

# News Release

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For Immediate Release

## **Medical Device Software: Verification, Validation, and Compliance**

### ***Textbook to Guide the Medical Device Industry in Complying with FDA Regulatory Requirements Related to Software and Validation***

**Westwood, Massachusetts – January 23, 2011** – Did you ever buy a new software package only to run into problems (i.e. software bugs) within minutes of first using it? Frustrating, right? Now imagine you are a surgeon using a software controlled instrument. Discovering software problems in the operating room simply is not an option. Software validation is required by the FDA to protect medical device patients and users from such software failures.

Some companies and individuals in the Medical Device Industry feel that the FDA's Design Control Regulations are a waste of time and impede product development. Many feel that their validation budgets are disproportionately large or that their validation efforts are not effective enough at finding defects to legitimize the cost. Software developers seem to be in a constant tug-of-war with the compliance and quality professionals. Too many developers spend too much time coming up with clever ways to get around the quality system, or to convince themselves that the efforts of the validation team are worthless.

Dr. David Vogel of Intertech Engineering Associates, Inc. ([www.inea.com](http://www.inea.com)) has written the first book that specifically helps medical device software engineers, quality assurance experts, validation engineers, compliance professionals and corporate business managers better understand and implement critical verification and validation processes. These processes which are required by regulation, apply to software that is part of a medical device, or that is simply used in the design, development, or manufacture of the medical device. [Medical Device Software: Verification, Validation, and Compliance](#) (ISBN 978-1-59693-422-1) helps readers think critically about software validation to build confidence in their software's safety and effectiveness.

Dr. Vogel is founder and president of Intertech Engineering Associates, Inc. ([www.inea.com](http://www.inea.com)) in Westwood, MA. Since, 1982, Intertech has specialized in the development and validation of medical devices that are controlled by software. Dr. Vogel's experience in the medical device field has shaped and refined his opinions about which development and validation techniques work, and which do not.

When asked what need the new book fills, Dr. Vogel responded:

“The first guidance on FDA expectations for software validation was published in 1997. Fourteen years later, parts of the industry are unaware of those expectations, deny them, avoid them or just don’t understand them. There are plenty of good books on the market that are more detailed than mine on the mechanics of developing software or testing software, but I am unaware of any that address *why* the FDA is so focused on software validation, and *how* software validation makes devices safer. [Medical Device Software: Verification, Validation, and Compliance](#) includes plenty of pragmatic technical and project management advice related to medical device software and validation that is condensed from our experience at Intertech over dozens of projects in the last 29 years. However, each technical subject is introduced by a reminder of *why* the activity is important, how it makes devices safer, and, hopefully, why it is *not* a waste of time.

I’ve often said that if those responsible for validating software feel that they are wasting their time ... they probably are. That’s not to say that validation is a waste of time, but perhaps the way *they* are validating *is* a waste of time. A well planned, well managed validation program with all parties in full cooperation actually produces devices that are safer, more effective devices, *and* can reduce time to market.”

The text is written in three parts:

- Part I – Background (Historical and Regulatory)
- Part II – Verification and Validation of Medical Device Software
- Part III – Verification and Validation of Nondevice Software (i.e. software that is simply used to aid in the design, development, manufacture, or could otherwise impact the quality of a medical device)

[Medical Device Software: Verification, Validation, and Compliance](#) is over 400 pages long with numerous illustrations and lists at \$129. The book is available in traditional hardcover print, or in eBook format. It can be ordered from the Intertech website ([www.validationtext.com](http://www.validationtext.com)), from Artech House Publishing directly ([www.artechhouse.com/Detail.aspx?strIsbn=978-1-59693-422-1](http://www.artechhouse.com/Detail.aspx?strIsbn=978-1-59693-422-1)) or from the following textbook retailers and distributors:

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To learn more about Intertech Engineering Associates, Inc. and how they can help apply the fundamentals described in Dr. Vogel's textbook, please visit [www.inea.com](http://www.inea.com).

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