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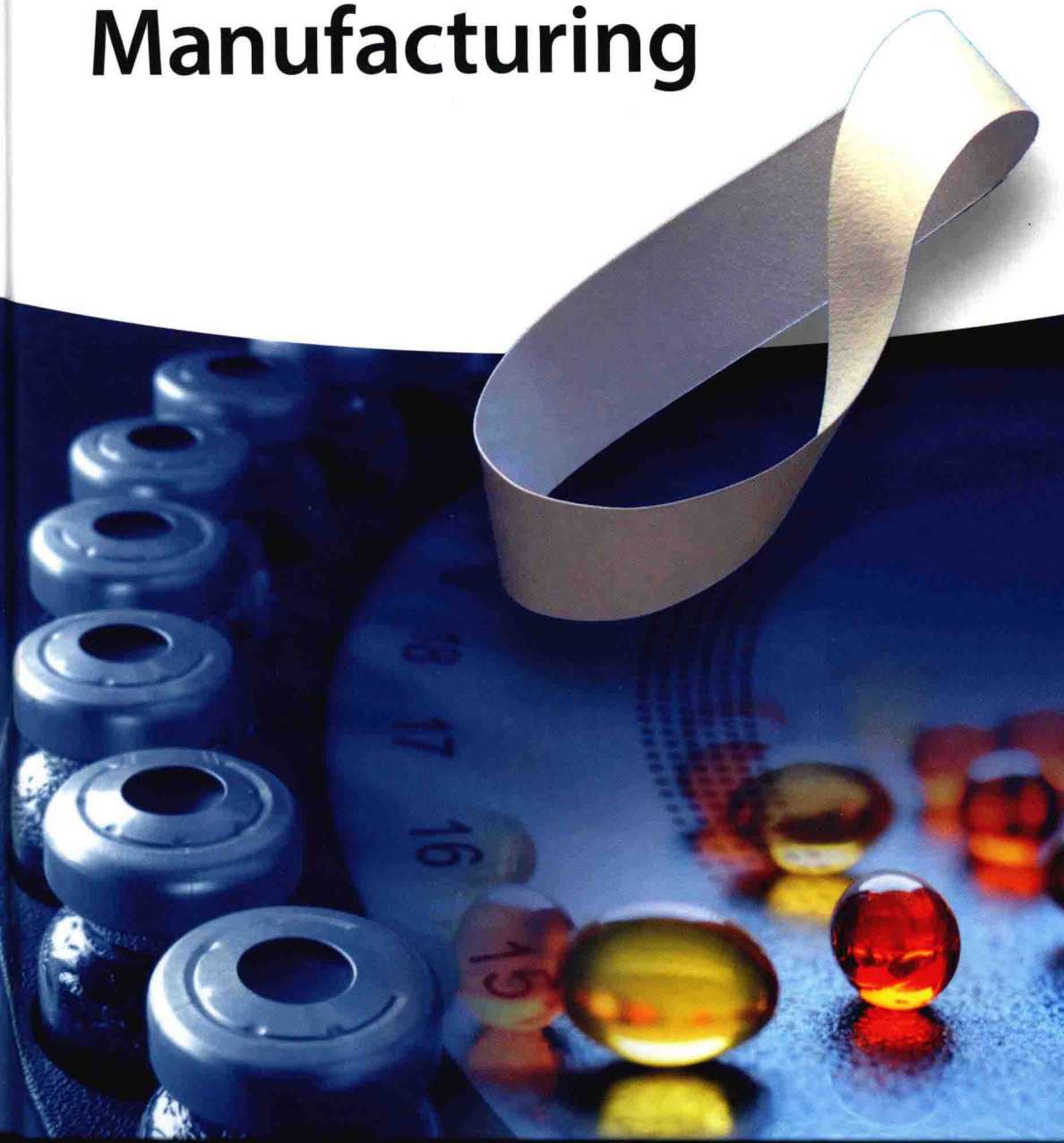
Ganapathy Subramanian

Continuous Processing in Pharmaceutical Manufacturing



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Preface

A continuous process requires the ability to think laterally and have a proactive mindset across the entire team from lab development through to production. Continuous manufacturing process is not new. It has been in use by the chemical, food, and beverage industries successfully. The biopharmaceutical industries are reluctant to engage in applying advanced technology on continuous processes, and are still using the batch process, which has been is use since the nineteenth century. The batch process is an archaic process that progresses sequentially step by step, creating a specified and fixed amount of therapeutic product, which in modern times is not state-of-the art. Several reviews and articles have shown that considerable advances have been made by technologist in offering systems for continuous processes. It has been established that continuous processing promises efficiency because it is a well controlled and flexible process, and there is less waste and produces higher quality products. There is considerable economic benefit in applying the continuous process in manufacturing.

Momentum is gathering pace behind the implementation of continuous manufacturing in the pharmaceutical industry. The regulatory bodies are now encouraging companies to move toward continuous manufacturing. Consequently, leading biopharma industries seem to be in the mend of thinking that the time is right for a major effort in the development of continuous processes in their organizations. As more companies look at the practical evidence from pilot and demonstration units, the adoption and commercialization of the new technology is picking up speed and currently several leading global biopharmaceutical industries are moving to implement continuous manufacturing processes in collaboration with technologist and suppliers. It will not be far away that industries will apply the continuous manufacturing process and thus we are setting up a Gold standard for the future, maybe in 10 years or more.

This book presents the most recent scientific and technological advances of continuous processing, as well as methods and applications in the field of biomanufacturing. Each chapter provides introductory material with an overview of the topic of interest; a description of the technology and methods, protocols, instrumentation, and application, and a collection of published data with an extensive list of references for further details.

It is our hope that this book will stimulate a greater appreciation of the usefulness, efficiency, and the potential of single-use systems in continuous processing of biopharmaceuticals, and that it will stimulate further progress and advances in the field of continuous processing to meet the ever-increasing demands and challenges in the manufacturing of therapeutic products.

The completion of this book has been made possible with the help and encouragements of many friends and colleagues. It is a great pleasure for me to acknowledge, with deep gratitude, the contribution of 19 authors of the chapters in this book. Their outstanding work and thoughtful advice throughout the project have been important in achieving the breadth and depth of this book.

I would be most grateful for any suggestions that could serve to improve future editions of this volume.

Finally, my deep appreciation to Dr Frank Weinreich of Wiley-VCH for inviting me to edit the volume and also to Lesley Fenske and her colleagues for their sustained encouragement and help.

Maidenhead, UK
June 2014

G. Subramanian

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