Code of Federal Regulations

FDA Guidance

2023

Book 10

Selected Regulations & Guidance on Biologics, Blood Products & Good Tissue Practice

(April 1, 2023 - March 31, 2024)

CFR Title 21 Food & Drugs

Revised as of April 1, 2023

Part 600	Biological Products; General
Part 601	Licensing
Part 606	Current Good Manufacturing Practice for Blood and Blood Components
Part 607	Establishment Registration and Product Listing for Manufacturers of Human Blood and Blood Products
Part 610	General Biological Products Standards
Part 630	General Requirements for Blood, Blood Components, and Blood Derivatives
Part 640	Additional Standards for Human Blood and Blood Products
Part 660	Additional Standards for Diagnostic Substances for Laboratory Tests
Part 680	Additional Standards for Miscellaneous Products
Part 1270	Human Tissue Intended for Transplantation
Part 1271	Human Cells, Tissues, and Cellular and Tissue-Based Products

FDA Guidance for Industry

Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)

Current Good Tissue Practice (CGTP) and Additional Requirements for Manufacturers of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)

CLINICAL RESEARCH RESOURCES