CLEANING VALIDATION

PRACTICAL COMPLIANCE SOLUTIONS FOR PHARMACEUTICAL MANUFACTURING

Volume Two

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FOREWORD

This is Volume II, complementing my earlier book 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 2005 through December 2008. Each *Cleaning Memo* is presented as a chapter, with the chapters then organized by common topics. For example, all topics related to setting limits are in one section, those related to sampling in another section, and so forth. There are only two *Cleaning Memos* from that period that were omitted, one which was focused on cleaning validation for medical device manufacture and one on objectionable organisms that was written by another subject matter expert. 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 and to modify the text with new information.

I have also added two appendices, one that explains my use of the terms L1, L2, L3 and L4 for expressing residue limits (since I will refer to limits in those ways in some of the chapters) and a second with a list of acronyms used in this volume.

This book is dedicated to those regulatory inspectors who labor in the "vineyards" of process equipment cleaning validation in the pharmaceutical industry. Your job is tough — you are expected to know what to look for in numerous aspects of pharmaceutical manufacturing, not just cleaning validation. Keep asking the right questions. My hats off also to the FDA in specific, who in this past decade has become much more open to science-based and risk-based approaches to validation.

I would also like to encourage pharmaceutical manufacturers, and particularly upper management, to meet the challenges of the FDA and begin utilizing more 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.

Soli Deo Gloria!
Destin A. LeBlanc
Kodak, TN
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