

## **FDA COMPLIANCE CORNER**

**BY DAVID WALKER, MS**

*The goal of this column is to provide valuable information to Software Division members employed in FDA-regulated industries such as medical devices, laboratories, clinical research and development, and manufacturing of food, drugs, and cosmetics. David Walker is self employed Senior Software Validation Specialist.*

Those working on medical device software should be very interested in a new standard currently undergoing approval, ISO 62304: Medical Device Software – Software Life Cycle Processes. This standard was developed in a cooperative effort between FDA and industry, coordinated through the Association for the Advancement of Medical Instrumentation (AAMI) Software Standards Committee. It builds on AAMI SW68 and integrates software risk management. Approval is expected early in 2006. Sherman Eagles, AAMI Software Standards Committee Chair will be presenting on this new standard at the 2006 World Conference on Quality and Improvement in Milwaukee on May 1, 2006. Watch for details at: [http://wcqi.asq.org/perl/search/search\\_session.pl](http://wcqi.asq.org/perl/search/search_session.pl)

There is some focus right now on the use of Off-The-Shelf software in networked medical devices. See new guidance documents:

Guidance for Industry - Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software: <http://www.fda.gov/cdrh/comp/guidance/1553.html>

Information for Healthcare Organizations about FDA's "Guidance for Industry: Cybersecurity for Networked Medical Devices Containing Off-The-Shelf (OTS) Software": <http://www.fda.gov/cdrh/osb/1553faq.html>

### **Must Reads:**

**ISO 14971:** Risk Management - Part 1: Application of Risk Management

**FDA Guidance:** General Principles of Software Validation:  
<http://www.fda.gov/cdrh/comp/guidance/938.html>

**FDA Guidance:** Guidance for Industry, FDA Reviewers and Compliance on Off-the-Shelf Software Use in Medical Devices:  
<http://www.fda.gov/cdrh/ode/guidance/585.pdf>

**IEC 60601-1-4:** Medical Electrical Equipment--Part 1: General Requirements for Safety-4. Collateral Standard: Programmable Electrical Medical Systems

### **Great Sites:**

Software CPR

A collection of Searchable Software 483's.

<http://www.softwarecpr.com/warningletterframepage.HTM>

Yahoo CFR21Part11 Discussion Group

Excellent discussion of various computer validation topics, primarily E Records & Sigs

<http://groups.yahoo.com/group/21cfrpart11/>

**Please send me more great stuff to share in this column:**

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