Online Resources and Links for the 9th Edition Standards for Hematopoietic Cellular Therapy and Accreditation Manual

Resource Name/URL	Location Regular font indicates that the resource appears in the Accreditation Manual. **Bold font** indicates that the resource appears in both the Standards and the Accreditation Manual.
FACT Email fact@factglobal.org	**Contact Information**
JACIE Email jacie@ebmt.org	**Contact Information**
FACT Home Page http://www.factglobal.org	**Contact Information**, **Introduction**
JACIE Home Page https://www.ebmt.org/jacie	**Contact Information**, **Introduction**
NetCord-FACT International Standards for Cord Blood Collection, Banking, and Release for Administration https://www.factglobal.org/standards/cbb-standards	Introduction (Standards only)
Regulation (EC) No 765/2008 http://data.europa.eu/eli/reg/2008/765/2021-07-16	**Introduction**
FACT Accredited Organizations https://accredited.factglobal.org	**Introduction**
JACIE Certified Centres https://www.ebmt.org/jacie-certified-centres	**Introduction**
21 USC 351: Adulterated drugs and devices https://uscode.house.gov/view.xhtml?req=(title:21%20section:351%20edition:prelim)	**A4** (*Good Manufacturing Practice*)
ISBT 128 Standard Terminology for Medical Products of Human Origin (ST-002) https://www.isbt128.org/standard-terminology	**A4** (*Product name*), C7.1.1, C7.1.2, D7.1.1, D7.1.2, **Appendix II**
21 CFR Part 1271 Subpart D—Current Good Tissue Practice https://www.ecfr.gov/current/title-21/chapter-I/subchapter-L/part-1271/subpart-D	B1.2, B4.4.2.5, C1.2, C4.4.2.5, D1.2, D4.4.2.5

Resource Name/URL	Location Regular font indicates that the resource appears in the Accreditation Manual. **Bold font** indicates that the resource appears in both the Standards and the Accreditation Manual.
Title 21 Food and Drugs https://www.ecfr.gov/current/title-21	B1.2, C1.2
Directive 2004/23/EC http://data.europa.eu/eli/dir/2004/23/2009-08-07	B1.2, B4.11.4.2, B8.2.1.4, B10.3.5, C1.2, C4.11.4.2, D1.2, D3.1.1, D3.2.1, D4.11.4.2, D13.3.5
Directive 2006/17/EC http://data.europa.eu/eli/dir/2006/17/2012-12-17	B1.2, B4.11.4.2, C1.2, C4.11.4.2, C8.3.9, D1.2, D4.11.4.2, D6.3.9, D11.1.1
Directive 2006/86/EC http://data.europa.eu/eli/dir/2006/86/2015-04-29	B1.2, B4.11.4.2, B6.1, B7.4, B10.3.6, C1.2, C4.11.4.2, C10.2.2, C12.3.1, D1.2, D4.11.4.2, D7.3.1.3, D7.4.3, D11.1.1
Directive 2001/83/EC http://data.europa.eu/eli/dir/2001/83/2025-01-01	B1.2, C1.2, D1.1, D1.2
Regulation (EC) No 1394/2007 http://data.europa.eu/eli/reg/2007/1394/2019-07-26	B1.2, C1.2, D1.1, D1.2
Regulation (EU) 2024/1938 *http://data.europa.eu/eli/reg/2024/1938/2024-07-17*	B1.2, C1.2, D1.2
Haute Autorité de Santé (HAS) https://www.has-sante.fr/	B1.9
Deutsche Krebsgesellschaft (DKG) https://www.krebsgesellschaft.de/	B1.9
Care Quality Commission (CQC) https://www.cqc.org.uk/	B1.9
Qualicor https://www.qualicor.eu/	B1.9
FACT Policies and Standard Operating Procedures (see Maintaining Accreditation under Organizations, Policies) https://www.factglobal.org/education-and-resources/general/fact-policies-and-standard-operating-procedures/	B2.1

Resource Name/URL	Location Regular font indicates that the resource appears in the Accreditation Manual. **Bold font** indicates that the resource appears in both the Standards and the Accreditation Manual.
Maintenance of Certification 2.0 — Strong Start, Continued Evolution https://www.nejm.org/doi/full/10.1056/NEJMp1409923	B3.1.1
Boarded to Death — Why Maintenance of Certification Is Bad for Doctors and Patients https://www.nejm.org/doi/full/10.1056/NEJMp1407422	B3.1.1
General Medical Council – Specialist or GP applications https://www.gmc-uk.org/registration-and-licensing/our-registers/a-guide-to-our-registers/specialist-and-gp-application-types	B3.1.1, B3.2.3
Educational Activities Form (under General Forms on the FACT Hematopoietic Cellular Therapy Library) https://factglobal.org/education-and-resources/general/hematopoietic-cellular-therapy-library/	B3.1.5, B3.4.2, B3.10.2, C3.1.3.3, D3.1.4
ASTCT – The Learning Center https://learn.astct.org/	B3.1.5, B3.4.2, C3.1.3.3, D3.1.4
ESH – eLearning https://elearning.esh.org/esh	B3.1.5, B3.3.4, B3.4.2, B3.5.2, C3.1.3.3, D3.1.4
EBMT – e-Learning https://www.ebmt.org/learning-projects/e-learning	B3.1.5, B3.3.4, B3.4.2, B3.5.2, C3.1.3.3, D3.1.4
BSBMTCT – e-Learning https://bsbmtct.org/e-learning/	B3.3.4, B3.5.2
AABB – Cellular Therapy: A Handbook, 2nd Edition https://www.aabb.org/aabb-store/product/cellular-therapy-a-handbook-2nd-edition---print-17073790	B3.3.4.16, C9.2
AABB - Transfusion Therapy: Clinical Principles and Practice, 5th Edition https://www.aabb.org/aabb-store/product/transfusion-therapy-clinical-principles-and-practice-5th-edition-digital-19608685	B3.3.4.16, C9.2
NIH Chronic Graft-Versus-Host Disease Consensus Conference 2025 Update https://pubmed.ncbi.nlm.nih.gov/40409691/	B3.3.5.6
Consensus Conference on Clinical Practice in Chronic GVHD: Second-Line Treatment of Chronic Graft-versus-Host Disease https://pubmed.ncbi.nlm.nih.gov/20685255/	B3.3.6.5, C9.11.2

Resource Name/URL	Location Regular font indicates that the resource appears in the Accreditation Manual. **Bold font** indicates that the resource appears in both the Standards and the Accreditation Manual.
Extracorporeal photopheresis for the treatment of acute and chronic graft-versus-host disease in adults and children: best practice recommendations from an Italian Society of Hemapheresis and Cell Manipulation (SIdEM) and Italian Group for Bone Marrow Transplantation (GITMO) consensus process https://pubmed.ncbi.nlm.nih.gov/23305044/	B3.3.6.5, C9.11.2
Extracorporeal photopheresis for treatment of adults and children with acute GVHD: UK consensus statement and review of published literature https://pubmed.ncbi.nlm.nih.gov/24887389/	B3.3.6.5, C9.11.2
Diagnosis and management of chronic graft-versus-host disease https://pubmed.ncbi.nlm.nih.gov/22533811/	B3.3.6.5, C9.11.2
Diagnosis and management of acute graft-versus-host disease https://pubmed.ncbi.nlm.nih.gov/22533831/	B3.3.6.5, C9.11.2
Guidelines on the Use of Therapeutic Apheresis in Clinical Practice - Evidence-Based Approach from the Writing Committee of the American Society for Apheresis: The Ninth Special Issue https://pubmed.ncbi.nlm.nih.gov/37017433/	B3.3.6.5, C9.11.2
NMDP – The evolution of HCT self-paced learning course https://network.nmdp.org/training-education/catalog/the-evolution-of-hct-self-paced-learning-course	B3.4.2
ASTCT Special Interest Groups https://www.astct.org/Membership/Special-Interest-Groups	B3.5.2, B3.7.4
ONCC – Blood & Marrow Transplant Certified Nurse (BMTCN®) https://www.oncc.org/blood-marrow-transplant-certified-nurse-bmtcn	B3.6.1
The EBMT Textbook for Nurses, EBMT Online Learning Course for Nurses https://www.ebmt.org/ebmt-jacie-books/ebmt-textbook-nurses	B3.6.2.7
American Nurses Association – Nurse Staffing https://www.nursingworld.org/practice-policy/nurse-staffing/	B3.6.4

Resource Name/URL	Location Regular font indicates that the resource appears in the Accreditation Manual. **Bold font** indicates that the resource appears in both the Standards and the Accreditation Manual.
Press Ganey National Database of Nursing Quality Indicators (NDNQI) https://info.pressganey.com/press-ganey-blog-healthcare-experience-insights/your-comprehensive-guide-to-the-press-ganey-national-database-of-nursing-quality-indicators-ndnqi	B3.6.4
Conditioning Chemotherapy Dose Adjustment in Obese Patients: A Review and Position Statement by the American Society for Blood and Marrow Transplantation Practice Guideline Committee https://www.astctjournal.org/article/S1083-8791(14)00050-0/fulltext	B3.7.2.5
The Hematopoietic Cell Transplant Pharmacist: Roles, Responsibilities, and Recommendations from the ASBMT Pharmacy Special Interest Group https://pubmed.ncbi.nlm.nih.gov/29292057/	B3.7.2.5
Consensus recommendations for the role and competencies of the EBMT clinical pharmacist and clinical pharmacologist involved in hematopoietic stem cell transplantation https://pubmed.ncbi.nlm.nih.gov/31101890/	B3.7.2.5
EBMT – Pharmacist Committee https://www.ebmt.org/pharmacist-committee	B3.7.4
UK BMT Pharmacists Group (training passport) https://www.bopa.org.uk/membergroups/specialist-advisory-groups/bmt-group/	B3.7.4
American Society for Quality (ASQ) – Certification Pathway Tool https://www.asq.org/cert	B3.9.2, C3.3.2, D3.3.2
National Association for Healthcare Quality (NAHQ) https://nahq.org/credentials/	B3.9.2, C3.3.2, D3.3.2
FACT Quality Management Resource Center (see FACT Quality Handbook, FACT Quality Management Series Webinars) https://www.factglobal.org/education-and-resources/general/quality-management-resource-center/	B3.9.2, B4.8, B4.14, B4.15, B5.1, C3.3.2, C4.8, C4.14, C4.15, C5.1, D3.3.2, D4.8, D4.14, D4.15, D5.1
EBMT – The JACIE Guide https://www.ebmt.org/education/jacie-guide	B3.9.2, B4.8, B4.14, B4.15, B5.1, C3.3.2, C4.8, C4.14, C4.15, C5.1, D3.3.2, D4.8, D4.14, D4.15, D5.1

Resource Name/URL	Location Regular font indicates that the resource appears in the Accreditation Manual. **Bold font** indicates that the resource appears in both the Standards and the Accreditation Manual.
FACT Data Management Resource Center https://www.factglobal.org/education-and-resources/general/data-management-resource-center	B3.10.2
The EBMT Registry https://www.ebmt.org/registry/ebmt-registry	B3.10.2
Anthony Nolan – Psychological Assessment Guidance in HSCT (adults) https://www.anthonynolan.org/clinicians-researchers-hub/healthcare-professionals/patient-services/latest-clinical-guidelines	B3.11.1.2
Psychological Consequences of Hematopoietic Stem Cell Transplant https://pmc.ncbi.nlm.nih.gov/articles/PMC3105969/	B3.11.1.2
Code G: Donation of allogeneic bone marrow and peripheral blood stem cells for transplantation https://www.hta.gov.uk/guidance-professionals/codes-practice-standards-and-legislation/codes-practice	B4.4, B6.4.3, C4.4, C6.4.1, D4.4
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	B4.4, C4.4, D4.4
ISO 9001:2015 https://www.iso.org/standard/62085.html	B4.4.2.5, C4.4.2.5, D4.4.2.5
21 CFR PART 211—CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-211	B4.4.2.5, C4.4.2.5, D4.4.2.5
EDQM – Guide to the quality and safety of tissues and cells for human application https://freepub.edqm.eu/publications/AUTOPUB_17/detail	B4.4.2.5, C4.4.2.5, D4.4.2.5
CIBMTR Stem Cell Therapeutic Outcomes Database (SCTOD) https://cibmtr.org/CIBMTR/About/Our-Impact/SCTOD	B4.7.5.1, B9.2.1
EBMT – Benchmarking https://www.ebmt.org/registry/benchmarking	B4.7.5.1
CIBMTR Data Collection Forms (Transplant Essential Data [TED] forms, Cellular Therapy Essential Data [CTED] forms) https://cibmtr.org/CIBMTR/Data-Operations/Data-Collection-Forms	B4.8.5.1, B9.2, B9.3

Resource Name/URL	Location Regular font indicates that the resource appears in the Accreditation Manual. **Bold font** indicates that the resource appears in both the Standards and the Accreditation Manual.
EBMT Registry Data Collection Forms https://www.ebmt.org/registry/ebmt-data-collection	B4.8.5.1, B9.2, B9.3
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	B4.10.6, C1.2.1, C4.10.4, D1.2.1, D4.10.7
E2E Pharmacovigilance Planning https://www.fda.gov/regulatory-information/search-fda-guidance-documents/e2e-pharmacovigilance-planning	B4.11.4.2, C4.11.4.2
Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment https://www.fda.gov/regulatory-information/search-fda-guidance-documents/good-pharmacovigilance-practices-and-pharmacoepidemiologic-assessment	B4.11.4.2, C4.11.4.2
The science and practice of current environmental risk assessment for gene therapy: a review https://www.isct-cytotherapy.org/article/S1465-3249(24)00677-7/abstract	B5.1.18
Preparing for the Unthinkable: Emergency Preparedness for the Hematopoietic Cell Transplant Program https://pmc.ncbi.nlm.nih.gov/articles/PMC7129195/	B5.1.19, C5.1.20, D5.1.19
Impact of Severe Weather Conditions on Biological Products https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/impact-severe-weather-conditions-biological-products	B5.1.19, C5.1.20, D5.1.19
The Art of Writing and Implementing Standard Operating Procedures (SOPs) for Laboratories in Low-Resource Settings: Review of Guidelines and Best Practices https://journals.plos.org/plosntds/article?id=10.1371/journal.pntd.0005053	B5.3, C5.3, D5.3
Adolescents and Young Adults with Cancer https://www.cancer.gov/types/aya	B5.3.6
Integrating Geriatric Assessment into Cancer Care: A Conversation with Dr. Supriya Mohile https://www.cancer.gov/news-events/cancer-currents-blog/2018/geriatric-assessment-cancer-care-mohile	B5.3.6
CLSI Home Page https://clsi.org/	B5.3.10

Resource Name/URL	Location Regular font indicates that the resource appears in the Accreditation Manual. **Bold font** indicates that the resource appears in both the Standards and the Accreditation Manual.
Hematopoietic Cell Transplantation–Specific Comorbidity Index Predicts Morbidity and Mortality in Autologous Stem Cell Transplantation https://www.astctjournal.org/article/S1083-8791(17)30523-2/fulltext	B6.3.1, C6.3.1
The Hematopoietic Cell Transplant Comorbidity Index predicts survival after allogeneic transplant for nonmalignant diseases https://ashpublications.org/blood/article/133/7/754/260555/The-Hematopoietic-Cell-Transplant-Comorbidity	B6.3.1, C6.3.1
Hematopoietic Cell Transplantation-specific Comorbidity Index (HCT-CI) https://www.mdcalc.com/calc/3980/hematopoietic-cell-transplantation-specific-comorbidity-index-hct-ci	B6.3.1, C6.3.1
Family donor care management: principles and recommendations https://pubmed.ncbi.nlm.nih.gov/20023708/	B6.3.1.2, B6.4.3, C6.3.1.2, C6.4.1
WMDA S(P)EAR alert: August 2011 https://wmda.info/wp-content/uploads/2020/08/20110824-CLWG-SEAR-Alert-August-2011.pdf	B6.3.2.1, C6.3.10, C6.3.11
Granulocyte colony-stimulating factor (G-CSF) administration in individuals with sickle cell disease: time for a moratorium? https://pubmed.ncbi.nlm.nih.gov/19513902/	B6.3.6.2, C6.3.6.1
Granulocyte colony-stimulating factor-based stem cell mobilization in patients with sickle cell disease https://pubmed.ncbi.nlm.nih.gov/18489998/	B6.3.6.2, C6.3.6.1
Mobilization, collection, and processing of peripheral blood stem cells in individuals with sickle cell trait https://pubmed.ncbi.nlm.nih.gov/11806986/	B6.3.6.2, C6.3.6.1
WHO guiding principles on human cell, tissue and organ transplantation https://iris.who.int/handle/10665/341814	B6.3.12.1, C6.3.12.1
Allogeneic hematopoietic stem cell donation-standardized assessment of donor outcome data: a consensus statement from the Worldwide Network for Blood and Marrow Transplantation (WBMT) https://pubmed.ncbi.nlm.nih.gov/22773129/	B6.3.12.1
NMDP Home Page https://www.nmdp.org/	B6.4.2

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Anthony Nolan Home Page https://www.anthonynolan.org/	B6.4.2
Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (2007) https://www.fda.gov/regulatory-information/search-fda-guidance-documents/eligibility-determination-donors-human-cells-tissues-and-cellular-and-tissue-based-products	B6.4.4.1, B6.4.9, B6.4.17, C6.1, C6.4.7, C7.4.5
Recommendations for Determining Eligibility of Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) (2025 draft) https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommendations-determining-eligibility-donors-human-cells-tissues-and-cellular-and-tissue-based	B6.4.4.1, B6.4.9, B6.4.17, C6.1, C6.4.2.1, C6.4.7, C7.4.5
21 CFR 1271.80(d)(2) https://www.ecfr.gov/current/title-21/chapter-I/subchapter-L/part-1271/subpart-C/section-1271.80#p-1271.80(d)(2)	B6.4.4.1, C6.4.2.1
Chapter 7: haemodilution, transfusion and donor testing (Guidance from the UK's Dept. of Health & Social Care) https://www.gov.uk/government/publications/guidance-on-the-microbiological-safety-of-human-organs-tissues-and-cells-used-in-transplantation/chapter-7-haemodilution-transfusion-and-donor-testing	B6.4.4.1, C6.4.2.1
FACT– Hematopoietic Progenitor Cell, Apheresis and Marrow Donor History Questionnaire https://factglobal.org/education-and-resources/general/applicant-education-and-resources/resources/donor-history-questionnaires-hpc-apheresis-and-hpc-marrow/	B6.4.8.8
21 CFR 1271.75 How do I screen a donor? https://www.ecfr.gov/current/title-21/chapter-I/subchapter-L/part-1271/subpart-C/section-1271.75	B6.4.8.8
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	B6.4.8.8
21 CFR 1271.55 What records must accompany an HCT/P after the donor-eligibility determination is complete; and what records must I retain? https://www.ecfr.gov/current/title-21/chapter-I/subchapter-L/part-1271/subpart-C/section-1271.55	B6.4.17, C6.1, C6.4.7, C7.4.5
NMDP – Donor and cord blood unit selection guidelines https://network.nmdp.org/training-education/catalog/donor-and-cord-blood-unit-selection-guidelines	B7.6.4.2

Resource Name/URL	Location Regular font indicates that the resource appears in the Accreditation Manual. **Bold font** indicates that the resource appears in both the Standards and the Accreditation Manual.
Circular of Information for the Use of Cellular Therapy Products, June 2024 https://factglobal.org/education-and-resources/general/applicant-education-and-resources/resources/	B7.6.8, **C7.4.4**, D7.4.2, **D7.4.4**, D11.2.4.3
The why, what, and how of the new FACT standards for immune effector cells https://jitc.biomedcentral.com/articles/10.1186/s40425-017-0239-0	B7.8
Production of chimeric antigen receptor (CAR) T cells https://www.nature.com/nprot/posters	B7.8
ASTCT Consensus Grading for Cytokine Release Syndrome and Neurologic Toxicity Associated with Immune Effector Cells https://pubmed.ncbi.nlm.nih.gov/30592986/	B7.8
CDC – Adult Immunization Schedule Notes https://www.cdc.gov/vaccines/hcp/imz-schedules/adult-notes.html	B7.11.1
Physical, psychological, and social sequelae following hematopoietic stem cell transplantation: a review of the literature https://onlinelibrary.wiley.com/doi/10.1002/pon.1399	B7.11.2
Psychosocial aspects of hematopoietic stem cell transplantation https://pmc.ncbi.nlm.nih.gov/articles/PMC8290998/	B7.11.2
Commission Directive (EU) 2015/565 http://data.europa.eu/eli/dir/2015/565/oj	B8.2.1.4
21 CFR PART 54—FINANCIAL DISCLOSURE BY CLINICAL INVESTIGATORS https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-54	B8.4
Adoptive Cellular Therapies (ACT) Stakeholder's Council https://cibmtr.org/CIBMTR/About/Administrative-Committees/Adoptive-Cellular-Therapies-ACT-Council	B9.2
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	B10.4.1, C12.6.1, D13.4.1
MoReq® https://www.moreq.info/	B10.4.1, C12.6.1, D13.4.1

Resource Name/URL	Location Regular font indicates that the resource appears in the Accreditation Manual. **Bold font** indicates that the resource appears in both the Standards and the Accreditation Manual.
NMDP – Policies & Protocols (see Data Use and Processing Policies under Transplant centers, Additional Resources) https://network.nmdp.org/policies-protocols	B10.5.2
21 CFR PART 207—REQUIREMENTS FOR FOREIGN AND DOMESTIC ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN DRUGS, INCLUDING DRUGS THAT ARE REGULATED UNDER A BIOLOGICS LICENSE APPLICATION, AND ANIMAL DRUGS, AND THE NATIONAL DRUG CODE https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-207	C1.2.1, D1.2.1
21 CFR PART 807—ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND INITIAL IMPORTERS OF DEVICES https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-807	C1.2.1, D1.2.1
Tissue Establishment Registration https://www.fda.gov/vaccines-blood-biologics/biologics-establishment-registration/tissue-establishment-registration	C1.2.1, D1.2.1
21 CFR 211.42(b) https://www.ecfr.gov/current/title-21/part-211/section-211.42#p-211.42(b)	C2.1.3, D2.1.3
CAR-T Cell Therapies From the Transfusion Medicine Perspective https://pubmed.ncbi.nlm.nih.gov/27067907/	C5.1.6
NICE – Guidance on the use of ultrasound locating devices for placing central venous catheters http://guidance.nice.org.uk/TA49	C6.3.11
Practice Guidelines for Central Venous Access 2020: An Updated Report by the American Society of Anesthesiologists Task Force on Central Venous Access https://journals.lww.com/anesthesiology/fulltext/2020/01000/practice_guidelines_for_central_venous_access.9.aspx	C6.3.11
ICCBBA Home Page https://www.isbt128.org/	C7.1.1, C7.1.2, D7.1.1, D7.1.2
ISO 3166 https://www.iso.org/iso-3166-country-codes.html	C7.1.1, D7.1.1
Eurocode-IBLS Home Page https://www.eurocode.org/	C7.1.1, C7.1.2, D7.1.1, D7.1.2

Resource Name/URL	Location Regular font indicates that the resource appears in the Accreditation Manual. **Bold font** indicates that the resource appears in both the Standards and the Accreditation Manual.
ICCBBA ST-018 (ISBT 128 Standard Labeling of Collection Products for Cellular Therapy Manufacturing) https://www.isbt128.org/ST-018	**C7.1.3**, C7.3.2.1, **D7.1.3**, D7.3.2.1
Recognition and Use of a Standard for Uniform Blood and Blood Component Container Labels https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recognition-and-use-standard-uniform-blood-and-blood-component-container-labels	C7.2.11, D7.2.11
FACT ISBT 128 Hybrid (Split) Label Webinar https://learn.factglobal.org/2024-on-demand-webinar-isbt128-hybrid-split-label	C7.3.2.1, D7.3.2.1
ST-004 ISBT 128 Standard Labeling of Cellular Therapy Products https://www.isbt128.org/ST-004	C7.4.1, D7.4.1
European Commission https://commission.europa.eu/index_en	C8.3.9
21 CFR 1271.200 Equipment https://www.ecfr.gov/current/title-21/chapter-I/subchapter-L/part-1271/subpart-D/section-1271.200	C8.4.2.3
21 CFR Part 211 Subpart D—Equipment https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-211/subpart-D	C8.4.2.3
21 CFR 1271.270(a) Records. General. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-L/part-1271/subpart-D/section-1271.270	C9.10.1, D8.9.2
Regulation (EU) 2016/679 http://data.europa.eu/eli/reg/2016/679/2016-05-04	C12.4
Directive 2001/20/EC http://data.europa.eu/eli/dir/2001/20/2022-01-01	D1.1
21 CFR PART 210—CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PROCESSING, PACKING, OR HOLDING OF DRUGS; GENERAL https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-210	D1.2, D2.5
21 CFR PART 211—CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-211	D1.2, D2.5

Resource Name/URL	Location Regular font indicates that the resource appears in the Accreditation Manual. **Bold font** indicates that the resource appears in both the Standards and the Accreditation Manual.
21 CFR 211.52 Washing and toilet facilities. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-211/subpart-C/section-211.52	D2.1.2
21 CFR 1271.190 Facilities https://www.ecfr.gov/current/title-21/chapter-I/subchapter-L/part-1271/subpart-D/section-1271.190	D2.1.2
21 CFR PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS https://www.ecfr.gov/current/title-21/chapter-I/subchapter-F/part-610	D2.5
EU GMP Annex 1: Manufacture of Sterile Medicinal Products https://www.gmp-compliance.org/guidelines/gmp-guideline/eu-gmp-annex-1-manufacture-of-sterile-medicinal-products	D2.5
CSB Releases Final Report into 2021 Fatal Liquid Nitrogen Release at Foundation Food Group Facility in Georgia https://www.csb.gov/csb-releases-final-report-into-2021-fatal-liquid-nitrogen-release-at-foundation-food-group-facility-in-georgia/	D2.11.3
OSHA Standard 1926.1202 https://www.osha.gov/laws-regs/regulations/standardnumber/1926/1926.1202	D2.11.3
ABO incompatibile graft management in pediatric transplantation https://www.nature.com/articles/s41409-020-0981-7	D5.1.4
OSHA's Nationally Recognized Testing Laboratory (NRTL) Program https://www.osha.gov/nationally-recognized-testing-laboratory-program	D6.3.9
Cryopreserved hematopoietic stem/progenitor cells stability program-development, current status and recommendations: A brief report from the AABB-ISCT joint working group cellular therapy product stability project team https://pubmed.ncbi.nlm.nih.gov/35307845/	D8.1.4.2, D9.2.3.1
Current thawing and infusion practice of cryopreserved cord blood: the impact on graft quality, recipient safety, and transplantation outcomes https://pubmed.ncbi.nlm.nih.gov/24894338/	D8.4.4
21 CFR PART 820—QUALITY SYSTEM REGULATION https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-820	D8.12.2

Resource Name/URL	Location Regular font indicates that the resource appears in the Accreditation Manual. **Bold font** indicates that the resource appears in both the Standards and the Accreditation Manual.
Current Good Tissue Practice (CGTP) and Additional Requirements for Manufacturers of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) https://www.fda.gov/regulatory-information/search-fda-guidance-documents/current-good-tissue-practice-cgtp-and-additional-requirements-manufacturers-human-cells-tissues-and	D8.12.2
Hepatitis B transmission from contaminated cryopreservation tank https://pubmed.ncbi.nlm.nih.gov/7603227/	D9.4.3.3
21 CFR 312.6(a) https://www.ecfr.gov/current/title-21/chapter-I/subchapter-D/part-312/subpart-A/section-312.6	**Appendix II**