Online Resources and Links for the Third Edition – v3.1 Standards for Immune Effector Cells 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**
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**

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 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
Deutsche Krebsgesellschaft (DKG) https://www.krebsgesellschaft.de/	B1.9

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.
Care Quality Commission (CQC) https://www.cqc.org.uk/	B1.9
Qualicor https://www.qualicor.eu/	B1.9
FACT Maintaining Accreditation Policy https://factglobal.org/FACT-Policies-SOPs/	B2.1
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, B3.2.2
FACT Educational Activities Form https://www.factglobal.org/iecstandards	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, C3.1.3.3, D3.1.4
ESH – eLearning https://elearning.esh.org/esh	B3.1.5, B3.3.4, 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, B3.5.2, C3.1.3.3, D3.1.4

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.
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	B3.3.4.13, 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
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

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.
ASTCT Special Interest Groups https://www.astct.org/Membership/Special-Interest-Groups	B3.5.2, B3.7.4
Transplantation and Cellular Therapy Certified Nurse (TCTCN™) https://www.oncc.org/transplantation-cellular-therapy-certified-nurse-tctcn *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.*	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
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

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 – 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 Handbook https://www.factglobal.org/store	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
FACT Quality Management Series webinars *https://learn.factglobal.org/quality*	B3.9.2, C3.3.2, D3.3.2
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
FACT Data Management Resource Center https://www.factglobal.org/dm-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

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.
Psychological Consequences of Hematopoietic Stem Cell Transplant https://pmc.ncbi.nlm.nih.gov/articles/PMC3105969/	B3.11.1.2
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	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 Data Collection Forms (Cellular Therapy Essential Data [CTED] forms) https://cibmtr.org/CIBMTR/Data-Operations/Data-Collection-Forms	B4.8.5.1, B9.2
EBMT Registry Data Collection Forms https://www.ebmt.org/registry/ebmt-data-collection	B4.8.5.1, B9.2
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

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.
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	B5.1.16
Preparing for the Unthinkable: Emergency Preparedness for the Hematopoietic Cell Transplant Program https://pmc.ncbi.nlm.nih.gov/articles/PMC7129195/	B5.1.17, 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	B5.1.17, 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
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

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.
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
Anthony Nolan Home Page https://www.anthonynolan.org/	B6.4.2
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	B6.4.3, C6.4.1
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

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 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://www.factglobal.org/dhq-a-m/	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
Circular of Information for the Use of Cellular Therapy Products, June 2024 https://www.factglobal.org/resources/	B7.6.5, **C7.4.4**, D7.4.2, **D7.4.5**, 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

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.
ASTCT Consensus Grading for Cytokine Release Syndrome and Neurologic Toxicity Associated with Immune Effector Cells https://pubmed.ncbi.nlm.nih.gov/30592986/	B7.8
Recommended screening and preventive practices for long-term survivors after hematopoietic cell transplantation https://pubmed.ncbi.nlm.nih.gov/22178693/	B7.11
Lost in Transition: The Essential Need for Long-Term Follow-Up Clinic for Blood and Marrow Transplantation Survivors https://www.astctjournal.org/article/S1083-8791(14)00402-9/fulltext	B7.11
Late Effects after Allogeneic Hematopoietic Stem Cell Transplantation https://onlinelibrary.wiley.com/doi/10.1002/9781118473306.ch4	B7.11
Long-term survivorship care after CAR-T cell therapy Long-term survivorship care after CAR-T cell therapy	B7.11
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

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.
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
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

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.
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://iccbba.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
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

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 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
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

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.
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/	D9.2.3.1
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

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 312.6(a) https://www.ecfr.gov/current/title-21/chapter-I/subchapter-D/part-312/subpart-A/section-312.6	Appendix II