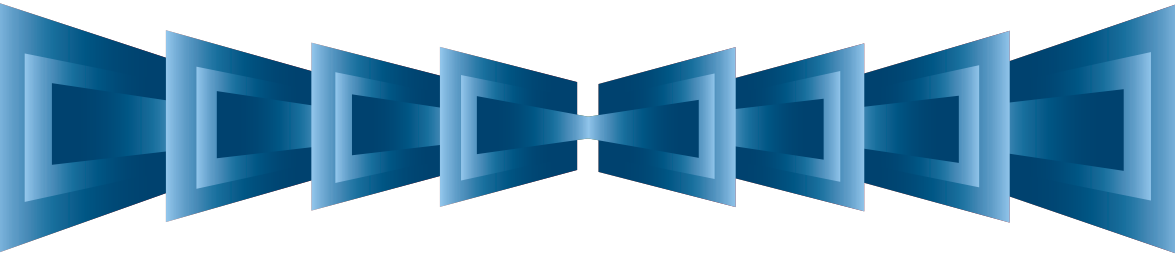
Cleaning Validation

Practical Compliance Solutions for Pharmaceutical Manufacturing

VOLUME 4



Destin A. LeBlanc

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Destin A. LeBlanc

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PDA Global Headquarters
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CONTENTS

FOREWORD

This Volume 4 complements my earlier three 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 2013 through December 2016. 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 updates 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. There is one appendix with a list of acronyms used in this volume, as well as a second appendix dealing with my shorthand method of expressing limits, just in case you get confused about what I mean by L0, L1, L2, L3 and L4.

A "hot topic" for these four years has been limits, and specifically health-based limits. More than half of these chapters deal with setting limits in one way or another, so the use of health-based limits will require balanced reading (and thinking) for an overall understanding.

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 strongly encouraged. In a manufacturing environment where process efficiencies as well as good compliance are mandatory, following "cookie cutter" recipes should be avoided.

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Destin A. LeBlanc
Winter Haven, FL
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