



Cleaning Validation: Practical Compliance Solutions for Pharmaceutical Manufacturing by Destin A. LeBlanc

Reviewing this book is a departure of sorts for the *PMF Newsletter*. Cleaning Validation: Practical Compliance Solutions for Pharmaceutical Manufacturing is not a book about microbiology (of the 49 short chapters in this compact book, only one deals with microbial studies and one with bacterial endotoxin studies). So why present this discussion?

There are a lot of myths, folk lore, “common practices” (call them what you will) in the pharmaceutical industry. Microbiology is full of them. In those areas where microbiology and chemistry overlap, these practices multiply. Cleaning validation is one such area where a great deal of confusion leads to questionable practices. The microbiology unit will (should) play a major role in the design of cleaning validation studies for Manufacturing, both in sterile and in non-sterile processing. However, the microbiology unit is concerned primarily with the reduction of viable contaminants, the cleaning validation must also demonstrate elimination of chemical contaminants, either from components of previously manufactured batches or from the cleaning agents used to remove them. It is important that the microbiologist on the project have an understanding and appreciation for these issues.

Cleaning Validation is a great place to start for a reference source on this information. Earlier in this newsletter we mentioned that much of pharmaceutical microbiology is not taught in a university, that you learn it on the job (“Who is a Microbiologist?”). Most of us learn cleaning validation that same way. However, we all have to be on guard against the tendency to ascribe “the XXXX way” (fill in the blank with any company name) with veracity merely because this is the way we have always done it. Repeating a mistake 100 times does not make it less of a mistake. This text can serve as an excellent “sanity check” for comprehension of specific topics, and as a start for examination of our own practices. The book is short (228 pages, excluding index) and very readable. However it is not designed to be read cover-to-cover.

Destin LeBlanc presents monthly *Cleaning Memos* on his web site <http://www.cleaningvalidation.com>. This book is a collection of these *Cleaning Memos* from 2000 to 2004, updated and revised to improve clarity. Each of the short

chapters (2-4 pages) was originally a different *Cleaning Memo*, with the book having the chapters organized into sections with similar themes:

- General Topics
- Special Situations
- Residue Limits
- Analytical Methods
- Sampling
- Sampling Recovery
- Protocol Issues
- Grouping Strategies
- Regulatory Issues
- Microbial Issues (2 chapters)
- Visually Clean Issues
- Validation Maintenance

In addition, the book boasts a modest index, but with such short chapters and such descriptive chapter headings the index is almost superfluous. As examples, chapter titles include:

- “What’s a contaminant?”
- “Why TOC Is Acceptable”
- “Selecting Swab Sampling Sites”
- “Cleaned Equipment Hold Times”
- “Understanding and Applying ‘Visually Clean’”

This book is not designed to provide educational instruction to someone new to the topic of cleaning validation. It does not follow the traditional method of starting with basic concepts and building to the complex. Rather, it is a great resource if you have a question about something you heard in a meeting that doesn’t sound quite right and you need to check it. In addition, each chapter provides references to allow the reader to do some research on the topic himself.

I recommend Cleaning Validation: Practical Compliance Solutions for Pharmaceutical Manufacturing by Destin LeBlanc to the QC microbiologist’s library. While it does not deal with microbiology as its primary topic, we find ourselves involved in cleaning validation discussions as part of cross-functional teams and need to understand the other aspects of the task. This treatment of the subject is clear, readable and level-headed.

Scott Sutton, Ph.D.

