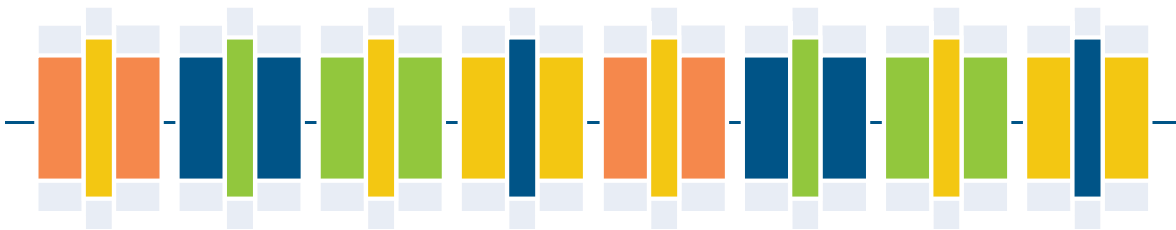


Software as a Service (SaaS)

RISK-BASED
VALIDATION WITH
TIME-SAVING
TEMPLATES



David Nettleton and
Janet Gough

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PREFACE

This book expands upon *Risk-Based Software Validation: Ten Easy Steps* and offers a systematic, step-by-step approach for validating configurable off-the-shelf (COTS) computer software that generates data or controls information about products and processes subject to binding regulations. It is for any application hosting: Software as a Service (SaaS) or in-house/on-site. Following the steps it delineates will take you from the determination to validate to the assessment of the validation outcome without time-consuming effort. The purchase of this book also gives you access to templates the authors have used as training tools for more than 1000 companies and components of over 300 validation projects. You will get from start to “go live” in the most efficient way.

About the Book

This book expands upon *Risk-Based Software Validation: Ten Easy Steps* and offers a systematic, step-by-step approach for validating Commercial off-the-Shelf (COTS) computer software that generates data or controls information about products and processes subject to binding regulations. It is for any application hosting: Software as a Service (SaaS) or in-house/on-site. Following the steps it delineates will take you from the determination to validate to the assessment of the validation outcome without time-consuming effort.

Here are answers to such questions as:

- Why do we need to validate software if vendors have already done so?
- What needs computer system validation?
- What is application hosting?
- What are typical data centers?
- What is Software as a Service (SaaS)?
- What is cloud hosting?
- Does hosting affect validation?

And much more relevant detail is also included to assist you establish a compliant, timely and successful program. An additional benefit of this text is the purchase of this book also gives you access to templates the authors have used as training tools for more than 1000 companies and components of over 300 validation projects. You will get from start to “go live” in the most efficient way.

About the Authors



David Nettleton

David Nettleton is an industry leader, author, and teacher for 21 CFR Part 11, Annex 11, HIPAA, EU General Data Protection Regulation (GDPR), software validation, and computer system validation. He is involved with the development, purchase, installation, operation, and maintenance of computerized systems used in FDA-compliant applications. He has completed more than 300 mission-critical laboratory, clinical, and manufacturing software implementation projects.

Janet Gough

Janet Gough trains staff in medical and technical writing within the regulated environment. She helps prepare documentation and assists companies in designing and implementing document management systems for compliance with 21 CFR Part 11 and the predicate rules. She has taught English in university graduate and undergraduate programs and served as a director of technical communications for a biotechnical company. She has written over 35 journal articles and authored and co-authored 15 industry books.



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