

Preface

ON BEHALF OF THE ASSOCIATE EDITORS, authors, and reviewers we are pleased to introduce the first edition of the *AABB Biotherapies Manual: Principles, Processes, and Practice*. As cell and gene therapies become increasingly integrated into clinical practice, the professionals responsible for collecting, manufacturing, testing, preserving, and administering these products need practical guidance. This manual was developed to help meet that need by describing current principles, processes, and practices related to acquisition of cellular starting material, product manufacturing, assessment, preservation and administration, operation of facilities and equipment, quality systems, and regulatory considerations.

By bringing these topics together in a single resource, the manual provides an integrated perspective across the cell and gene therapy product pathway. It is intended for professionals working in collection facilities, processing and testing laboratories, manufacturing organizations, clinical programs, pharmacies, quality departments, and other settings that support the delivery of these therapies.

AABB has been a cornerstone of blood banking and transfusion medicine in the United States and beyond for more than 75 years. One of AABB's many important contributions to the field has been the *AABB Technical Manual*, currently in its 22nd edition. The *AABB Biotherapies Manual* builds on AABB's longstanding experience in developing standards, accreditation programs, educational resources, and technical guidance

while addressing the distinct operational and quality considerations associated with biotherapies. We expect that this will become an essential reference for individuals and organizations who are advancing this rapidly evolving field.

The content quality of the *AABB Biotherapies Manual* is safe-guarded by a rigorous peer-review process. Each chapter underwent an initial review by the editors for content and style followed by review by subject-matter experts. We have followed the practice of the *AABB Technical Manual* by posting the appendices online with access available to users of both the print and digital formats.

We are especially grateful for the work and support of the associate editors—Ellen Lazarus, MD; Wade Atkins, MS, MLS(ASCP)SBB, CQA(ASQ), CABP(H)(AABB); Diane Kadidlo, BSc, MLS(ASCP)SBB; and Ena Wang, PhD—for their leadership and expertise. We also thank the many authors and reviewers whose contributions made this publication possible and the talented and dedicated staff at AABB who helped produce this edition.

On behalf of the associate editors, authors, and reviewers we hope that you enjoy using the first edition of the *AABB Biotherapies Manual*. May you find it a useful reference tool in your work and in the continued advancement of safe, high-quality cell and gene therapies.

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