The focus of our work is the creation of a 21 CFR part 11 compliant electronic records solution for the long term storage, archival and management of instrument data. The AnML data format was able to accommodate all the required data including standards, protocols, XML and other formats, as well as associated audit trails.

INTRODUCTION

In order to comply with FDA regulations (21 CFR Part 11), electronic records produced by analytical instruments and data analysis applications are required to be stored for a very long and indefinite period of time. This poses significant challenges for the organization on record storage and data integrity.

Traditionally, data has been stored on hard drives or tape in multiple formats, sometimes proprietary. This helps to ensure data authenticity, but these storage media can become obsolete and, as a result, the data is vulnerable to loss.

The inherent advantage with the introduction of XML (eXtensible Markup Language) is that it aims to be universal, however, it became apparent that agreement on a single proprietary data format that is human readable, non-proprietary and format portable is the key to ensuring that data can be accessed in the future. New tools are needed to keep this data alive.

Once your data is safely archived your next problem comes to light. Your data is now stored on a data tape or disk. How do you interact with this data while not taking on a significant burden to sustain the tools.

If proprietary data formats have been around for a long time from JCAMP-DX and ANDI to mzXML and mzData, these formats were designed to be universal, however, it became apparent that agreement on a single format was elusive. The inherent advantage with the introduction of XML is the ability to handle data in a format that is readable by many different tools. This format would be elusive. The inherent advantage with the introduction of XML is that it is an upcoming ASTM XML standard developed by Schaefer Analytical Information Markup Language (AnIML), it is an upcoming ASTM XML standard developed by Schaefer.

An analytical data longevity and management solution for regulated environments can be achieved using the AnML data format. The AnML format provides a human-readable solution free of concerns of operating systems, proprietary software and hardware versions. This solution is scalable and suitable for both local-based archival. AnIML is both an archival and digital signatures provide the required security measures to ensure data integrity.

DATA DURABILITY

− Security-SS1 supports data transfer over SSL and automatic encryption of data even if it is uploaded. Configuration of bucket policies to manage object permissions and control access to the data.
− Scalability—virtually unlimited in terms of infrastructure.
− Centralized storage with Global access.
− Indexing—Availability of tools with powerful infrastructure backend.

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