PREFACE

The Standards Program Committee (SPC) and the Cell and Gene Therapy Services for Pharmacy Standards Committee (CGT SC) are pleased to present this 1st edition of *Cell and Gene Therapy Standards for Pharmacy (CGT Standards)*.

The SPC is the umbrella committee whose primary role is to oversee the creation, development, and revision of all AABB standards to ensure harmonization and consistency in AABB's standard-setting activities. The SPC consists of a committee chair, the chair of the Standards Subcommittee for the Evaluation of International Variances, as well as the chairs of the 10 standards committees.

The CGT SC developed this 1st edition of *CGT Standards* using an evidence-based decision making process, when possible.

The CGT SC consists of a chair; full members from the pharmacy field (clinicians, medical and laboratory professionals, medical technologists, and quality experts); liaisons from other AABB committees; and representatives from other organizations.

The guiding principle of the *CGT Standards* is to cover the receipt, handling, storage, and dispensation of approved cell and gene therapy products to maintain the quality of the product while in possession of the pharmacy. This 1st edition focuses on organizational structure and quality management systems, critical agreements with product manufacturers and vendors, processes for handling products, documentation and record retention, deviations, nonconformances and contributions to outcomes reporting, process improvement and safety. This 1st edition is not intended to include activities outside the responsibilities of a pharmacy such as: starting material collection, product manufacturing, product characterization, or product administration.

Although the *CGT Standards* provides a great amount of technical information concerning CGT pharmacy programs, other AABB publications provide specific recommendations. Guidance for specific standards that appear in this edition of the *CGT Standards* is published in *Guidance for Cell and Gene Therapy Standards for Pharmacy,* available as part of the AABB Standards Portal and in print.

The CGT SC has published a document providing informal responses to the comments received during the comment period explaining why the CGT SC adopted a suggestion, or did not. This document can be found on the AABB website at the following address: http://www.aabb.org/sa/standards/Pages/library.aspx.

I am truly honored to have chaired this ground-breaking achievement demonstrating a valued expansion of the AABB Standards. I am incredibly grateful to the committee members and their dedication and commitment to these *CGT Standards* as well as the AABB staff who were fearless leaders. We look forward to their adoption and an incredible future in this area. AABB, as always, is open to feedback and to continuously improve our Standards.

Beth Shaz, MD, MBA
Chair, Cell and Gene Therapy Services for
Pharmacy Standards Committee

INTRODUCTION

The 1st edition of *Cell and Gene Therapy Standards for Pharmacy (CGT Standards)* was prepared by the Cell and Gene Therapy Services for Pharmacy Standards Committee (CGT SC) and the Standards Program Committee of the AABB. The goal of the *CGT Standards* is to maintain and enhance the quality and safety of procurement, processing, storage, and clinical administration of cellular therapy products and to provide a basis for the Accreditation Program of the AABB.

This 1st edition of Cell and Gene Therapy Standards for Pharmacy implements AABB's updated quality system essentials (QSEs). First introduced by AABB in 1997, a quality system approach has served as the framework for all sets of AABB Standards published since that date. In 2023, AABB updated the QSEs and has incorporated the update in all sets of AABB *Standards* as new editions are released. The updated QSEs include the following:

- All standards are written in the active voice.
- Once a requirement has been stated, it is not repeated.
- Each chapter begins with a description of what the standards therein cover.
- Each chapter contains a list of key terms that relate to the content of the chapter, with their definitions.
- Each chapter contains a list of examples of objective evidence that an assessor could look for during an on-site assessment; however, this list is not comprehensive, nor will it be assessed against by an assessor. It is merely for guidance purposes only.
- Each chapter now concludes with the record retention table for that chapter. Note that a comprehensive record retention table exists at the end of Chapter 6.

In addition to a quality system framework, AABB Standards also contain technical requirements, designated as Reference Standards. Adherence to both the quality and technical standards is required for accreditation. The AABB and the CGT SC feel that the updated QSEs

combined with the technical requirements of the *CGT Standards* will allow facilities handling and dispensing CGT products to take the next step in quality.

The following frequently asked questions will help users of this edition better understand this 1st edition of *CGT Standards:*

When does this edition go into effect?

The effective date of this edition is October 1, 2025.

Are the CGT Standards requirements or recommendations?

The *CGT Standards* contains requirements implemented by AABB-accredited cell and gene therapy pharmacies. A requirement contains the word "shall," which indicates that the statement is mandatory. Failure to meet the requirement would constitute a nonconformance under the AABB Accreditation Program. There are rare instances in which a standard uses the term "may." A statement that uses "may" is not a requirement.

How does this book relate to other laws and regulations?

The CGT Standards were developed on the basis of good medical practice and, when available, scientific and evidence-based data. The requirements in this book can be followed by a cell and gene therapy pharmacy located anywhere in the world, but they do not preempt federal, state, and/or local laws and regulations. Accredited facilities must follow the *CGT Standards* as written to ensure continued AABB accreditation in good standing. Although the majority of the standards are intended to be consistent with applicable laws and requirements, no assurances can be given that compliance with *CGT Standards* will result in compliance with all applicable laws and requirements. These *CGT Standards* are not intended as a substitute for legal advice and the content should not be relied upon for legal purposes. Therefore, users must make their own determinations as to how best to ensure compliance with all applicable laws and requirements, including consulting legal and regulatory counsel familiar with these issues.

Does this edition require me to follow my own local laws and regulations?

Yes. In many standards, the CGT SC chose to use the term "specified requirements." This phrase is defined in the glossary to include any applicable requirement under which a service might operate. These could include, but are not limited to, a federal regulation, a customer agreement, a practice standard, the instructions for the intended use of a device, or a requirement of an accrediting organization.

What does the pen symbol (✎) mean?

When the pen symbol precedes a standard, users have to maintain a record of that activity in order to meet the standard. Readers should refer to the reference standard at the end of each chapter and the comprehensive reference standard at the end of Chapter 6 to determine what that record must contain, as well as the required record retention time.

What other tools are available to help me implement the *CGT Standards*?

There are several other resources to assist users. This publication also includes:

- A glossary, which reflects the usage of specific words or phrases in the context of these *CGT Standards*.

In addition, users of this edition may also want to:

Visit the AABB website for a document that details the significant changes to this edition. This document is titled, "Significant Changes and Response to Comments to the 1st edition of Cell and Gene Therapy Standards for Pharmacy."

- Follow guidance to the 1st edition of *CGT Standards*, found in the AABB Standards Portal online, or in the printed *Guidance for Cell and Gene Therapy Services Standards for Pharmacy*. The guidance provides rationales behind significant changes to this edition of *CGT Standards* and provides recommendations on how to meet the intent of certain standards.

- Contact the Standards Department (standards@aabb.org) to ask for interpretations or to submit a variance request. Variances to standards are effective for the edition of *CGT Standards* for which they are received. Request forms for variances can be found on the AABB website at http://www.aabb.org/sa/standards/Pages/Requesting-a-Variance.aspx. Request for renewal of previously granted variance requests must be submitted before the effective date.