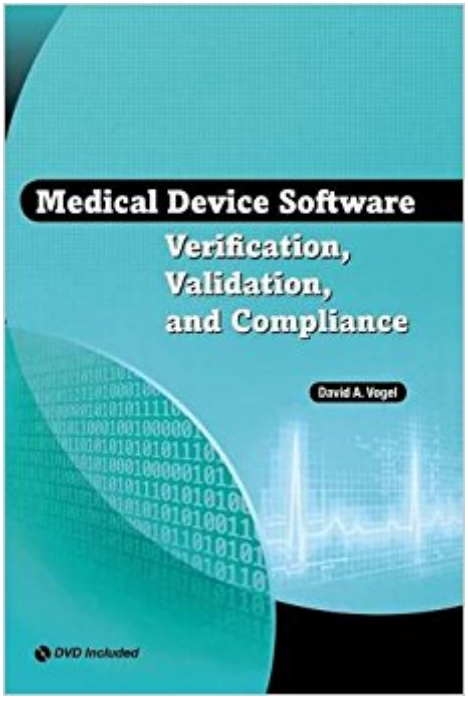
Medical Device Software Verification, Validation And Compliance



Synopsis

Note: This is a print on demand, reproduction of the original title and does not include any DVDHere s the first book 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. Offering you a much broader, higher-level picture than other books in this field, this book 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, and in compliance with regulations. Additionally, an entire part of the book is devoted to the validation of software that automates any part of a manufacturer s quality system and is regulated by 21 CFR 820.70(i).

Book Information

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Customer Reviews

David A. Vogel 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 has earned degrees in biomedical engineering and computer science from the University of Michigan and Massachusetts Institute of Technology.

A healthy dose of perspective on every page. David Vogel’s book is a gem for those new to the field. I’ve been working in this arena for only five years, and I have found the book to be extremely helpful. I keep catching myself thinking, "Wish I’d known this four years ago!"

This book is one of my favorite books on software validation and verification! I highly recommend it. I reread it once or twice a year and-- each time I do that, I pick up something new and interesting!

Missing DVD!

Strong overview of the subject. Did not include DVD with templates

It have all the guidance I was looking for to do my job. The author knows his business. Will read more.

Though the content of the book is useful, but the figures are not clear and it is blurred. Disappointed with this PC Kindle version.

First, a disclaimer. I’ve worked for Dave Vogel for the past 23 years. I was hired during my University Co-Op Education days and have been with Intertech Engineering (the company Dave Vogel founded in 1982) ever since. There is a reason I’ve stayed - Intertech gets it right. And, fortunately, so does this book.If I were asked to name reading material that would be a sure-fire cure for insomnia, you can bet the FDA’s Regulation and Guidance documents (21 CFR 820 and GPSV) would be high on the list. Those regulations and guidance documents are frequently mired in difficult to understand language and, occasionally, contradictory suggestions. For years we struggled as a company to institute a quality process that is both compliant and practical (this later desire is actually the harder of the two). Over the years we’ve seen the highs and lows when it comes to Verification & Validation of Medical Device Software and we’ve learned more than a few things along the way. Much of what we’ve learned has been laid out beautifully in this book. Very little of the technical content surprised me here - we’ve been living and using this stuff for many

years now. What did surprise me was the approachable and highly readable style of the book. Pulling in relevant sections of the Regulatory code and guidance along with advice and examples, the book lays out not only the "hows" but the "whys" when it comes to Verification & Validation. The no-nonsense approach should be a perfect fit for people who want a hands-on approach to thinking through their quality systems and has plenty of advice to guard against over-engineering the process (or worse, taking shortcuts to avoid the hard decisions). The book doesn't bog down in technical detail nor does it float along in abstract theory which makes it practical for the vast majority of readers. Dave is neither pretentious nor preachy in his writing style and I've found the book to be a welcome companion here in the workplace. If you're feeling lost, confused or frightened when it comes to Verification & Validation of Medical Device Software (and you're certainly not alone), I'd highly recommend you give this a read-through. I suspect you'll find it to be a valuable addition to your professional library.

This book is a fantastic resource for software developers, quality engineers, and technical managers working with software related to medical devices. Not only is the book comprehensive and detailed, it is also very well organized and readable. I have worked with medical device software for a large part of the past 25 years, and for the past four years have developed non-device software for medical device manufacturing test. For me this book does an excellent job of interpreting and explaining how to comply with regulatory requirements. Because of the author's credentials and frequent referencing of FDA documents and other standards, the book stands up as a very credible reference.My only two quibbles with the book are tiny: First, it contains quite a few typographic errors, apparently artifacts of the final editing process. The meaning is always clear, but one more proof-reading would have helped. Second, the author spends too many pages addressing software testing, something that is not unique to medical software and would be better left to other books. Both of these faults are easy to ignore.I have been looking for a good reference book on this subject for years, and this is the first I have found. I read it pretty much cover-to-cover over two weeks, and have recommended it to my colleagues. I am delighted with this book and recommend it highly.

Medical Device Software Verification, Validation and Compliance IEC 62304 Ed. 1.0 b:2006, Medical device software - Software life cycle processes Verification and Validation in Scientific Computing Validation for Medical Device and Diagnostic Manufacturers, Second Edition Software Engineering: The Current Practice (Chapman & Hall/CRC Innovations in Software Engineering and

Software Development Series) Health Care Fraud and Abuse: A Physician's Guide to Compliance (Billing and Compliance) Compliance Management: A How-to Guide for Executives, Lawyers, and Other Compliance Professionals How to Add a Device to Account: How to add a device to my account - 3 easy steps in few minutes Medical Terminology: Medical Terminology Easy Guide for Beginners (Medical Terminology, Anatomy and Physiology, Nursing School, Medical Books, Medical School, Physiology, Physiology) Medical Terminology: Medical Terminology Made Easy: Breakdown the Language of Medicine and Quickly Build Your Medical Vocabulary (Medical Terminology, Nursing School, Medical Books) Medical Device Register 1996: The Official Directory of Medical Suppliers (2 Vol Set) ISO 11135:2014, Second Edition: Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices The Software Requirements Memory Jogger: A Pocket Guide to Help Software And Business Teams Develop And Manage Requirements (Memory Jogger) Software Agreements Line by Line, 2nd ed.: A Detailed Look at Software Agreements and How to Draft Them to Meet Your Needs Logic Synthesis and Verification Algorithms The Politics of Weapons Inspections: Assessing WMD Monitoring and Verification Regimes Delmar's Comprehensive Medical Assisting: Administrative and Clinical Competencies (with Premium Website Printed Access Card and Medical Office Simulation Software 2.0 CD-ROM) Head First Software Development: A Learner's Companion to Software Development Agile Project Management: Agile Revolution, Beyond Software Limits: A Practical Guide to Implementing Agile Outside Software Development (Agile Business Leadership, Book 4) Don't Buy Software For Your Small Business Until You Read This Book: A guide to choosing the right software for your SME & achieving a rapid return on your investment