

Another Look at GPSV

By David Walker, Chair – ASQ Software Division

This column has listed various WEB links to important FDA guidance documents regarding software validation. About a year ago, a link was provided to the “General Principles of Software Validation” (GPSV) white paper, published by the CDRH (Center for Devices and Radiological Health) in 2005. This is a must read if you are developing software for use in a medical device.

Another good, related read is the summary of the public comment filed in the federal register on January 11, 2002. It is a 7 page record of the dialog between 36 organizations of industry and the FDA regarding specific topics covered in the 1997 version of GPSV.

This dialog allows us to see more clearly the expectations of the FDA as manifested in the GPSV guidance document. For example, one comment claimed that the use of a requirements traceability matrix for very large projects was overly burdensome. The FDA’s responds that the larger the project, the greater the need for the traceability matrix.

Here is the link to this GPSV Preamble:

<http://www.fda.gov/OHRMS/DOCKETS/98fr/011102a.pdf>

Have a great summer!