
GENERAL POLICIES

The following guidance is intended to assist in the understanding and practical application of the 1st edition of *Cell and Gene Therapy Standards for Pharmacy (CGT Standards)*. The document contains guidance on both the quality concepts that provide the framework for the *CGT Standards* and many of the technical elements contained therein.

It is important to note that the standards in the *CGT Standards* contain the imperative “shall.” The majority of the information in this document, on the other hand, is termed “guidance,” which is intended to serve as helpful advice or to provide examples of how to implement a specific standard; guidance is often characterized by use of the word “should.”

This document includes verbatim requirements from the *CGT Standards* interspersed with guidance. Language from the standards is presented; when there is appropriate guidance for that standard, the guidance language follows the standard with the heading “Guidance.” This format allows the reader to see both the requirement and the associated guidance side by side. Due to the interrelated nature of this guidance document and the standards, readers are encouraged to become familiar with the *CGT Standards* and its format. The Introduction and Preface to the *CGT Standards* contain information that is applicable to this document as well.

Please note that there is no guidance for some standards. The Cell and Gene Therapy Services for Pharmacy Standards Committee has chosen to focus this guidance document on those issues that may require additional context and/or examples to assist in attaining compliance with the *CGT Standards*.