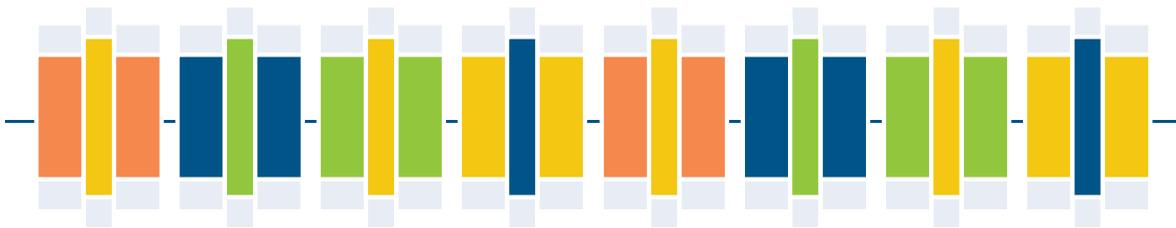


Software as a Service (SaaS)

RISK-BASED
VALIDATION WITH
TIME-SAVING
TEMPLATES



David Nettleton and
Janet Gough

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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

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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.

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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.

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