

Preface

THIS BOOK draws its content from the Cellular Bioprocess Technology short course that has been offered at the University of Minnesota for over three decades. Each year, a number of prominent academics and industry leaders come to the course to share their knowledge and best practices. This book is distilled from the topics and materials developed for those lectures. This second edition reflects the developments in cell technology since the publication of the first edition in 2012.

This book, like the short course, aims to serve practitioners of mammalian cell-based biologics production. A major goal of this book is to present the fundamentals of process technology and biology to industrial practitioners of diverse backgrounds and to students from different academic disciplines in a succinct and easy-to-grasp way. Another goal is to bring new knowledge from cutting-edge research and practice into the very practical setting of today's industrial laboratories. Over the course of developing a new therapy—from the discovery in a laboratory to developing a production process, successfully commercializing the product, and manufacturing the product with consistently high quality and efficiency—scientists and engineers of different disciplines and in different functional roles must effectively communicate in order to develop, advance, and innovate.

The first chapter in this book gives a historical overview of the evolution of the science and technology of cell culture and the trends of process technology in recent years. The second part of the book covers fundamental knowledge of cell biology, metabolism, cells' nutritional needs, the determinants of product quality, and the means to create cell lines as the workhorse for product manufacturing. The third group of chapters delves into the process engineering principles of stoichiometry, reactor kinetics, and scale-up. Since this book is written for readers of diverse backgrounds, the aim is to help engineers understand the key biological features of cells without requiring an extensive prior background in biology, and also to help non-engineers grasp basic engineering

principles without a prior two years of college math. This book was written to allow scientists to gain a process perspective while reading through biology-related topics, and to allow engineers to appreciate biological considerations while perusing engineering topics.

As a second edition, this book is based on and extended from its first edition, except for the addition of Chapter 4. Some chapters, especially those regarding engineering subjects (Chapters 5, 8, 11, and 12), bear a higher degree of resemblance to their counterparts in the first edition, reflecting that fundamental principles do not change over time. Some figures (including 1.3, 2.1, 2.3, 2.6, 2.7, 2.11–15, 3.2, 3.9, 3.11, 3.19, 3.21, 3.23, 5.3, 8.9–14, 11.3, 12.1, 12.2, 12.4, and 12.8) are also adopted from the first edition.

The content of the course and this book has been shaped by many who participated in teaching the course over the years since 1986. The delivery of the materials in this book has been polished through lecturing the more than three thousand biotechnologists who have attended the course in the past. I thank them sincerely for their participation. For this second edition, I would like to thank Susan Abu-Absi, Nitya M. Jacob, Rashmi Kshirsagar, Bhanu Chandra Mulukutla, Gargi Seth, and Weichang Zhou in particular. Susan prepared the draft of the second half of Chapter 4 and is acknowledged as a contributor to that chapter.

Many former and current members of my research laboratory at the University of Minnesota contributed to the preparation of course materials. For this edition I thank Tung Le, Sofie O'Brien, and Conor O'Brien in particular.

Many skillful hands have worked on this book. Kimberly Durand first took the notes to digital form two decades ago and continues to support the effort. For this edition, Victoria Roberts single-handedly took the book from a draft Word document and hand-sketched graphics to the laid-out and typeset product. She even learned some biology and engineering along the way. The dedication of both is remarkable.

Like its first edition, this book is dedicated to the students, fellows, and staff formerly and currently in my research group at the University of Minnesota. Without this group of individuals to help advance the content of the course, this book would not have been in the shape that it is today. Finally, I wish for my lovely family, Jenny, Kenny, Lauren, two granddaughters, Ya-Ling and Wen-Li, and my wife, Sheau-Ping, to share the joy of the book's completion.

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