

STARLIMS™

TECHNICAL NOTE

Document Management

Integrated Solution

Regulatory requirements for electronic record management specify the need for archiving not only traditional database fields but also all related information such as chromatograms, spectra and raw data files. STARLIMS Document Management provides tools for capturing, storing, retrieving, parsing and sharing the complete electronic record.

The mass of information a laboratory generates presents a challenge. Scientists are required to store and catalog the results and reports they create. In the past, information was printed and filed resulting in storage, retrieval, and tracking problems. Data sharing was available on a group basis only as no effective means to disseminate the information were available.

STARLIMS Document Management not only provides scientists with tools to securely store and share the “picture” of the scientific report but enables meaningful extraction of the data, setting the grounds for powerful querying and analysis of the information. The STARLIMS solution offers laboratory document and scientific data management in **one** easy to use CFR part 11 compliant platform.

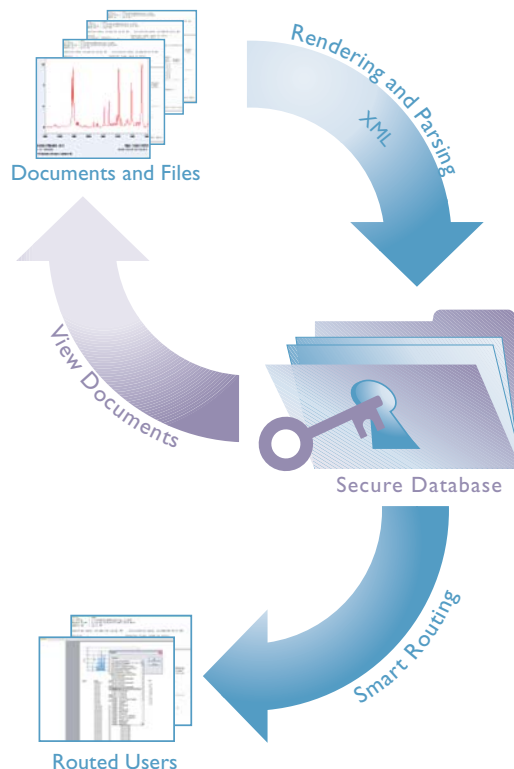
Rendering and Parsing

Companies utilizing the STARLIMS Document Management solution will be able to automatically retrieve both structured and unstructured data by leveraging STARLIMS XML rendering engine to transform the content into a highly flexible XML format.

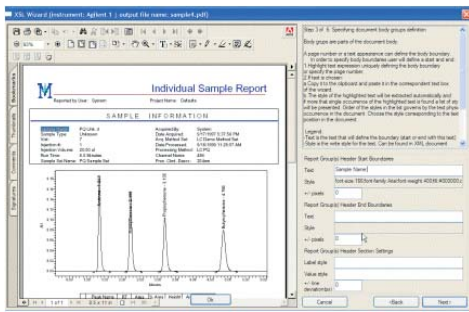
This XML file is then parsed to meet ongoing requirements to transform, search and assemble critical information that in turn is imported into appropriate STARLIMS tables and fields.

STARLIMS XML rendering and parsing capabilities are powered by licensed technology from Liquent, Inc., the world’s leading provider of content assembly, publishing, and regulatory and intellectual property information solutions for the life sciences industry.

STARLIMS file rendering capabilities support over 100 different file formats such as PDF, DOC, XLS, TXT, and many others.



STARLIMS Document Management creates a “Closed System” under 21 CFR Part 11.



Integrated XML Passing Wizard

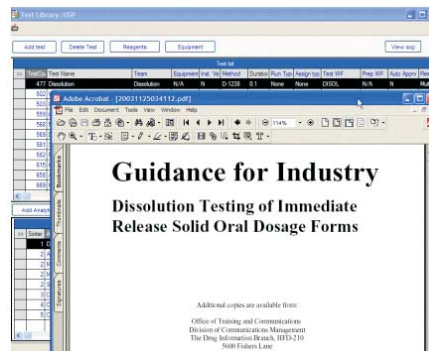
At the heart of the parsing process is the creation of an XSLT file, which serves as a template defining the data elements that need to be parsed from within the rendered XML. STARLIMS Document Management solution includes an easy to use graphical wizard designed to build these parsing templates.

Full STARLIMS Integration

The parsing process turns the raw data into meaningful and actionable information. This information now becomes fully available to “smart” routing functions, which automatically link captured documents to appropriate STARLIMS content making it available to routed users throughout the organization and beyond. Routed content and documents may include SOPs, analyst certifications, electronic training materials, investigation reports, captured instrument outputs, COAs generated by the lab to its users, scanned COAs received from suppliers and many more.

Chromatograms, spectra, and other reports created with original software are captured and stored in a scalable vector format that can be viewed and reproduced without access to the original source software, if in the future it becomes unavailable. STARLIMS Document Management will continue to maintain the original image and data captured at the time of creation.

Utilizing the functions within STARLIMS affords complete access to a set of powerful tools for storing, comparing, analyzing and routing the full electronic record as defined by regulatory requirements.



SOPs

