

LABVIEW™, TESTSTAND™ AND FDA COMPLIANT LIMS FOR ENTERPRISE WIDE MANUFACTURING TEST

XML PROVIDES MISSING LINK FOR FDA COMPLIANT DATA.

Client

Major pharmaceutical company

Problem Scope

The challenge was to integrate PC based test fixtures running LabVIEW™ and TestStand™ applications into a corporate wide, 21 CFR Part 11 FDA compliant Laboratory Information Management Systems (LIMS). The system needed the ability to support multiple products at multiple sites and be network fault tolerant.

Typically TestStand and LabVIEW are installed on fixtures and exist as "islands" of automation. Sometimes the stands publish the test results on a corporate network, but rarely do they fit into a LIMS system for definition and results compliant to 21 CFR Part 11.

Viewpoint's Solution

To solve the problem, Viewpoint Systems (www.ViewpointUSA.com) integrated the following tools:

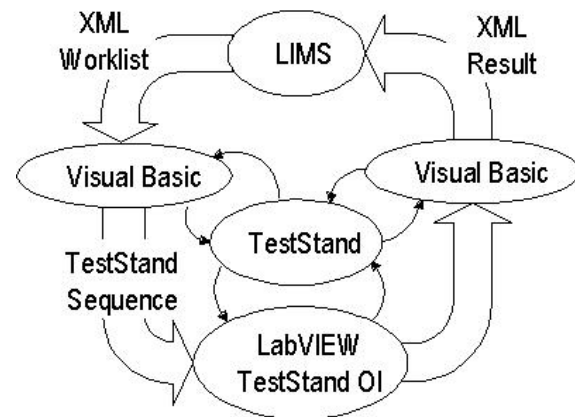
National Instruments (www.NI.com) TestStand 2.02 was interfaced with various test steps written in LabVIEW 6.1. TestStand controlled the fixtures by defining a sequence of test steps to be executed and the limits for the results. This provided a common test architecture for all fixtures with custom user interfaces (LabVIEW) and HTML reports after the test. The LabVIEW based tests were re-used from previous projects.

Q-DIS/QM, Q-DIS/AQV, Q-DIS/R from Creon Lab Control (www.CreonLabControl.com) was the LIMS system. It contained all test limits and results and provided the user interface to define test sequences. Q-DIS provides a 21 CFR Part 11 compliant database for the creation, maintenance and authorization of manufacturing and test procedures. It also provided revision control, audit trail, archival, and product certificates.

A custom application using Microsoft XML 3.0 and Visual Basic 6.0 provided the conversion of a Q-DIS worklist to a TestStand sequence.

The LIMS system acts as the test sequence editor and provides a structured environment for entry, maintenance, review, and authorization of the test procedures and limits. The user determines the sequence to use and the limits to apply, and the system creates an XML representation of this test procedure called a worklist. Depending on the LIMS system used, this

worklist may be written as an ASCII, XML, or other flat file format. The converter application converts this worklist into a sequence readable by the test sequencer. The test sequencer executes the sequence with the results recorded as HTML and XML files. The XML file is imported into the LIMS system, completing the circle.



The XML converter could have been written in TestStand, LabVIEW, or LabWindows/CVI.

To insure integrity, each file used by the system has an MD5 electronic signature. MD5 is the 128 bit "RSA Data Security, Inc. MD5 Message-Digest Algorithm". This in itself is not enough to comply with 21 CFR Part 11. Metadata, which is included with all files, is date, time, user, associated files, and other important common information. The LIMS system may import relevant information, but keeps a copy of the file plus the associated files for future data mining and auditing purposes. All files are checked before use to prevent unauthorized changes and data loss using the MD5 signature. All worklist files are cached on the local machine and all results files are pushed to the network while the network is connected. Alternatively, the file exchange can be accomplished using a CD.

Conclusion

In conclusion, the combination of a powerful test environment, LabVIEW and TestStand, and a 21 CFR Part 11 FDA compliant LIMS, Q-DIS, allowed Viewpoint to integrate a system that is maintainable and flexible for future requirements. This architecture will allow rapid deployment of new systems within the company.

LabVIEW™ and TestStand™ are trademarks of National Instruments.

