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Book Review

Pharmaceutical Process Validation
Second Edition, Revised and Expanded
Edited by: Ira R. Berry and Robert A. Nash
Published by: Marcel Dekker, Inc. 1993
648 pages, hard cover, $125.00

The first edition of this book established itself as a valuable reference text for pharmaceutical scientists, regulators and academicians with an interest in pharmaceutical validation. The second edition, which is revised and expanded, will undoubtedly be generally accepted as a useful source of data in both the principles and practices of pharmaceutical process validation. Of course, not everyone will agree with all the views expressed in this book. Thus, I suspect FDA investigators might like to "nuke" the whole of chapters eight and seventeen! However, on balance this book is likely to be most well-regarded by those active in this most important field.

In general the book is well written and suitably illustrated with clear figures and photographs. Of course, as with any multi-author book there is some unevenness in style and depth of treatment. Chapter three, for example, on Validation of Sterile Products (Akers and Anderson) is a gold mine of practical "how to" data. Whereas, chapter thirteen on Analytical Methods Validation is depressingly lacking in detailed, practical advice on this important topic. Thus, I could find no specific coverage of validation of stability indicating assay and details of assay validation such as the use of controls and standards, policies on outliers and repeat assays appear to be absent. Also there does seem to be considerable overlap between various chapters but perhaps this was deliberate.

This book is an essential purchase for any laboratory or office where pharmaceutical process validation is of interest.

Staff Review