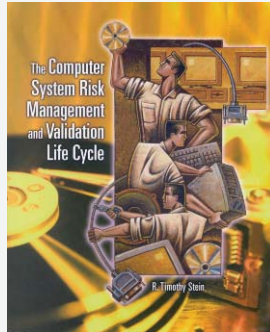


The Computer System Risk Management and Validation Life Cycle

Author: R. Timothy Stein
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Complex software systems have become common in many of today's business and critical use applications. *The Computer System Risk Management Validation Life Cycle* provides detailed guidance and actual "how to" examples to be used in the rigorous development and validation of these systems. A complete view of a robust, risk-based software validation life cycle is presented, along with numerous practical examples and references.

Audience: Those in the business world who are chartered with the important tasks of qualifying, implementing, and validating complex software systems would be a primary audience for this text. This includes information technology (IT) professionals, quality assurance (QA) professionals, and software system managers. In addition, due to the importance of software systems in medical applications and drug and device manufacture, this book provides a comprehensive treatment of the regulatory requirements intended to be used by regulatory staff who must understand the multiple software development regulations and guidances developed by FDA and the European Union (EU).

Features: R. Timothy Stein has developed a comprehensive model of the developmental life cycle phases

that are required to implement and validate well-engineered complex software systems. A unique contribution by the author is to incorporate the important concept of risk management into the proposed software life cycle model. The resultant software development process has been defined as the RiskVal Life Cycle, a term that has been service marked by the author.

Important inclusions and features of the book include:

1. An excellent and extensive reference section, with numerous entries providing a very comprehensive list of FDA, EU, engineering, and industry guidances and regulations related to complex software system development and validation.
2. A comprehensive glossary. Software development literature often makes use of seemingly obscure terminology, with specific meanings that are not generally known to those outside the software community.
3. The RiskVal Life Cycle, which defines a nine-phase software development process. Detailed information regarding each phase is provided, along with numerous examples and templates. The Life Cycle model provides an excellent frame-

work for understanding best practices in modern, complex software system development.

Assessment: The author has written an interesting, thorough, and useful book that provides a substantial framework for understanding the techniques required to implement and validate complex software systems. Some strong points for the book include combining the important business and regulatory concepts of risk management and offering plenty of suggestions and examples—a "how to" approach. In addition to being ideal for an IT, QA, or regulatory professional, it can also be the basis for a comprehensive introduction to this topic for beginners.

While not a one-night read, the book will be a frequently used reference for the industry professional, especially the excellent reference, glossary, and template sections. One topic to note: the techniques defined in the book are specifically to be applied to the development and validation of business system, quality system, and manufacturing process software. Excluded is software that is intended to perform as a medical device, such as embedded code in a defibrillator or diagnostic data analysis software. This category of software, for regulatory purposes, is governed by the requirements of Design Controls, 21 CFR part 820.30 and the related ISO 13485 sections.

Stein has built on his many years of software quality experience and has created a highly recommend text that deserves an easily accessible spot on your reference shelf. ■

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