Online Resources and Links for the 8th Edition Cord Blood Accreditation Manual

Resource Name/URL	Applicable Standard(s)
FACT Website Resources	
FACT Home Page https://www.factglobal.org	Contact Information, Introduction
Circular of Information (COI) (under FACT Education and Resources) https://www.factglobal.org/education-and-resources/general/applicant-education-and-resources/resources	B6.6.3, B6.6.4, E4.6
Donor History Questionnaires (under FACT Education and Resources) https://www.factglobal.org/education-and-resources/general/applicant-education-and-resources/resources	B3.1.2
FACT Guidelines for Histocompatibility Standards and Accreditation Programs (under FACT Policies and Standard Operating Procedures) https://www.factglobal.org/education-and-resources/general/fact-policies-and-standard-operating-procedures	B5.5
FACT Standards https://factglobal.org/standards/	E4.6

Resource Name/URL	Applicable Standard(s)
Other Resources *(Alphabetical)*	
21 CFR 211.150 Distribution procedures. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-211/subpart-H/section-211.150	B3.1.27
21 CFR 601.2 Applications for biologics licenses; procedures for filing. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-F/part-601/subpart-A/section-601.2	B1.3.1
21 CFR 1271.3(s) Relevant medical records. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-L/part-1271#p-1271.3(s)	C5.4.2
21 CFR 1271.47 What procedures must I establish and maintain? https://www.ecfr.gov/current/title-21/chapter-I/subchapter-L/part-1271/subpart-C/section-1271.47	C5.4.2
21 CFR 1271.55(a)(1) Accompanying records. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-L/part-1271/subpart-C/section-1271.55#p-1271.55(a)(1)	B6.4.2.3

FOUNDATION FOR THE ACCREDITATION OF CELLULAR THERAPY

Online Resources and Links for the 8th Edition Cord Blood Accreditation Manual

Resource Name/URL	Applicable Standard(s)
Other Resources *(Alphabetical)*	
21 CFR 1271.60 What quarantine and other requirements apply before the donor-eligibility determination is complete? https://www.ecfr.gov/current/title-21/chapter-I/subchapter-L/part-1271/subpart-C/section-1271.60	E3.4.4.1
21 CFR 1271.210 Supplies and reagents. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-L/part-1271/subpart-D/section-1271.210	B8.4.2
21 CFR 1271.260 Storage. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-L/part-1271/subpart-D/section-1271.260	B9.4
21 CFR 1271.270(b) Records management system. https://www.ecfr.gov/current/title-21/part-1271/section-1271.270#p-1271.270(b)	B11.4
21 CFR 1271.290(c) Distinct identification code. https://www.ecfr.gov/current/title-21/part-1271/section-1271.290#p-1271.290(c)	B6.4.2.3
21 CFR 1271.350(a) Adverse reaction reports. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-L/part-1271/subpart-E/section-1271.350#p-1271.350(a)	B2.12.8.1
21 CFR PART 211—CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-211	B2.5.4.4
21 CFR Part 1271—HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS https://www.ecfr.gov/current/title-21/chapter-I/subchapter-L/part-1271	B1.3.1, B2.12.3, B5.9.2, D1.1
Biologics Establishment Registration https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-establishment-registration	D1.1
Biologics License Applications for Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic and Immunologic Reconstitution in Patients with Disorders Affecting the Hematopoietic System https://www.fda.gov/regulatory-information/search-fda-guidance-documents/bla-minimally-manipulated-unrelated-allogeneic-placentalumbilical-cord-blood-intended-hematopoietic	B3.1.22, B6.6.1, D9.2, E4.6
Code A: Guiding Principles and the Fundamental Principle of Consent https://www.hta.gov.uk/guidance-professionals/codes-practice-standards-and-legislation/codes-practice	C4.1.1
Complete List of Donor Screening Assays for Infectious Agents and HIV Diagnostic Assays https://www.fda.gov/vaccines-blood-biologics/complete-list-donor-screening-assays-infectious-agents-and-hiv-diagnostic-assays	Appendix IV
Database of Adverse Event Notifications (DAEN) https://www.tga.gov.au/safety/safety/safety-monitoring-daen-database-adverse-event-notifications/database-adverse-event-notifications-daen	B2.12.8.1

Online Resources and Links for the 8th Edition Cord Blood Accreditation Manual

Resource Name/URL	Applicable Standard(s)
Other Resources *(Alphabetical)*	
Directive 2004/23/EC of the European Parliament http://data.europa.eu/eli/dir/2004/23/2009-08-07	B2.12.8.1
Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products https://www.fda.gov/regulatory-information/search-fda-guidance-documents/eligibility-determination-donors-human-cells-tissues-and-cellular-and-tissue-based-products	B5.4.4.1, C5.6.4, D3.1.14, D10.3, D11.1.1, E3.4.1.2, E4.2
Establishments involved in cord blood collection https://www.hta.gov.uk/guidance-professionals/guidance-sector/human-application/establishments-involved-cord-blood	B5.4.4.1
EUROCODE-IBLS https://www.eurocode.org	B6.1.1, B6.1.2
General Principles of Software Validation (Guidance Document, Guidance for Industry and FDA Staff) https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-principles-software-validation	B11.8.8
Guidance Document for Source Establishments - Reporting Adverse Reactions to Human Cells, Tissues and Organs https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/reporting-adverse-reactions-human-cells-tissues-organs.html	B2.12.8.1
Guidance on the Safety of Human Cells, Tissues and Organs for Transplantation Regulations: Overview https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/regulatory-initiatives/cells-tissues-organs/guidance-document-safety-human-cells-tissues-organs-transplantation.html	B6.6.4
Guide to the quality and safety of tissues and cells for human application https://www.edqm.eu/en/guide-to-the-quality-and-safety-of-tissues-and-cells-for-human-application1	E4.2
HTA Guide to Quality and Safety Assurance for Tissues and Cells for Patient Treatment https://www.hta.gov.uk/guidance-professionals/regulated-sectors/human-application/hta-guide-quality-and-safety-assurance	B6.6.4
ICCBBA website - Home Page https://www.isbt128.org	B6.1.1, B6.1.2
Investigational New Drug Applications for Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic and Immunologic Reconstitution in Patients with Disorders Affecting the Hematopoietic System https://www.fda.gov/regulatory-information/search-fda-guidance-documents/ind-applications-minimally-manipulated-unrelated-allogeneic-placentalumbilical-cord-blood-intended	B1.3.1
ISBT 128 Standard Terminology document (PDF) https://www.isbt128.org/standard-terminology	A4, B6.1.1, Appendix II

Online Resources and Links for the 8th Edition Cord Blood Accreditation Manual

Resource Name/URL	Applicable Standard(s)
Other Resources *(Alphabetical)*	
MoReq2 specification, model requirements for the management of electronic records https://op.europa.eu/en/publication-detail/-/publication/034484f3-e6fb-4299-9676-79dc89b433e1/language-en	B11.8.8
Part 11, Electronic Records; Electronic Signatures - Scope and Application https://www.fda.gov/regulatory-information/search-fda-guidance-documents/part-11-electronic-records-electronic-signatures-scope-and-application	B11.8.8
Postmarketing Adverse Experience Reporting for Human Drug and Licensed Biological Products: Clarification of What to Report https://www.fda.gov/regulatory-information/search-fda-guidance-documents/postmarketing-adverse-experience-reporting-human-drug-and-licensed-biological-products-clarification	B2.12.8.1
Potency Tests for Cellular and Gene Therapy Products https://www.fda.gov/regulatory-information/search-fda-guidance-documents/potency-tests-cellular-and-gene-therapy-products	D10.3
Tissues and cells (European Commission Public Health guide) https://health.ec.europa.eu/blood-tissues-cells-and-organs/tissues-and-cells_en	E3.4.1.2
Reference guide to consent for examination or treatment (second edition) https://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatment-second-edition	C4.1.1
SPEAR Reporting Tool https://spear.wmda.info/	B2.12.8.1
Testing Human Cells, Tissues, and Cellular and Tissue-Based Product (HCT/P) Donors for Relevant Communicable Disease Agents and Diseases https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/testing-human-cells-tissues-and-cellular-and-tissue-based-product-hctp-donors-relevant-communicable	D10.3
WMDA Share – New & Emerging Organisations https://wmda.info/pathway-new_emerging-organisations/	B1.4.1.3