FOUNDATION FOR THE ACCREDITATION OF CELLULAR THERAPY

Summary of Changes
Fourth Edition FACT Common Standards

This document summarizes the major changes in the draft fourth edition *FACT Common Standards*. Many of the revisions to the Standards were influenced by advances in the field of cellular therapy as determined by the Standards Committee and reflect alignment with modern cell and gene therapy practice; traceability, product identity, and labeling standardization; governance and accountability structures; and strengthened quality management. The examples below are representative only and do not include all revisions. Please refer to the redlined document for a comprehensive view of all changes.

Revision Theme	Examples
1. Alignment across FACT Standards to ensure applicability across cell and gene therapy manufacturing environments.	• Edited definitions for "Cellular therapy product" and "Genetically modified cell" to reflect processing and manufacturing practices. • Added definition for "Immune effector cell (IEC)." • Introduced new Standards B2.3, B2.13, C2.4.3. • Removed Standard D2.12.2, D2.12.3.
2. Greater emphasis on traceability, product identity, and labeling standardization.	• Edited definitions for "Exceptional release," "ISBT 128," "Product code," and "Product name" which strengthen product tracking from origin through processing, distribution, and administration, to follow-up. • Introduced new Standards B7.2.2, C7.4.2.1, D7.4.4.
3. Clarification of governance and accountability structures in response to legal guidance.	Clarification of organization structure to include the following: • Added Tenet 2.4. • For Collection, changed title of "Medical Director" to "Collection Facility overseeing physician." • Edited definitions for "Clinical Program" and "New recipient." • Added definitions for "Acuity," "Assent," "Clinical Site," "Collection Site," and "Consent process." • Edited definition of "Collection Facility" accompanied by a statement defining its scope. • Introduced new Standards B3.9.2, B3.10. • Edited Standard C3.1.1, D3.1.1.
4. Enhanced Quality Management framework.	Notable harmonization and standardization of QM terminology across the FACT Standards to reduce interpretive variability, including the following: • Added definitions for "Corrective Action Plan," "Quality assurance," "Quality improvement," and "Risk assessment." • Edited definitions for "Corrective action," "Deviation," and "Preventive action." • Introduced new Standards B4.4, C4.2, D4.4.