Compliant Systems Integration

Winter Update 2006

Welcome to our Winter 2006 Newsletter. Our focus is in providing you with useful information on industry quality standards and regulatory compliance. Highlights for this issue include helpful software validation information with suggested references.
Happy Holidays and all our best in the New Year from CSI!

October 12, 2006 saw the launch of our first joint CSI and the RIT Center for Bioscience Education and Technology (CBET) workshop on Software and System Validation for Pharmaceutical, Biotechnology or Medical Device Organizations. Some workshop highlights on key validation principles were:

1. System Requirements: A user requirements document is essential for any validation process. It is simply impossible to confirm your system consistently meets end user needs or predicate rule requirements if you don't know what they are!

2. Documentation of Validation: Remember the saying "If it's not documented, it's not done." Written validation plans also act as a roadmap to keep the validation on track.

3. Additional Requirements Prior to Test Execution: Verifying and documenting correct equipment installation (both hardware and software) before starting system testing is more than just a good idea. It's required.

4. Dynamic Testing of the System Include:
a. Normal and stress conditions tests
b. Simulation tests
c. Structural tests (contemporary standards)
d. Functional tests (define inputs & outcomes)
e. Program build tests (integration test modules)
f. Live user-site tests (conduct under actual operating conditions)

Things to Consider

- The user is responsible for a program's suitability as used in a regulatory environment.
- Even Commercial Off-the-Shelf Software may require validation to demonstrate suitability for a specific application use.
- Approaches to validation may vary, but key principles for successful validation should be covered by each approach.

Looking for some handy Validation References?
Much has been written about activities that support computer systems validation. You may find the following references useful to your validation efforts.

Guidance for Industry and for FDA Staff: General Principles of Software Validation, Center for Devices and Radiological Health, Food and Drug Administration, Draft – June 1997.

Guidance for Industry, FDA Reviewers and Compliance on Off-the-Shelf Software Use in Medical Devices, Office of Device Evaluation, Center for Devices and Radiological Health,

Food and Drug Administration, September 1999.

Electronic Records; Electronic Signatures Final Rule, 62 Federal Register 13430 (March 20, 1997).

A revision of 21 CFR Part 11is expected by May'07. Watch our newsletter for more information.

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