

## Online Resources and Links for the Ninth Edition – v9.1 Standards for Hematopoietic Cellular Therapy and Accreditation Manual

Resource Name/URL	Location
FACT Email <a href="mailto:fact@factglobal.org">fact@factglobal.org</a>	Contact Information
JACIE Email <a href="mailto:jacie@ebmt.org">jacie@ebmt.org</a>	Contact Information
FACT Home Page <a href="https://www.factglobal.org">https://www.factglobal.org</a>	Contact Information, Introduction
JACIE Home Page <a href="https://www.ebmt.org/jacie">https://www.ebmt.org/jacie</a>	Contact Information, Introduction
<i>NetCord-FACT International Standards for Cord Blood Collection, Banking, and Release for Administration</i> <a href="https://www.factglobal.org/cbstandards">https://www.factglobal.org/cbstandards</a>	Introduction (Standards only)
Regulation (EC) No 765/2008 <a href="http://data.europa.eu/eli/reg/2008/765/2021-07-16">http://data.europa.eu/eli/reg/2008/765/2021-07-16</a>	Introduction
FACT Accredited Organizations <a href="https://accredited.factglobal.org">https://accredited.factglobal.org</a>	Introduction
JACIE Certified Centres <a href="https://www.ebmt.org/jacie-certified-centres">https://www.ebmt.org/jacie-certified-centres</a>	Introduction
21 USC 351: Adulterated drugs and devices <a href="https://uscode.house.gov/view.xhtml?req=(title:21%20section:351%20edition:prelim)">https://uscode.house.gov/view.xhtml?req=(title:21%20section:351%20edition:prelim)</a>	A4 (Good Manufacturing Practice)

Resource Name/URL	Location
<i>ISBT 128 Standard Terminology for Medical Products of Human Origin (ST-002)</i> <a href="https://www.isbt128.org/standard-terminology">https://www.isbt128.org/standard-terminology</a>	<b>A4</b> (Product name), C7.1.1, C7.1.2, D7.1.1, D7.1.2, <b>Appendix II</b>
<i>21 CFR Part 1271 Subpart D—Current Good Tissue Practice</i> <a href="https://www.ecfr.gov/current/title-21/chapter-I/subchapter-L/part-1271/subpart-D">https://www.ecfr.gov/current/title-21/chapter-I/subchapter-L/part-1271/subpart-D</a>	B1.2, B4.4.2.5, C1.2, C4.4.2.5, D1.2, D4.4.2.5
<i>Title 21 Food and Drugs</i> <a href="https://www.ecfr.gov/current/title-21">https://www.ecfr.gov/current/title-21</a>	B1.2, C1.2
<i>Directive 2004/23/EC</i> <a href="http://data.europa.eu/eli/dir/2004/23/2009-08-07">http://data.europa.eu/eli/dir/2004/23/2009-08-07</a>	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
<i>Directive 2006/17/EC</i> <a href="http://data.europa.eu/eli/dir/2006/17/2012-12-17">http://data.europa.eu/eli/dir/2006/17/2012-12-17</a>	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
<i>Directive 2006/86/EC</i> <a href="http://data.europa.eu/eli/dir/2006/86/2015-04-29">http://data.europa.eu/eli/dir/2006/86/2015-04-29</a>	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
<i>Directive 2001/83/EC</i> <a href="http://data.europa.eu/eli/dir/2001/83/2025-01-01">http://data.europa.eu/eli/dir/2001/83/2025-01-01</a>	B1.2, C1.2, D1.1, D1.2
<i>Regulation (EC) No 1394/2007</i> <a href="http://data.europa.eu/eli/reg/2007/1394/2019-07-26">http://data.europa.eu/eli/reg/2007/1394/2019-07-26</a>	B1.2, C1.2, D1.1, D1.2
<i>Regulation (EU) 2024/1938</i> <a href="http://data.europa.eu/eli/reg/2024/1938/2024-07-17">http://data.europa.eu/eli/reg/2024/1938/2024-07-17</a>	B1.2, C1.2, D1.2
<i>Haute Autorité de Santé (HAS)</i> <a href="https://www.has-sante.fr/">https://www.has-sante.fr/</a>	B1.9

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

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

Resource Name/URL	Location
<p><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></p> <p><a href="https://pubmed.ncbi.nlm.nih.gov/37017433/">https://pubmed.ncbi.nlm.nih.gov/37017433/</a></p>	B3.3.6.5, C9.11.2
<p><i>NMDP – The evolution of HCT self-paced learning course</i></p> <p><a href="https://network.nmdp.org/training-education/catalog/the-evolution-of-hct-self-paced-learning-course">https://network.nmdp.org/training-education/catalog/the-evolution-of-hct-self-paced-learning-course</a></p>	B3.4.2
<p><i>ASTCT Special Interest Groups</i></p> <p><a href="https://www.astct.org/Membership/Special-Interest-Groups">https://www.astct.org/Membership/Special-Interest-Groups</a></p>	B3.5.2, B3.7.4
<p><i>Transplantation and Cellular Therapy Certified Nurse (TCTCN™)</i></p> <p><a href="https://www.oncc.org/transplantation-cellular-therapy-certified-nurse-tctcn">https://www.oncc.org/transplantation-cellular-therapy-certified-nurse-tctcn</a></p> <p>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.</p>	B3.6.1
<p><i>The EBMT Textbook for Nurses, EBMT Online Learning Course for Nurses</i></p> <p><a href="https://www.ebmt.org/ebmt-jacie-books/ebmt-textbook-nurses">https://www.ebmt.org/ebmt-jacie-books/ebmt-textbook-nurses</a></p>	B3.6.2.7
<p><i>American Nurses Association – Nurse Staffing</i></p> <p><a href="https://www.nursingworld.org/practice-policy/nurse-staffing/">https://www.nursingworld.org/practice-policy/nurse-staffing/</a></p>	B3.6.4
<p><i>Press Ganey National Database of Nursing Quality Indicators (NDNQI)</i></p> <p><a href="https://info.pressganey.com/press-ganey-blog-healthcare-experience-insights/your-comprehensive-guide-to-the-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</a></p>	B3.6.4
<p><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></p> <p><a href="https://www.astctjournal.org/article/S1083-8791(14)00050-0/fulltext">https://www.astctjournal.org/article/S1083-8791(14)00050-0/fulltext</a></p>	B3.7.2.5

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

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

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



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

Resource Name/URL	Location
<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> <a href="https://pubmed.ncbi.nlm.nih.gov/22773129/">https://pubmed.ncbi.nlm.nih.gov/22773129/</a>	B6.3.12.1
NMDP Home Page <a href="https://www.nmdp.org/">https://www.nmdp.org/</a>	B6.4.2
Anthony Nolan Home Page <a href="https://www.anthonynolan.org/">https://www.anthonynolan.org/</a>	B6.4.2
<i>Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (2007)</i> <a href="https://www.fda.gov/regulatory-information/search-fda-guidance-documents/eligibility-determination-donors-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</a>	B6.4.4.1, B6.4.9, B6.4.17, C6.1, C6.4.7, C7.4.5
<i>Recommendations for Determining Eligibility of Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/PS) (2025 draft)</i> <a href="https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommendations-determining-eligibility-donors-human-cells-tissues-and-cellular-and-tissue-based">https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommendations-determining-eligibility-donors-human-cells-tissues-and-cellular-and-tissue-based</a>	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) <a href="https://www.ecfr.gov/current/title-21/chapter-I/subchapter-L/part-1271/subpart-C/section-1271.80#p-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)</a>	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) <a href="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">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</a>	B6.4.4.1, C6.4.2.1
FACT– Hematopoietic Progenitor Cell, Apheresis and Marrow Donor History Questionnaire <a href="https://factglobal.org/dhq-a-m">https://factglobal.org/dhq-a-m</a>	B6.4.8.8
21 CFR 1271.75 How do I screen a donor? <a href="https://www.ecfr.gov/current/title-21/chapter-I/subchapter-L/part-1271/subpart-C/section-1271.75">https://www.ecfr.gov/current/title-21/chapter-I/subchapter-L/part-1271/subpart-C/section-1271.75</a>	B6.4.8.8

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

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

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

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

<b>Resource Name/URL</b> <div> Regular font indicates that the resource appears in the Accreditation Manual.  <b>Bold font</b> indicates that the resource appears in both the Standards and the Accreditation Manual. </div>	<b>Location</b>
<i>Directive 2001/20/EC</i> <a href="http://data.europa.eu/eli/dir/2001/20/2022-01-01">http://data.europa.eu/eli/dir/2001/20/2022-01-01</a>	D1.1
<b>21 CFR PART 210—CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PROCESSING, PACKING, OR HOLDING OF DRUGS; GENERAL</b> <a href="https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-210">https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-210</a>	D1.2, D2.5
<b>21 CFR PART 211—CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS</b> <a href="https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-211">https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-211</a>	D1.2, D2.5
<b>21 CFR 211.52 Washing and toilet facilities.</b> <a href="https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-211/subpart-C/section-211.52">https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-211/subpart-C/section-211.52</a>	C2.2, D2.1.2
<b>21 CFR 1271.190 Facilities</b> <a href="https://www.ecfr.gov/current/title-21/chapter-I/subchapter-L/part-1271/subpart-D/section-1271.190">https://www.ecfr.gov/current/title-21/chapter-I/subchapter-L/part-1271/subpart-D/section-1271.190</a>	D2.1.2
<b>21 CFR PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS</b> <a href="https://www.ecfr.gov/current/title-21/chapter-I/subchapter-F/part-610">https://www.ecfr.gov/current/title-21/chapter-I/subchapter-F/part-610</a>	D2.5
<b>EU GMP Annex 1: Manufacture of Sterile Medicinal Products</b> <a href="https://www.gmp-compliance.org/guidelines/gmp-guideline/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</a>	D2.5
<b>CSB Releases Final Report into 2021 Fatal Liquid Nitrogen Release at Foundation Food Group Facility in Georgia</b> <a href="https://www.csb.gov/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/</a>	D2.11.3
<b>OSHA Standard 1926.1202</b> <a href="https://www.osha.gov/laws-regs/regulations/standardnumber/1926/1926.1202">https://www.osha.gov/laws-regs/regulations/standardnumber/1926/1926.1202</a>	D2.11.3
<b>ABO incompatible graft management in pediatric transplantation</b> <a href="https://www.nature.com/articles/s41409-020-0981-7">https://www.nature.com/articles/s41409-020-0981-7</a>	D5.1.4

Resource Name/URL	Location
<p>OSHA's Nationally Recognized Testing Laboratory (NRTL) Program</p> <p><a href="https://www.osha.gov/nationally-recognized-testing-laboratory-program">https://www.osha.gov/nationally-recognized-testing-laboratory-program</a></p>	D6.3.9
<p>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</p> <p><a href="https://pubmed.ncbi.nlm.nih.gov/35307845/">https://pubmed.ncbi.nlm.nih.gov/35307845/</a></p>	D8.1.4.2, D9.2.3.1
<p>Current thawing and infusion practice of cryopreserved cord blood: the impact on graft quality, recipient safety, and transplantation outcomes</p> <p><a href="https://pubmed.ncbi.nlm.nih.gov/24894338/">https://pubmed.ncbi.nlm.nih.gov/24894338/</a></p>	D8.4.4
<p>21 CFR PART 820—QUALITY SYSTEM REGULATION</p> <p><a href="https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-820">https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-820</a></p>	D8.12.2
<p>Current Good Tissue Practice (CGTP) and Additional Requirements for Manufacturers of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)</p> <p><a href="https://www.fda.gov/regulatory-information/search-fda-guidance-documents/current-good-tissue-practice-cgtp-and-additional-requirements-manufacturers-human-cells-tissues-and">https://www.fda.gov/regulatory-information/search-fda-guidance-documents/current-good-tissue-practice-cgtp-and-additional-requirements-manufacturers-human-cells-tissues-and</a></p>	D8.12.2
<p>Hepatitis B transmission from contaminated cryopreservation tank</p> <p><a href="https://pubmed.ncbi.nlm.nih.gov/7603227/">https://pubmed.ncbi.nlm.nih.gov/7603227/</a></p>	D9.4.3.3
<p>21 CFR 312.6(a)</p> <p><a href="https://www.ecfr.gov/current/title-21/chapter-I/subchapter-D/part-312/subpart-A/section-312.6">https://www.ecfr.gov/current/title-21/chapter-I/subchapter-D/part-312/subpart-A/section-312.6</a></p>	<b>Appendix II</b>