the data integrity requirements of 21 CFR parts 211 and 212.

The guidance document goes on to define an audit trail as "a secure, computer-generated, time-stamped electronic record that allows for reconstruction of the course of events relating to the creation, modification, or deletion of an electronic record". For example, an instrument run should include the name of the user, date/time stamp for the run, any processing or reprocessing details.

The majority of the lab testing workflow related data integrity requirements are well addressed by many LIMS, ELN and CDS solutions. However, equipment interfacing, equipment raw data and processed data handling, storage, search and archival of equipment produced data and other scientific data generated throughout the lab is a challenge that can still lead to data integrity issues.

Abbott Informatics has identified this as major threat to the regulated industries such as Pharma, Biotech, Healthcare and FMCG labs and designed a standalone SDMS tools that addresses data integrity challenges.

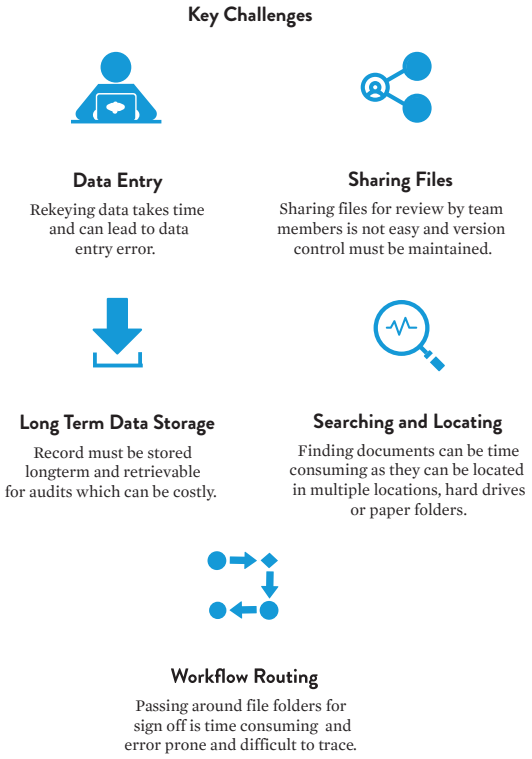
Why STARLIMS SDMS Solution

STARLIMS SDMS (Scientific Data Management System) is one tool that can help organizations comply with data integrity requirements because STARLIMS SDMS:

- Was specifically designed for 21CFR Part 11 compliance to ensure compliant record creation, audit trails, electronic signatures, and data security.
- Can identify equipment data files in native format, parse data, store in the native formats, include extracted metadata, and does not require availability of the original software that was used to create the record.
- Will enforce the document workflow and review process before the data is stored or pushed to native LIMS or ELN applications for an extra level of analytical quality testing.
- Provides enterprise level data sharing and access controls across sites and geographic locations.
- Permits users to search the data across multiple files to make informed decisions.
- Technology platform that is secured, scalable, high performance, and facilitates enterprise deployments.

STARLIMS SDMS Features

Data security and data integrity are maintained by requiring users to login with a valid user name and password. Additional permission settings are used to configure what a user has access to and what that user can do. In addition, STARLIMS SDMS provides the tools to support retention polices and ensure long term accessibility. STARLIMS SDMS allows for document lock-down and version control and provides full traceability. With STARLIMS SDMS, you get a controlled environment that allows automatic uploading of multiple file types from multiple sources. Finally, SDMS ensures compliance by allowing you to back-up the raw data from an instrument, which you can have available in the event of an audit or you need to retrieve that data years down the road.



A standalone SDMS fills an important gap in data integrity for many agencies. Some laboratories may not have a Laboratory Information Management System (LIMS) or they may have LIMS that does not have SDMS capability.

STARLIMS Standalone SDMS Can Work with Your Existing LIMS Without Replacing it

For laboratories that have a LIMS without SDMS capability, changing to a new LIMS with SDMS may be a task too daunting to undertake. This where STARLIMS standalone SDMS can support the rigorous documentation needs that are lacking.

The standalone SDMS can be utilized in conjunction with an existing LIMS thereby reducing the time to achieve data integrity improvements.

The Application Programming Interface (API) of the SDMS facilitates web service methods to integrate the SDMS with the LIMS.

Web methods include the ability to receive sample information from the LIMS, send results data to the LIMS, get raw data files from SDMS, send raw data files to LIMS, and archival based on the original instrument file structure required for raw data (See Figure 2).

STARLIMS Standalone SDMS Can Work Without a LIMS

If your organization does not have a LIMS, you can start with STARLIMS SDMS standalone solution and later scale up to Enterprise STARLIMS version or integrate with another LIMS of your choice. Laboratories without a LIMS can also use the standalone SDMS to help meet data integrity standards. In this case, SDMS would be used to house the data files in a folder structure that would permit auditors to view the data in a sensible way (See Figure 2).

Even without the LIMS component the standalone SDMS helps meet many of the requirements stated in 21 CFR parts 211 and 212 for data integrity that just a chromatography data system (CDS) may not. For example, data is backed-up, it's protected from deterioration and loss, the data is captured in real time, and the raw data is an original record. Finally, using the standalone SDMS can be an important first phase to permit laboratories to achieve compliance as a first step before undertaking a LIMS implementation.

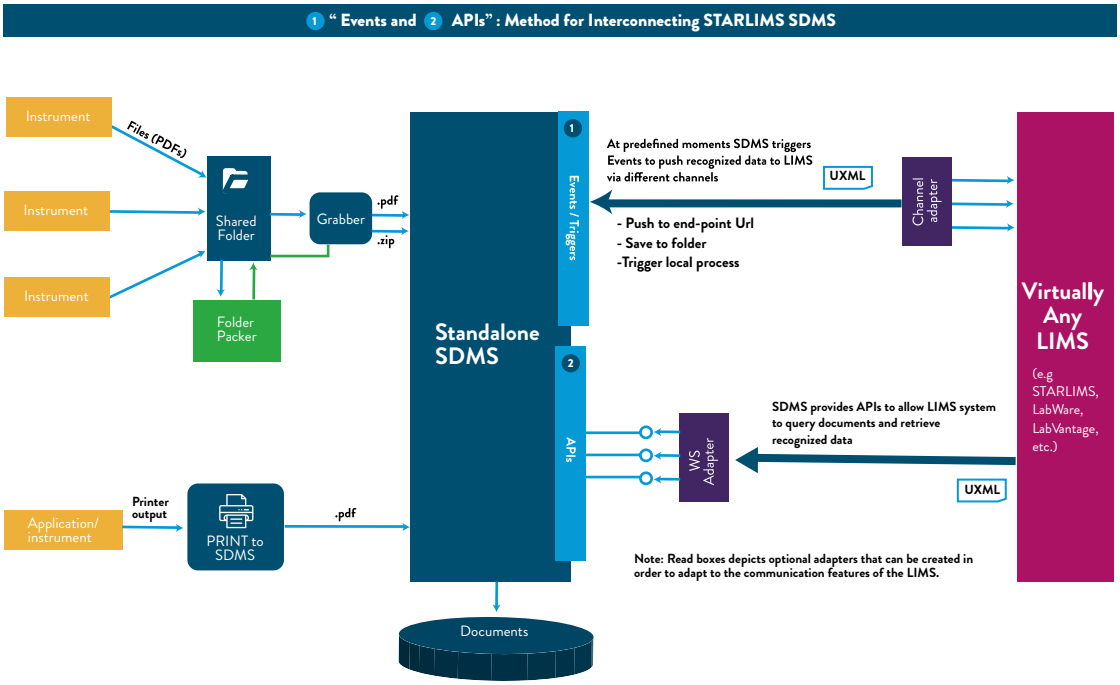


Figure 2: Methods for interconnecting STARLIMS SDMS

Innovative Roadmap*

Abbott Informatics has already planned even more features for release later this year and beyond. Stay tuned to learn what features are coming next.

Top 5 Reasons to choose STARLIMS SDMS Solution

1. Works as standalone or enterprise systems

2. Can interface effectively with virtually any LIMS, CDS, ELN, and other lab systems through webservices without replacing them

3. Technology tools that doesn't require lot of user trainings, validations and big implementation cycles

4. Modern technology and System architecture supporting large scale data management, storage, archival, search and scalability

5. 36+ years of Abbott Informatics STARLIMS proven lab automation product, process and people.

References:

1. The Pharma Innovation Journal 2019; 8(1): 306-313.

2. http://www.pharmtech.com/data-integrity-analytical-laboratory.

3. An Analysis of FDA FY2018 Drug GMP Warning Letters Guest Column | February 1, 2019 By Barbara Unger, Unger Consulting Inc.

4. Data Integrity and Compliance with Drug CGMP: Questions and Answers Guidance for Industry (https://www.fda.gov/media/119267/download).

*The product roadmap is a snapshot of current planned enhancements based on current priorities. New features and timetable is subject to change.

informatics.abbott

ABBOTT INFORMATICS
Tel: +1 954 964 8663
4000 Hollywood Blvd, Suite 333 South, Hollywood, FL 33021-6755 USA

UNITED KINGDOM
Tel: +44 161 711 0340

GERMANY
Tel: +49 2302 915 245

FRANCE
Tel: +33 1 61 37 02 00

SPAIN
Tel: +34 91 663 67 64

NETHERLANDS
Tel: +31 72 511 8100

ASIA PACIFIC
Tel: +852 2793 0699

LATIN AMERICA
Tel: +1 954 964 8663

CANADA
Tel: +1 888 455 5467

AUSTRALIA
Tel: +61 3 9670 0678

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