Book excerpt: Medical Device Software Verification, Validation, and Compliance (Part 1 of 2)

David A. Vogel, Ph.D., Intertech Engineering Associates, Inc. - May 16, 2011

This just-published book is written specifically to help medical device and software engineers, QA and compliance professionals, and corporate business managers better understand and implement critical verification and validation processes for medical device software.

It helps you think critically about software validation -- to build confidence in your software’s safety and effectiveness. The book presents validation activities for each phase of the development lifecycle and shows: why these activities are important and add value; how to undertake them; and what outputs need to be created to document the validation process.

From software embedded within medical devices, to software that performs as a medical device itself, this comprehensive book explains how properly handled validation throughout the development lifecycle can help bring medical devices to completion sooner, at higher quality, in compliance with regulations. It also includes a DVD with a collection of FDA regulations and guidance documents related to software in the medical device industry, valuable sample forms and templates, and supplemental figures that support key topics covered in the book.

We are pleased to present all of Chapter 6, "Verification and Validation: What They Are, What They Are Not" in two parts:

• **Part 1:** What Validation is NOT; Validation and Its Relationship to Verification and Testing; Software Validation According to Regulatory Guidance; click here.

• **Part 2:** Can Other Definitions of Validation Be Used?; User Needs and Intended Uses; Software Verification According to Regulatory Guidance; How Design Controls, Verification, and Validation Are Related; Validation Commensurate with Complexity and Risk; Is All Validation Created Equal?; Reference; it will be posted on May 19, 2011.
You can also click here to see the complete, detailed table of contents, and here to see the publisher's web page for the book.

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About the author

David A. Vogel, Ph.D is founder and president of Intertech Engineering Associates, Inc. in Westwood, Massachusetts. The company specializes in the management of hardware and embedded software development and verification/validation projects for medical devices. He has also served as principal bioengineer at Becton Dickinson Medical Systems, and as software engineer for Honeywell Information Systems. He earned a Ph.D. in biomedical engineering at The University of Michigan, Ann Arbor.