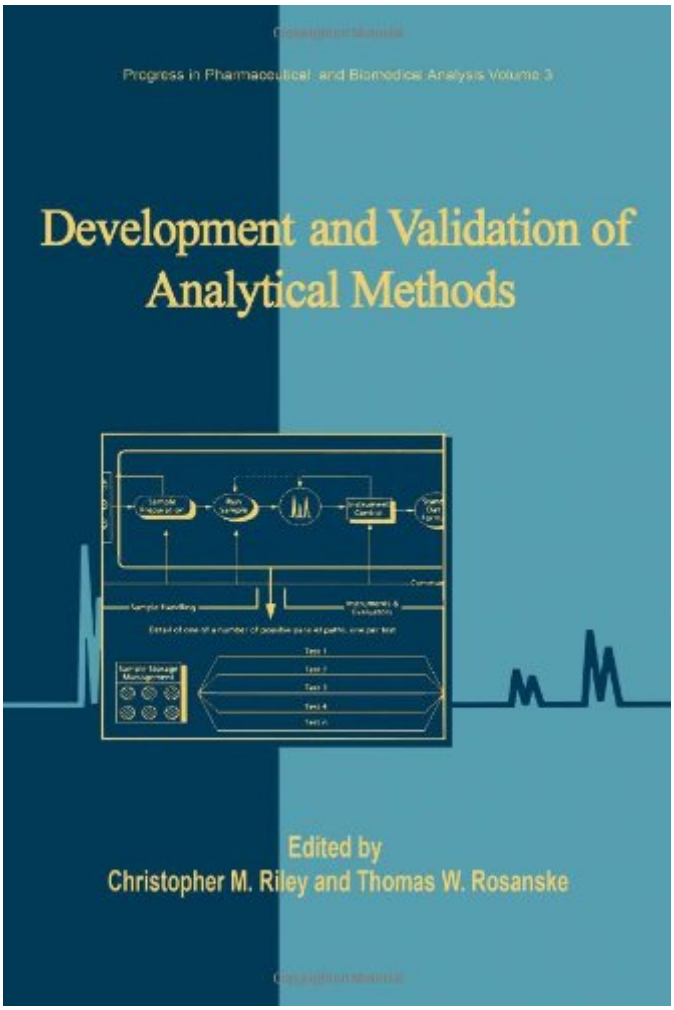
Development and Validation of Analytical Methods, Volume 3 (Progress in Pharmaceutical and Biomedical Analysis) PDF



Development and Validation of Analytical Methods, Volume 3 (Progress in Pharmaceutical and Biomedical Analysis) by Christopher M. Riley, Thomas W. Rosanske ISBN 0080427928

The need to validate an analytical or bioanalytical method is encountered by analysts in the pharmaceutical industry on an almost daily basis, because adequately validated methods are a necessity for approvable regulatory filings. What constitutes a validated method, however, is subject to analyst interpretation because there is no universally accepted industry practice for assay validation. This book is intended to serve as a guide to the analyst in terms of the issues and

parameters that must be considered in the development and validation of analytical methods. In addition to the critical issues surrounding method validation, this book also deals with other related factors such as method development, data acquisition, automation, cleaning validation and regulatory considerations.

The book is divided into three parts. Part One, comprising two chapters, looks at some of the basic concepts of method validation. Chapter 1 discusses the general concept of validation and its role in the process of transferring methods from laboratory to laboratory. Chapter 2 looks at some of the critical parameters included in a validation program and the various statistical treatments given to these parameters.

Part Two (Chapters 3, 4 and 5) of the book focuses on the regulatory perspective of analytical validation. Chapter 3 discusses in some detail how validation is treated by various regulatory agencies around the world, including the United States, Canada, the European Community, Australia and Japan. This chapter also discusses the International Conference on Harmonization (ICH) treatment of assay validation. Chapters 4 and 5 cover the issues and various perspectives of the recent United States vs. Barr Laboratories Inc. case involving the retesting of samples.

Part Three (Chapters 6 - 12) covers the development and validation of various analytical components of the pharmaceutical product development process. This part of the book contains specific chapters dedicated to bulk drug substances and finished products, dissolution studies, robotics and automated workstations, biotechnology products, biological samples, analytical methods for cleaning procedures and computer systems and computer-aided validation. Each chapter goes into some detail describing the critical development and related validation considerations for each topic.

This book is not intended to be a practical description of the analytical validation process, but more of a guide to the critical parameters and considerations that must be attended to in a pharmaceutical development program. Despite the existence of numerous guidelines including the recent attempts by the ICH to be implemented in 1998, the practical part of assay validation will always remain, to a certain extent, a matter of the personal preference of the analyst or company. Nevertheless, this book brings together the perspectives of several experts having extensive experience in different capacities in the pharmaceutical industry in an attempt to bring some consistency to analytical method development and validation.

Development and Validation of Analytical Methods, Volume 3 (Progress in Pharmaceutical and Biomedical Analysis) Review

This Development and Validation of Analytical Methods, Volume 3 (Progress in Pharmaceutical and Biomedical Analysis) book is not really ordinary book, you have it then the world is in your hands. The benefit you get by reading this book is actually information inside this reserve incredible fresh, you will get information which is getting deeper an individual read a lot of information you will get. This kind of Development and Validation of Analytical Methods, Volume 3 (Progress in Pharmaceutical and Biomedical Analysis) without we recognize teach the one who looking at it become critical in imagining and analyzing. Don’t be worry Development and Validation of Analytical Methods, Volume 3 (Progress in Pharmaceutical and Biomedical Analysis) can bring any time you are and not make your tote space or bookshelves’ grow to be full because you can have it inside your lovely laptop even cell phone. This Development and Validation of Analytical Methods, Volume 3 (Progress in Pharmaceutical and Biomedical Analysis) having great arrangement in word and layout, so you will not really feel uninterested in reading.