

FDA COMPLIANCE CORNER

BY DAVID WALKER

This column provides a concise update each quarter on computer validation subject matter. 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.

As expected, risk management is heating up in all sectors of the FDA regulated industry. Age old, proven techniques such as Hazard Analysis, HACCP, FMEA, FTA, HAZOP not only assist in safety management, but provide meaning in prioritizing work.

“Should I write a test plan for using this off-the-shelf software?”

“How much documentation does this test fixture need?”

“We only have one more week. Where should we focus our tests?”

Risk analysis can provide answers to these questions. Qualitative approaches require expert judgement of severity and probability. In the end, testing can verify that judgement.

Must Reads:

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

FDA Guidance: General Principles of Software Validation

FDA Guidance: Guidance for Industry, FDA Reviewers and Compliance on Off-the-Shelf Software Use in Medical Devices

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: walkercsqe@juno.com