



**INDUSTRY STANDARD PLATFORM
FOR FDA-REGULATED
MEDICAL DEVICE TESTING**

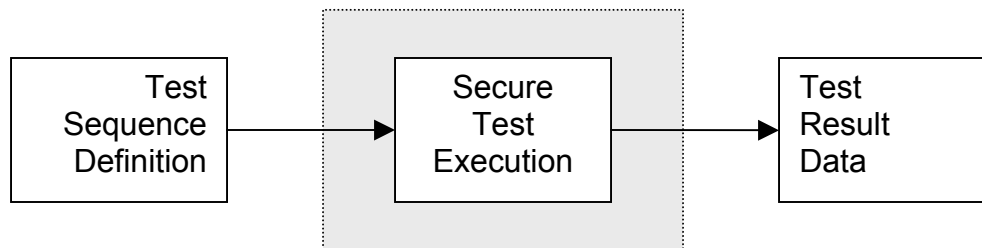
Why Reinvent the Wheel?

In the world of product validation and manufacturing test, today's engineers can choose from a vast array of tools. For most engineers, National Instruments products, such as LabVIEW™ and TestStand™ are among the most standard to assure compliance. But in the FDA-regulated world, these products fall short of compliance requirements in CGMP and 21 CFR Part II. The test engineer is required to write additional software to assure compliance.

MedTest/TS is a software code base that provides a proven stable platform for developing medical device test systems. MedTest/TS was developed for the test engineer in the FDA-regulated world. MedTest/TS leverages TestStand and LabVIEW to provide a secure framework in which you can develop and execute validated test sequences and test steps.

Test Sequences In – Test Data Out

How does MedTest/TS supply this security? We've done the work for you to create an environment that treats input test sequences and output result data as managed documents, complete with versioning, timestamps, and e-signatures.



MedTest/TS uses industry standard XML data descriptions for the input test sequences and the output test results.



MEDTEST/TS COMPLIANT TESTING PLATFORM FOR MEDICAL DEVICES



Industry Standard Components

The backbone of MedTest/TS is TestStand and LabVIEW. Test steps are written in LabVIEW and are executed in the usual TestStand environment. Test step results are generated using the default TestStand XML output. MedTest/TS adds a framework for creating and executing TestStand test sequences in a controlled environment.

MedTest/TS uses industry standard XML. MedTest/TS is supplied with a default XML interface for test sequence input and test result output which can be used out of the box. In addition, the source code and data configurations can be configured to interface to any existing LIMS or other compliant database system in use for test management simply by adding translation layers to the XML I/O.

Highlights

- Adds security to medical device testing for FDA compliance
- Based on industry standard TestStand and LabVIEW
- Test steps written in LabVIEW; test sequences executed in TestStand
- Industry standard XML for test sequences and test results
- Easy interfacing to existing LIMS, SQL Server, Access, or other data management systems
- Output reports can be customizable in a variety of different formats, such as HTML, Text, or plain XML
- Option of licensing for your organization or let Viewpoint customize a solution for you!



LabView and TestStand are trademarks of National Instruments.