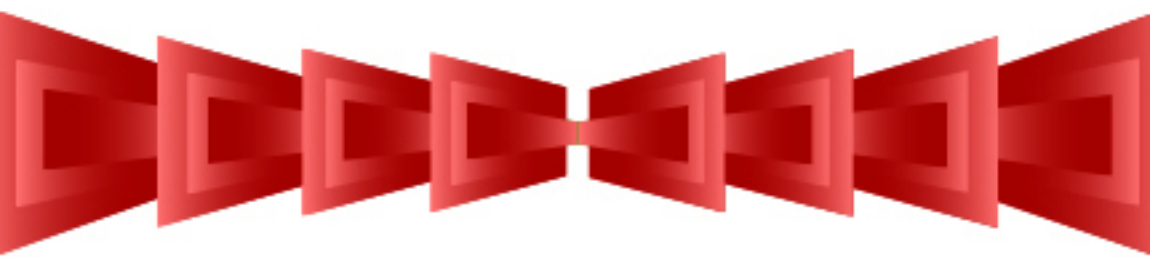
Cleaning Validation

Practical Compliance Solutions for Pharmaceutical Manufacturing

VOLUME 3



Destin A. LeBlanc

CLEANING VALIDATION

PRACTICAL COMPLIANCE SOLUTIONS FOR PHARMACEUTICAL MANUFACTURING

Volume Three

Destin A. LeBlanc

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FOREWORD

This is Volume 3, complementing my earlier two books on the same subject. What are presented in this book are modifications and updates of my monthly *Cleaning Memos* originally published on my web site, www.cleaningvalidation.com, in the period from January 2009 through December 2012. Each Cleaning Memo is presented as a chapter, with the chapters then organized by common topics. For example, topics related to setting limits are in one section, those related to sampling in another section, and so forth. The changes made are sometimes relatively simple, and sometimes more detailed. In all cases, I have tried to focus on changes for improving clarity and applicability, as well as to modify the text with new information. I have also added an appendix with a list of acronyms used in this volume. While Volume 2 in this series had an appendix summarizing my shorthand method of expressing limits as I used in 2009, my revised shorthand method is presented in Chapter 16. Therefore I have not elaborated on it in a separate appendix.

I would also like to encourage pharmaceutical manufacturers, and particularly upper management, to meet the challenges of the science-based and risk-based approaches to cleaning validation. Using some of the principles and practices in this volume may help in designing a more effective and efficient cleaning validation program.

I should add a caveat here, much like the caveat before each of the FDA's guidance documents — nothing in this book should be considered mandatory or binding. I have tried to present alternatives where possible. However, achieving the same objectives by utilizing scientifically justified procedures that are applicable to a manufacturer's specific situation is certainly encouraged.

Semper Eadem!
Destin A. LeBlanc
Kodak, TN
February 2013

GENERAL TOPICS

The following seven chapters cover general topics related to cleaning validation in most pharmaceutical manufacturing facilities.