KIM HUYNH-BA
Editor

Handbook of Stability Testing in Pharmaceutical Development

Regulations, Methodologies, and Best Practices

Springer

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ISBN: 978-0-387-85626-1 e-ISBN: 978-0-387-85627-8
DOI 10.1007/978-0-387-85627-8

Library of Congress Control Number: 2008940845

Printed on acid-free paper

springer.com

A dream you dream alone is only a dream
A dream you dream together is reality
John Lennon

Preface

In my professional career as a pharmaceutical scientist, I have been involved with several aspects of the drug development process from pre-IND to commercialization and, somehow, I usually found myself coming back to a stability-related issue. The stability area seemed to draw my utmost interest because in my day-to-day work, my opportunities involved more than one product, and none of the issues were the same. Each situation posed challenges that usually required an exercise of judgment, an understanding of regulations, a knowledge of science, a grasp of compliance, and an appreciation of common practices.

Since early 2000, I have also been involved with several training opportunities and I struggled to find good, concise, practical resources, one of which I could just hand to a new scientist who wishes to gain a greater understanding of stability sciences. In addition, I encountered the same questions posted over and over on different stability best practices discussion forums.

As a book lover, I also have a good collection of technical books. Unfortunately, most of the stability related volumes are outdated. Many of these materials are theoretical and do not contain much practical information. I understand that the pharmaceutical industry during this period is quite volatile, and guidelines are changing rapidly while regulatory agencies are working closely with the pharmaceutical industry to accommodate these changes; however, the fundamental information continues to remain quite the same, just as current Good Manufacturing Practices (cGMP) continue to be the standard industry practice. Therefore, I hoped to assemble a practical handbook to fill this void.

Handbook of Stability Testing in Pharmaceutical Development is a product of several dedicated stability scientists. Collectively, we have over 300 years of experience working in all aspects of the pharmaceutical industry. This volume is intended to bring together a comprehensive overview of a stability program coupled with practical best practices. It can be used to serve the stability community as a handbook to train new scientists who find themselves involved with stability sciences in multidisciplinary functions. It can also be used in an academic setting so students can gain more practical understanding of the pharmaceutical industry.It contains

essential information to guide best practices for development and management of a compliant stability program.

July 2008 Kim Huynh-Ba

Editorial Notes

Contributing authors are responsible for the content and ideas included in their chapters. Although much information is presented and recommendations are drawn based on scientific knowledge of the experts, review perspectives may vary depending on technical background, personal experiences, and discussion preference. In addition, many references are cited from web links that appear to be valid at time of press. Great efforts were made to assure the book is as accurate as possible; however, the editor wishes to hold no responsibility for, nor can she endorse, the material published in this publication.

Acknowledgments

This project would not be possible without support from the following individuals. To them, I am in debt with appreciation.

I would like to thank all contributors for their work. They exemplify the expertise of their field and I am humble to have the privilege of editing and coordinating their work. Many of them have been my mentors, colleagues, and friends who provide enormous support throughout my professional career. I honor their trust in me leading this important project.

I would like to thank the support of all reviewers: Dr. Steve Baertschi, Mr. John C. Brown, Ms. Ellen Carsch, Dr. Sean (Xiaoming) Chen, Dr. Dilip Choudhury, Dr. Frank Diana, Dr. Anthony DeStefano, Dr. Michael Dong, Dr. David Lin, Dr. Oscar Liu, Dr. Mary Ellen McNally, Ms. Winona Matheson, Ms. Mikie McGinnes, Dr. Alvin Melveger, Ms. Lisa Neiss, Dr. Linda Ng, Dr. Christopher Riley, Dr. Mark Schreiber, Dr. James Shea, Dr. James Sullivan, Ms. Carol Thomas. They have helped to critically review and comment on these chapters.

I would like to thank my graduate school mentor and a special friend, the late Dr. Robert Lee Grob, who was an exceptional role model and who had encouraged me to initiate this project.

Last but not least, I would like to thank my family – my husband Thai, my sons John and James – for their encouragement and for putting up with me while getting this important work done. My appreciation also goes to my parents, Mr. Hong Nguon Cao and Mrs. Kimhoa Ngoc Bach, for their unconditional support.

Contents

Preface vii

Editorial Notes ix

Acknowledgments xi

Contributors xv

1 Introduction 1
Kim Huynh-Ba

Part I Stability Regulations

2 Critical Regulatory Requirements for a Stability Program 9
Alvin J. Melveger and Kim Huynh-Ba

3 Understanding ICH Guidelines Applicable to Stability Testing 21
Kim Huynh-Ba and Manuel Zahn

4 Global Stability Practices 43
Manuel Zahn

5 Post-approval Changes – Stability Requirements and Regulations . . . 93
Frank J. Diana

6 Understanding and Predicting Pharmaceutical Product Shelf-Life . . 115
Kenneth C. Waterman

Part II Stability Methodologies and Best Practices

7 Development of Stability Indicating Methods 139
Anne-Françoise Aubry, Peter Tattersall, and Joan Ruan

8 Method Validation and Transfer 163
Frank J. Diana

9 Overview of USP-NF Requirements for Stability Purposes 189
Susan Schniepp

10 Non-chromatographic Methods to Support Stability Program 201
Timothy Rhines

11 Vibrational Spectroscopic Methods for Quantitative Analysis 223
Frederick H. Long

12 Impact of Solid-State Characteristics to the Physical Stability of Drug Substance and Drug Product 241
Yushen Guo

13 Evaluation of Stability Data 263
Nanda Subbarao and Kim Huynh-Ba

14 Qualification, Calibration, and Maintenance of Stability Chambers 285
Jack B. Davis

15 Stability Operation Practices 303
Kim Huynh-Ba

Part III Other Stability Programs

16 Combination Products/Drugs in Devices 323
Jon V. Beaman and Roisin Wallace

17 Stability Studies for Biologics 353
Anthony Mazzeo and Patrick Carpenter

List of Abbreviations 371

Index 375

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