

Online Resources and Links for the Ninth Edition – v9.1 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 https://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/cbstandards	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)

Resource Name/URL	Location
	Regular font indicates that the resource appears in the Accreditation Manual.
ISBT 128 Standard Terminology for Medical Products of Human Origin (ST-002) https://www.isbt128.org/standard-terminology	A4 (<i>Product name</i>), 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
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

Resource Name/URL	Location
<i>Deutsche Krebsgesellschaft (DKG)</i>	B1.9
https://www.krebsgesellschaft.de/	
<i>Care Quality Commission (CQC)</i>	B1.9
https://www.cqc.org.uk/	
<i>Qualicor</i>	B1.9
https://www.qualicor.eu/	
<i>FACT Maintaining Accreditation Policy</i>	B2.1
https://www.factglobal.org/FACT-Policies-SOPs/	
<i>Maintenance of Certification 2.0 — Strong Start, Continued Evolution</i>	B3.1.1
https://www.nejm.org/doi/full/10.1056/NEJMp1409923	
<i>Boarded to Death — Why Maintenance of Certification Is Bad for Doctors and Patients</i>	B3.1.1
https://www.nejm.org/doi/full/10.1056/NEJMp1407422	
<i>General Medical Council – Specialist or GP applications</i>	B3.1.1, B3.2.3
https://www.gmc-uk.org/registration-and-licensing/our-registers/a-guide-to-our-registers/specialist-and-gp-application-types	
<i>FACT Educational Activities Form</i>	B3.1.5, B3.4.2, B3.10.2, C3.1.3.3, D3.1.4
https://factglobal.org/ctstandards/	
<i>ASTCT – The Learning Center</i>	B3.1.5, B3.4.2, C3.1.3.3, D3.1.4
https://learn.astct.org/	
<i>ESH – eLearning</i>	B3.1.5, B3.3.4, B3.4.2, B3.5.2, C3.1.3.3, D3.1.4
https://elearning.esh.org/esh	
<i>EBMT – e-Learning</i>	B3.1.5, B3.3.4, B3.4.2, B3.5.2, C3.1.3.3, D3.1.4
https://www.ebmt.org/learning-projects/e-learning	

Resource Name/URL	Location
BSBMTCT – e-Learning	B3.3.4, B3.5.2
https://bsbmtct.org/e-learning/	
AABB – Cellular Therapy: A Handbook, 2 nd Edition	B3.3.4.16, C9.2
https://www.aabb.org/aabb-store/product/cellular-therapy-a-handbook-2nd-edition---print-17073790	
AABB – Transfusion Therapy: Clinical Principles and Practice, 5 th Edition	B3.3.4.16, C9.2
https://www.aabb.org/aabb-store/product/transfusion-therapy-clinical-principles-and-practice-5th-edition-digital-19608685	
NIH Chronic Graft-Versus-Host Disease Consensus Conference 2025 Update	B3.3.5.6
https://pubmed.ncbi.nlm.nih.gov/40409691/	
Consensus Conference on Clinical Practice in Chronic GVHD: Second-Line Treatment of Chronic Graft-versus-Host Disease	B3.3.6.5, C9.11.2
https://pubmed.ncbi.nlm.nih.gov/20685255/	
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	B3.3.6.5, C9.11.2
https://pubmed.ncbi.nlm.nih.gov/23305044/	
Extracorporeal photopheresis for treatment of adults and children with acute GVHD: UK consensus statement and review of published literature	B3.3.6.5, C9.11.2
https://pubmed.ncbi.nlm.nih.gov/24887389/	
Diagnosis and management of chronic graft-versus-host disease	B3.3.6.5, C9.11.2
https://pubmed.ncbi.nlm.nih.gov/22533811/	
Diagnosis and management of acute graft-versus-host disease	B3.3.6.5, C9.11.2
https://pubmed.ncbi.nlm.nih.gov/22533831/	

Resource Name/URL	Location
<i>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</i>	Regular font indicates that the resource appears in the Accreditation Manual.
https://pubmed.ncbi.nlm.nih.gov/37017433/	Bold font indicates that the resource appears in both the Standards and the Accreditation Manual.
<i>NMDP – The evolution of HCT self-paced learning course</i>	B3.4.2
https://network.nmdp.org/training-education/catalog/the-evolution-of-hct-self-paced-learning-course	
<i>ASTCT Special Interest Groups</i>	B3.5.2, B3.7.4
https://www.astct.org/Membership/Special-Interest-Groups	
<i>Transplantation and Cellular Therapy Certified Nurse (TCTCN™)</i>	B3.6.1
https://www.oncc.org/transplantation-cellular-therapy-certified-nurse-tctcn	
<i>NOTE: The Oncology Nursing Certification Corporation (ONCC) announced its Blood and Marrow Transplant Certified Nurse (BMTCN®) program has been renamed to the Transplantation and Cellular Therapy Certified Nurse (TCTCN™) program beginning in 2026. The link in the manual will be updated in the next published version.</i>	
<i>The EBMT Textbook for Nurses, EBMT Online Learning Course for Nurses</i>	B3.6.2.7
https://www.ebmt.org/ebmt-jacie-books/ebmt-textbook-nurses	
<i>American Nurses Association – Nurse Staffing</i>	B3.6.4
https://www.nursingworld.org/practice-policy/nurse-staffing/	
<i>Press Ganey National Database of Nursing Quality Indicators (NDNQI)</i>	B3.6.4
https://info.pressganey.com/press-ganey-blog-healthcare-experience-insights/your-comprehensive-guide-to-the-press-ganey-national-database-of-nursing-quality-indicators-ndnqi	
<i>Conditioning Chemotherapy Dose Adjustment in Obese Patients: A Review and Position Statement by the American Society for Blood and Marrow Transplantation Practice Guideline Committee</i>	B3.7.2.5
https://www.astctjournal.org/article/S1083-8791(14)00050-0/fulltext	

Resource Name/URL	Location
<p><i>The Hematopoietic Cell Transplant Pharmacist: Roles, Responsibilities, and Recommendations from the ASBMT Pharmacy Special Interest Group</i></p>	B3.7.2.5
<p>https://pubmed.ncbi.nlm.nih.gov/29292057/</p>	Regular font indicates that the resource appears in the Accreditation Manual.
<p><i>Consensus recommendations for the role and competencies of the EBMT clinical pharmacist and clinical pharmacologist involved in hematopoietic stem cell transplantation</i></p>	B3.7.2.5
<p>https://pubmed.ncbi.nlm.nih.gov/31101890/</p>	Bold font indicates that the resource appears in both the Standards and the Accreditation Manual.
<p><i>EBMT – Pharmacist Committee</i></p>	B3.7.4
<p>https://www.ebmt.org/pharmacist-committee</p>	
<p><i>UK BMT Pharmacists Group (training passport)</i></p>	B3.7.4
<p>https://www.bopa.org.uk/membergroups/specialist-advisory-groups/bmt-group/</p>	
<p><i>American Society for Quality (ASQ) – Certification Pathway Tool</i></p>	B3.9.2, C3.3.2, D3.3.2
<p>https://www.asq.org/cert</p>	
<p><i>National Association for Healthcare Quality (NAHQ)</i></p>	B3.9.2, C3.3.2, D3.3.2
<p>https://nahq.org/credentials/</p>	
<p><i>FACT Quality Handbook</i></p>	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
<p>https://www фактglobal.org/store</p>	
<p><i>FACT Quality Management Series webinars</i></p>	B3.9.2, C3.3.2, D3.3.2
<p>https://learn фактglobal.org/quality</p>	
<p><i>The JACIE Guide</i></p>	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
<p>https://www.ebmt.org/education/jacie-guide</p>	
<p><i>FACT Data Management Resource Center</i></p>	B3.10.2
<p>https://factglobal.org/dm-resource-center/</p>	

Resource Name/URL	Location
<i>The EBMT Registry</i>	B3.10.2
https://www.ebmt.org/registry/ebmt-registry	
<i>Anthony Nolan – Psychological Assessment Guidance in HSCT (adults)</i>	B3.11.1.2
https://www.anthonynolan.org/clinicians-researchers-hub/healthcare-professionals/patient-services/latest-clinical-guidelines	
<i>Psychological Consequences of Hematopoietic Stem Cell Transplant</i>	B3.11.1.2
https://pmc.ncbi.nlm.nih.gov/articles/PMC3105969/	
<i>Code G: Donation of allogeneic bone marrow and peripheral blood stem cells for transplantation</i>	B4.4, B6.4.3, C4.4, C6.4.1, D4.4
https://www.hta.gov.uk/guidance-professionals/codes-practice-standards-and-legislation/codes-practice	
<i>HTA Guide to Quality and Safety Assurance for Tissues and Cells for Patient Treatment</i>	B4.4, C4.4, D4.4
https://www.hta.gov.uk/guidance-professionals/regulated-sectors/human-application/hta-guide-quality-and-safety-assurance	
<i>ISO 9001:2015</i>	B4.4.2.5, C4.4.2.5, D4.4.2.5
https://www.iso.org/standard/62085.html	
<i>21 CFR PART 211—CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS</i>	B4.4.2.5, C4.4.2.5, D4.4.2.5
https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-211	
<i>EDQM – Guide to the quality and safety of tissues and cells for human application</i>	B4.4.2.5, C4.4.2.5, D4.4.2.5
https://freepub.edqmeu/publications/AUTOPUB_17/detail	
<i>CIBMTR Stem Cell Therapeutic Outcomes Database (SCTOD)</i>	B4.7.5.1, B9.2.1
https://cibmtr.org/CIBMTR/About/Our-Impact/SCTOD	
<i>EBMT – Benchmarking</i>	B4.7.5.1
https://www.ebmt.org/registry/benchmarking	
<i>CIBMTR Data Collection Forms (Transplant Essential Data [TED] forms, Cellular Therapy Essential Data [CTED] forms)</i>	B4.8.5.1, B9.2, B9.3
https://cibmtr.org/CIBMTR/Data-Operations/Data-Collection-Forms	

Resource Name/URL	Location
<i>EBMT Registry Data Collection Forms</i>	B4.8.5.1, B9.2, B9.3
https://www.ebmt.org/registry/ebmt-data-collection	
<i>21 CFR PART 1271—HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS</i>	B4.10.6, C1.2.1, C4.10.4, D1.2.1, D4.10.7
https://www.ecfr.gov/current/title-21/chapter-I/subchapter-L/part-1271	
<i>E2E Pharmacovigilance Planning</i>	B4.11.4.2, C4.11.4.2
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/e2e-pharmacovigilance-planning	
<i>Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment</i>	B4.11.4.2, C4.11.4.2
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/good-pharmacovigilance-practices-and-pharmacoepidemiologic-assessment	
<i>The science and practice of current environmental risk assessment for gene therapy: a review</i>	B5.1.18
https://www.isct-cyotherapy.org/article/S1465-3249(24)00677-7/abstract	
<i>Preparing for the Unthinkable: Emergency Preparedness for the Hematopoietic Cell Transplant Program</i>	B5.1.19, C5.1.20, D5.1.19
https://pmc.ncbi.nlm.nih.gov/articles/PMC7129195/	
<i>Impact of Severe Weather Conditions on Biological Products</i>	B5.1.19, C5.1.20, D5.1.19
https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/impact-severe-weather-conditions-biological-products	
<i>The Art of Writing and Implementing Standard Operating Procedures (SOPs) for Laboratories in Low-Resource Settings: Review of Guidelines and Best Practices</i>	B5.3, C5.3, D5.3
https://journals.plos.org/plosntds/article?id=10.1371/journal.pntd.0005053	
<i>Adolescents and Young Adults with Cancer</i>	B5.3.6
https://www.cancer.gov/types/aya	
<i>Integrating Geriatric Assessment into Cancer Care: A Conversation with Dr. Supriya Mohile</i>	B5.3.6
https://www.cancer.gov/news-events/cancer-currents-blog/2018/geriatric-assessment-cancer-care-mohile	

Resource Name/URL	Location
CLSI Home Page	B5.3.10
https://clsi.org/	
<i>Hematopoietic Cell Transplantation-Specific Comorbidity Index Predicts Morbidity and Mortality in Autologous Stem Cell Transplantation</i>	B6.3.1, C6.3.1
https://www.astctjournal.org/article/S1083-8791(17)30523-2/fulltext	
<i>The Hematopoietic Cell Transplant Comorbidity Index predicts survival after allogeneic transplant for nonmalignant diseases</i>	B6.3.1, C6.3.1
https://ashpublications.org/blood/article/133/7/754/260555/The-Hematopoietic-Cell-Transplant-Comorbidity	
<i>Hematopoietic Cell Transplantation-specific Comorbidity Index (HCT-CI)</i>	B6.3.1, C6.3.1
https://www.mdcalc.com/calc/3980/hematopoietic-cell-transplantation-specific-comorbidity-index-hct-ci	
<i>Family donor care management: principles and recommendations</i>	B6.3.1.2, B6.4.3, C6.3.1.2, C6.4.1
https://pubmed.ncbi.nlm.nih.gov/20023708/	
<i>WMDA S(P)EAR alert: August 2011</i>	B6.3.2.1, C6.3.10, C6.3.11
https://wmda.info/wp-content/uploads/2020/08/20110824-CLWG-SEAR-Alert-August-2011.pdf	
<i>Granulocyte colony-stimulating factor (G-CSF) administration in individuals with sickle cell disease: time for a moratorium?</i>	B6.3.6.2, C6.3.6.1
https://pubmed.ncbi.nlm.nih.gov/19513902/	
<i>Granulocyte colony-stimulating factor-based stem cell mobilization in patients with sickle cell disease</i>	B6.3.6.2, C6.3.6.1
https://pubmed.ncbi.nlm.nih.gov/18489998/	
<i>Mobilization, collection, and processing of peripheral blood stem cells in individuals with sickle cell trait</i>	B6.3.6.2, C6.3.6.1
https://pubmed.ncbi.nlm.nih.gov/11806986/	
<i>WHO guiding principles on human cell, tissue and organ transplantation</i>	B6.3.12.1, C6.3.12.1
https://iris.who.int/handle/10665/341814	

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.
<i>Allogeneic hematopoietic stem cell donation-standardized assessment of donor outcome data: a consensus statement from the Worldwide Network for Blood and Marrow Transplantation (WBMT)</i>	B6.3.12.1
https://pubmed.ncbi.nlm.nih.gov/22773129/	
<i>NMDP Home Page</i>	B6.4.2
https://www.nmdp.org/	
<i>Anthony Nolan Home Page</i>	B6.4.2
https://www.anthonynolan.org/	
<i>Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (2007)</i>	B6.4.4.1, B6.4.9, B6.4.17, C6.1, C6.4.7, C7.4.5
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/eligibility-determination-donors-human-cells-tissues-and-cellular-and-tissue-based-products	
<i>Recommendations for Determining Eligibility of Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) (2025 draft)</i>	B6.4.4.1, B6.4.9, B6.4.17, C6.1, C6.4.2.1, C6.4.7, C7.4.5
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommendations-determining-eligibility-donors-human-cells-tissues-and-cellular-and-tissue-based	
<i>21 CFR 1271.80(d)(2)</i>	B6.4.4.1, C6.4.2.1
https://www.ecfr.gov/current/title-21/chapter-I/subchapter-L/part-1271/subpart-C/section-1271.80#p-1271.80(d)(2)	
<i>Chapter 7: haemodilution, transfusion and donor testing (Guidance from the UK's Dept. of Health & Social Care)</i>	B6.4.4.1, C6.4.2.1
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	
<i>FACT- Hematopoietic Progenitor Cell, Apheresis and Marrow Donor History Questionnaire</i>	B6.4.8.8
https://factglobal.org/dhq-a-m	
<i>21 CFR 1271.75 How do I screen a donor?</i>	B6.4.8.8
https://www.ecfr.gov/current/title-21/chapter-I/subchapter-L/part-1271/subpart-C/section-1271.75	

Resource Name/URL	Location
<p><i>Testing Human Cells, Tissues, and Cellular and Tissue-Based Product (HCT/P) Donors for Relevant Communicable Disease Agents and Diseases</i></p> <p>https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/testing-human-cells-tissues-and-cellular-and-tissue-based-product-hctp-donors-relevant-communicable</p>	B6.4.8.8
<p><i>21 CFR 1271.55 What records must accompany an HCT/P after the donor-eligibility determination is complete; and what records must I retain?</i></p> <p>https://www.ecfr.gov/current/title-21/chapter-I/subchapter-L/part-1271/subpart-C/section-1271.55</p>	B6.4.17, C6.1, C6.4.7, C7.4.5
<p><i>NMDP – Donor and cord blood unit selection guidelines</i></p> <p>https://network.nmdp.org/training-education/catalog/donor-and-cord-blood-unit-selection-guidelines</p>	B7.6.4.2
<p><i>Circular of Information for the Use of Cellular Therapy Products, June 2024</i></p> <p>https://factglobal.org/resources/</p>	B7.6.8, C7.4.4 , D7.4.2, D7.4.5 , D11.2.4.3
<p><i>The why, what, and how of the new FACT standards for immune effector cells</i></p> <p>https://jtc.biomedcentral.com/articles/10.1186/s40425-017-0239-0</p>	B7.8
<p><i>Production of chimeric antigen receptor (CAR) T cells</i></p> <p>https://www.nature.com/nprot/posters</p>	B7.8
<p><i>ASTCT Consensus Grading for Cytokine Release Syndrome and Neurologic Toxicity Associated with Immune Effector Cells</i></p> <p>https://pubmed.ncbi.nlm.nih.gov/30592986/</p>	B7.8
<p><i>Recommended screening and preventive practices for long-term survivors after hematopoietic cell transplantation</i></p> <p>https://pubmed.ncbi.nlm.nih.gov/22178693/</p>	B7.11
<p><i>Lost in Transition: The Essential Need for Long-Term Follow-Up Clinic for Blood and Marrow Transplantation Survivors</i></p> <p>https://www.astctjournal.org/article/S1083-8791(14)00402-9/fulltext</p>	B7.11
<p><i>Late Effects after Allogeneic Hematopoietic Stem Cell Transplantation</i></p> <p>https://onlinelibrary.wiley.com/doi/10.1002/9781118473306.ch4</p>	B7.11

Resource Name/URL	Location
<i>Long-term survivorship care after CAR-T cell therapy</i>	B7.11
https://onlinelibrary.wiley.com/doi/10.1111/ejh.14100	Regular font indicates that the resource appears in the Accreditation Manual.
<i>CDC – Adult Immunization Schedule Notes</i>	B7.11.1
https://www.cdc.gov/vaccines/hcp/imz-schedules/adult-notes.html	
<i>Physical, psychological, and social sequelae following hematopoietic stem cell transplantation: a review of the literature</i>	B7.11.2
https://onlinelibrary.wiley.com/doi/10.1002/pon.1399	
<i>Psychosocial aspects of hematopoietic stem cell transplantation</i>	B7.11.2
https://pmc.ncbi.nlm.nih.gov/articles/PMC8290998/	
<i>Commission Directive (EU) 2015/565</i>	B8.2.1.4
http://data.europa.eu/eli/dir/2015/565/oj	
<i>21 CFR PART 54—FINANCIAL DISCLOSURE BY CLINICAL INVESTIGATORS</i>	B8.4
https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-54	
<i>Adoptive Cellular Therapies (ACT) Stakeholder's Council</i>	B9.2
https://cibmtr.org/CIBMTR/About/Administrative-Committees/Adoptive-Cellular-Therapies-ACT-Council	
<i>Part 11, Electronic Records; Electronic Signatures - Scope and Application</i>	B10.4.1, C12.6.1, D13.4.1
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/part-11-electronic-records-electronic-signatures-scope-and-application	
<i>MoReq®</i>	B10.4.1, C12.6.1, D13.4.1
https://www.moreq.info/	
<i>NMDP – Policies & Protocols (see Data Use and Processing Policies under Transplant centers, Additional Resources)</i>	B10.5.2
https://network.nmdp.org/policies-protocols	

Resource Name/URL	Location
<p><i>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</i></p> <p>https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-207</p>	C1.2.1, D1.2.1
<p><i>21 CFR PART 807—ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND INITIAL IMPORTERS OF DEVICES</i></p> <p>https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-807</p>	C1.2.1, D1.2.1
<p><i>Tissue Establishment Registration</i></p> <p>https://www.fda.gov/vaccines-blood-biologics/biologics-establishment-registration/tissue-establishment-registration</p>	C1.2.1, D1.2.1
<p><i>21 CFR 211.42(b)</i></p> <p>https://www.ecfr.gov/current/title-21/part-211/section-211.42#p-211.42(b)</p>	C2.1.3, D2.1.3
<p><i>CAR-T Cell Therapies From the Transfusion Medicine Perspective</i></p> <p>https://pubmed.ncbi.nlm.nih.gov/27067907/</p>	C5.1.6
<p><i>NICE – Guidance on the use of ultrasound locating devices for placing central venous catheters</i></p> <p>http://guidance.nice.org.uk/TA49</p>	C6.3.11
<p><i>Practice Guidelines for Central Venous Access 2020: An Updated Report by the American Society of Anesthesiologists Task Force on Central Venous Access</i></p> <p>https://journals.lww.com/anesthesiology/fulltext/2020/01000/practice_guidelines_for_central_venous_access.9.aspx</p>	C6.3.11
<p><i>ICCBBA Home Page</i></p> <p>https://iccbba.org/</p>	C7.1.1, C7.1.2, D7.1.1, D7.1.2
<p><i>ISO 3166</i></p> <p>https://www.iso.org/iso-3166-country-codes.html</p>	C7.1.1, D7.1.1

Resource Name/URL	Location
Eurocode-IBLS Home Page	Regular font indicates that the resource appears in the Accreditation Manual.
https://www.eurocode.org/	C7.1.1, C7.1.2, D7.1.1, D7.1.2
ICCBBA ST-018 (ISBT 128 Standard Labeling of Collection Products for Cellular Therapy Manufacturing)	C7.1.3, C7.3.2.1, D7.1.3, D7.3.2.1
https://www.isbt128.org/ST-018	
Recognition and Use of a Standard for Uniform Blood and Blood Component Container Labels	C7.2.11, D7.2.11
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recognition-and-use-standard-uniform-blood-and-blood-component-container-labels	
FACT ISBT 128 Hybrid (Split) Label Webinar	C7.3.2.1, D7.3.2.1
https://learn фактglobal.org/2024-on-demand-webinar-isbt128-hybrid-split-label	
ST-004 ISBT 128 Standard Labeling of Cellular Therapy Products	C7.4.1, D7.4.1
https://www.isbt128.org/ST-004	
European Commission	C8.3.9
https://commission.europa.eu/index_en	
21 CFR 1271.200 Equipment	C8.4.2.3
https://www.ecfr.gov/current/title-21/chapter-I/subchapter-L/part-1271/subpart-D/section-1271.200	
21 CFR Part 211 Subpart D—Equipment	C8.4.2.3
https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-211/subpart-D	
21 CFR 1271.270(a) Records. General	C9.10.1, D8.9.2
https://www.ecfr.gov/current/title-21/chapter-I/subchapter-L/part-1271/subpart-D/section-1271.270	
Regulation (EU) 2016/679	C12.4
http://data.europa.eu/eli/reg/2016/679/2016-05-04	

Resource Name/URL	Location
<i>Directive 2001/20/EC</i>	D1.1
http://data.europa.eu/eli/dir/2001/20/2022-01-01	
<i>21 CFR PART 210—CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PROCESSING, PACKING, OR HOLDING OF DRUGS; GENERAL</i>	D1.2, D2.5
https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-210	
<i>21 CFR PART 211—CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS</i>	D1.2, D2.5
https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-211	
<i>21 CFR 211.52 Washing and toilet facilities.</i>	C2.2, D2.1.2
https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-211/subpart-C/section-211.52	
<i>21 CFR 1271.190 Facilities</i>	D2.1.2
https://www.ecfr.gov/current/title-21/chapter-I/subchapter-L/part-1271/subpart-D/section-1271.190	
<i>21 CFR PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS</i>	D2.5
https://www.ecfr.gov/current/title-21/chapter-I/subchapter-F/part-610	
<i>EU GMP Annex 1: Manufacture of Sterile Medicinal Products</i>	D2.5
https://www.gmp-compliance.org/guidelines/gmp-guideline/eu-gmp-annex-1-manufacture-of-sterile-medicinal-products	
<i>CSB Releases Final Report into 2021 Fatal Liquid Nitrogen Release at Foundation Food Group Facility in Georgia</i>	D2.11.3
https://www.csb.gov/csb-releases-final-report-into-2021-fatal-liquid-nitrogen-release-at-foundation-food-group-facility-in-georgia/	
<i>OSHA Standard 1926.1202</i>	D2.11.3
https://www.osha.gov/laws-regulations/regulations/standardnumber/1926/1926.1202	
<i>ABO incompatible graft management in pediatric transplantation</i>	D5.1.4
https://www.nature.com/articles/s41409-020-0981-7	

Resource Name/URL	Location
OSHA's Nationally Recognized Testing Laboratory (NRTL) Program	D6.3.9
https://www.osha.gov/nationally-recognized-testing-laboratory-program	
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
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