Preface to the second edition

The preface to the first edition of this book conveyed the key motivation for writing it: to provide concise, comprehensive coverage of the foundations of biopharmaceutical production, inspired by the dynamic learning environment of the Biomanufacturing Training and Education Center at NC State University. This aim and inspiration are as true now as in 2021 when the first edition of this book was published.

So why a second edition and why now?

The biopharmaceutical industry continues to experience unprecedented growth, driving transformative advancements in human health. Innovations in biopharmaceuticals not only fuel economic growth but also profoundly impact millions of lives worldwide, offering hope and improved quality of life. While estimates vary, one source projects that the global biopharmaceutical market will grow from approximately US$511 billion in 2023 to US$1,375 billion by 2033.* The list of diseases preventable or treatable by biopharmaceuticals is long and expanding, now bolstered by cutting-edge modalities such as mRNA vaccines, gene therapies, and cell therapies. Among these breakthroughs is the first United States Food and Drug Administration-approved therapy utilizing CRISPR (clustered regularly interspaced short palindromic repeats) gene-editing technology – Casgevy®, now available on the market to treat sickle cell disease. Ensuring that their impact continues and grows requires a workforce that is highly educated and skilled in the complex processes and regulations required of biopharmaceutical production. Now, more than ever, resources like this book must remain clear, current, and comprehensive to meet the growing demands of the industry.

As with the first edition, the second edition offers a unique blend of theoretical concepts and practical applications, making it an invaluable resource for both students and professionals alike. While the topics of chapters remain unchanged, this edition includes several updates and enhancements, including

- New examples of impactful biopharmaceuticals like Ozempic®, a treatment for type 2 diabetes, and Comirnaty®, a vaccine against COVID-19.
- Updated content on rapidly evolving technologies, such as single-use systems and continuous processing, to reflect the latest advancements.
- Refined explanations of a number of key concepts to enhance clarity and ensure the book remains an engaging resource for students and professionals.
- New review questions added to Chapter 3 and updates to review questions in most other chapters.

*Biologics Market Size, Share & Trends Analysis Report By Source (Microbial, Mammalian), By Product (MABs, Recombinant Proteins, Antisense & RNAi), By Disease Category, By Manufacturing, By Region, and Segment – Global Industry Analysis, Size, Share, Growth, Trends, Regional Outlook, and Forecast 2024–2033. 2023. Nova One Advisor. (Accessed August 13, 2024, at https://www.novaoneadvisor.com/report/biologics-market#:~:text=Report%20Description,11.8%25%20during%20the%20forecast%20period).

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These revisions ensure that the book continues to serve as an engaging, up-to-date resource for learning and reference.

In the first edition, we acknowledged a number of colleagues and friends who helped in many ways to bring the book together. Their foundational contributions remain vital to this second edition, and so our appreciation bears mentioning again.

Lauren Lancaster, Ben Lyons, Michele Ray-Davis, Arjun Shastry, and John van Zanten provided data and process-related information that helped in creating real-world examples and problems. Mark Burdick, Sahr James, Mark Pergerson, Jennifer Sasser, and John Taylor supported the creation of a number of figures. Donna Gilleskie, Matt Gilleskie, Erik Henry, Russ McCuen, Baley Reeves, and Caroline Smith-Moore all read through early versions of various chapters and provided helpful feedback that led to continuous improvement in content and clarity during the writing process. John Amara, Suzanne Bellemore, Akshat Gupta, Thomas Parker, and Jonathan Steen from MilliporeSigma provided images and reviewed filtration chapters, greatly enhancing their quality.

Brian Herring worked tirelessly to create most of the figures that are included in the book, and did the same to update figures for this second edition. And Patty Brown undertook many editing duties.

We also want to express special thanks to those whose contributions enriched this second edition. Our appreciation extends to Jennifer Pancorbo for her expertise in vaccines; Sara Siegel and Kurt Selle for their contributions in microbiology and molecular biology; Lucia Clontz for her insights into microbial contamination control; and Danny Schmitt for his expertise in lyophilization. Their contributions have made this edition stronger and more valuable.

We are deeply grateful for the collective contributions of these individuals, without whom this second edition would not have been possible.

On behalf of the authors,
Gary Gilleskie