Immune Effector Cells

**DOCUMENT SUBMISSION REQUIREMENTS**

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**FACT Standards for**

**Immune Effector Cells**

**Second Edition**

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**FACT ACCREDITATION OFFICE**

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**IMMUNE EFFECTOR CELLS**

**DOCUMENT SUBMISSION REQUIREMENTS**

Copies of the following items are required prior to the on-site inspection and must be uploaded via the online Compliance Application within the FACT Accreditation Portal. For additional information, see the referenced standard and the accompanying information in the Accreditation Manual.

Do not use patient names on the documents submitted. All submitted documents, policies, and procedures must be in English unless otherwise specified. If your facility uses electronic records, hard copies of the primary source data must be assembled and flagged before the inspection and must be ready for inspector review on-site. Those items not provided for inspector review by the end of the on-site inspection will be marked as a deficiency.

The documents listed in the following pages are only a subset of what inspectors will need to review. Documentation of compliance with each standard must be readily available to the inspectors during the on-site inspection. See the Applicant Guidelines on the FACT website at www.factwebsite.org for tips on how to prepare on-site documentation.

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Foundation for the Accreditation of

Cellular Therapy (FACT)

**CLINICAL PROGRAM DOCUMENTATION**

**All Personnel**

[ ]  Complete and upload the Personnel List that includes all Clinical Program Director(s), Attending Physicians, Advance Practice Providers, and Pharmacists in your organization. [B1.4]

**Clinical Program Director(s)**

[ ]  Copy of the current license to practice medicine in the jurisdiction in which the program is located for each Program Director. If the license is in a language other than English, include a general description in English. [B3.1.1]

[ ]  Copy(ies) of specialty certification(s) for each Clinical Program Director. If the documentation is in a language other than English, include a general description in English. [B3.1.1]

**or**

Physicians who received all or part of their medical and specialty training outside of the United States or Canada must submit documentation of training and experience and a copy of registrations or certifications in the therapeutic disease area. Documentation should describe the specifics of the training received and may be submitted in the form of curriculum vitaes, letters from the directors of the referenced training programs or current department chair, or other similar information. If the documentation is in a language other than English, include a general description in English. [B3.1.1]

[ ]  Curriculum vitae for each Clinical Program Director. If one individual serves as a director for multiple facilities, submit this individual’s curriculum vitae whenever applicable. If the curriculum vitae is in a language other than English, include a summary in English. [B3.1.2]

[ ]  Documentation of at least ten (10) hours annually of continuing education since the previous accreditation date (at a minimum 2 years) for each Clinical Program Director in educational activities related to cellular therapy. For initial applicants submit documentation of at least ten (10) hours of continuing education for the previous 12 months. Complete and upload the [Educational Activities Form](https://www.factglobal.org/files?a=EducationalActivitiesForm/) or submit other documentation that contains the equivalent information for each activity: [B3.1.6] (Meeting names and topics must be defined).

[ ]  Date of activity

[ ]  Title of activity

[ ]  Type of activity (e.g., webinar, meeting, grand rounds)

[ ]  Topic of activity (e.g., hematology, cell administration)

[ ]  Approximate number of hours of activity

[ ]  Complete and upload the [Immune Effector Cells Standards Training and Competency Form](https://www.factglobal.org/files?a=IECTrainingAndCompetencyForm/) or submit the following for each Clinical Program Director: [B3.3]

[ ]  Documentation of specific training and competency in the skills listed in Standard B3.3.4.

[ ]  For programs requesting accreditation for allogeneic cell therapy, documentation of specific training and competency in each of the skills listed in Standard B3.3.5.

[ ]  Documentation of knowledge in the procedures listed in Standard B3.3.6.

**Attending Physicians** (specify adult and pediatric programs if applicable):

[ ]  Copy of the current license to practice medicine in the jurisdiction in which the program is located for each attending physician. If the license or certificate is in a language other than English, include a general description in English. [B3.2.1]

[ ]  Copy(ies) of specialty certification(s) for each attending physician, if appropriate. If the documentation is in a language other than English, include a general description in English. [B3.2.1]

**or**

Physicians who received all or part of their medical and specialty training outside of the United States or Canada must submit documentation of training and experience and a copy of registrations or certifications in the therapeutic disease area. Documentation should describe the specifics of the training received and may be submitted in the form of curriculum vitaes, letters from the directors of the referenced training programs or current department chair, or other similar information. If the documentation is in a language other than English, include a general description in English. [B3.2.1] (Meeting names and topics must be defined).

[ ]  Documentation of at least ten (10) hours annually of participation since the previous accreditation date (at a minimum 2 years) for each attending physician in educational activities related to cellular therapy. For initial applicants submit documentation of at least ten (10) hours of continuing education for the previous 12 months. Complete and upload the [Educational Activities Form](https://www.factglobal.org/files?a=EducationalActivitiesForm/) or submit other documentation that contains the equivalent information for each activity: [B3.2.3] (Meeting names and topics must be defined).

[ ]  Date of activity

[ ]  Title of activity

[ ]  Type of activity (e.g., webinar, meeting, grand rounds)

[ ]  Topic of activity (e.g., hematology, cell administration)

[ ]  Approximate number of hours of activity

[ ]  Complete and upload the [Immune Effector Cells Standards Training and Competency Form](https://www.factglobal.org/files?a=IECTrainingAndCompetencyForm/) or submit the following for each attending physician: [B3.3]

[ ]  Documentation of specific training and competency in the skills listed in Standard B3.3.4.

[ ]  For programs requesting accreditation for allogeneic cell therapy, documentation of specific training and competency in each of the skills listed in Standard B3.3.5.

[ ]  Documentation of knowledge in the procedures listed in Standard B3.3.6.

**Physicians-in-Training**

[ ]  If physicians-in-training are receiving their training within a program accredited by the Accreditation Council for Graduate Medical Education (ACGME) or equivalent, documentation that physicians-in-training are residents or fellows in an accredited graduate medical education program. [B3.4.1]

[ ]  For physicians-in-training not in an accredited graduate medical education program, copy of the current license to practice medicine in the jurisdiction in which the program is located for each physician-in-training. If the license or certificate is in a language other than English, include a general description in English. [B3.4.1]

[ ]  For physicians-in-training not in an accredited graduate medical education program, complete and upload the [Immune Effector Cells Standards Training and Competency Form](https://www.factglobal.org/files?a=IECTrainingAndCompetencyForm/) or submit the following for each physician-in-training: [B3.4.2]

[ ]  Documentation of specific training and competency development in the skills listed in Standard B3.3.4.

[ ]  For programs requesting accreditation for allogeneic cell therapy, documentation of specific training and competency development in each of the skills listed in Standard B3.3.5.

**Advanced Practice Providers/Professionals (APPs)**

[ ]  Copy of the current license to practice as required in the jurisdiction in which the program is located for each APP. If the license or certificate is in a language other than English, include a general description in English. [B3.5.1]

[ ]  Complete and upload the [Immune Effector Cells Standards Training and Competency Form](https://www.factglobal.org/files?a=IECTrainingAndCompetencyForm/) or submit the following for each APP in the therapeutic-related cognitive and procedural skills that he/she routinely practices: [B3.5.2]

[ ]  Documentation of specific training and competency in the skills listed in Standard B3.3.4 for each APP as applicable.

[ ]  For programs requesting accreditation for allogeneic cellular therapy, documentation of specific training and competency in each of the skills listed in Standard B3.3.5 for each APP as applicable.

[ ]  Documentation of at least ten (10) hours of participation annually since the previous accreditation (at a minimum 2 years) for each APP in educational activities related to cellular therapy. For initial applicants submit documentation of at least ten (10) hours of continuing education for the previous 12 months. Complete and upload the [Educational Activities Form](https://www.factglobal.org/files?a=EducationalActivitiesForm/) or submit other documentation that contains the equivalent information for each activity: [B3.5.3] (Meeting names and topics must be defined).

[ ]  Date of activity

[ ]  Title of activity

[ ]  Type of activity (e.g., webinar, meeting, grand rounds)

[ ]  Topic of activity (e.g., hematology, cell administration)

[ ]  Approximate number of hours of activity

### Pharmacists

[ ]  Copy of the current license to practice as required in the jurisdiction in which the program is located for each designated pharmacist. If the license is in a language other than English, include a general description in English. [B3.7.1]

[ ]  Documentation of at least ten (10) hours of participation annually since the previous accreditation date (at a minimum 2 years) for each designated pharmacist in educational activities, including cytokine release syndrome and neurological toxicities resulting from cellular therapies. For initial applicants submit documentation of at least ten (10) hours of continuing education for the previous 12 months. Complete and upload the [Educational Activities Form](https://www.factglobal.org/files?a=EducationalActivitiesForm/) or submit other documentation that contains the equivalent information for each activity: [B3.7.4] (Meeting names and topics must be defined).

[ ]  Date of activity

[ ]  Title of activity

[ ]  Type of activity (e.g., webinar, meeting, grand rounds)

[ ]  Topic of activity (e.g., hematology, cell administration)

[ ]  Approximate number of hours of activity

### Consulting Specialists

Submit a copy of board certification or documentation of training and experience for at least one (1) specialist in each specialty field. For programs that treat pediatric patients, documentation of specialist certification or training for consultants qualified to manage pediatric patients must be submitted. Documentation of specialty certification in the U.S. can be accessed from [ABIM](https://www.abim.org/), [ABMS](https://www.certificationmatters.org/), [ABP](https://www.abp.org/), [ABPN](https://abpn.org/), [the ABR](https://www.theabr.org/), [the ABA](https://www.theaba.org/), and [AOA](https://osteopathic.org/). If the documentation is in a language other than English, include a general description in English. [B3.8]

Peds Adult Peds Adult

[ ]  [ ]  Cardiology\*\* [B3.8.1.1] [ ]  [ ]  Dermatology\*\* [B3.8.1.2]

[ ]  [ ]  Gastroenterology\*\* [B3.8.1.3] [ ]  [ ]  Infectious disease\*\* [B3.8.1.4]

[ ]  [ ]  Intensive care\*\* [B3.8.1.5] [ ]  [ ]  Nephrology\*\* [B3.8.1.6]

[ ]  [ ]  Neurology\*\* [B3.8.1.7] [ ]  [ ]  Obstetrics/Gynecology [B3.8.1.8]

[ ]  [ ]  Ophthalmology [B3.8.1.9] [ ]  [ ]  Pathology\*\* [B3.8.1.10]

[ ]  [ ]  Psychiatry\*\* [B3.8.1.11] [ ]  [ ]  Pulmonary medicine\*\* [B3.8.1.12]

[ ]  [ ]  Radiation therapy [B3.8.1.13] [ ]  [ ]  Radiology\*\* [B3.8.1.14]

[ ]  [ ]  Surgery\*\* [B3.8.1.15] [ ]  [ ]  Transfusion medicine\* [B3.8.1.16]

[ ]  [ ]  Palliative and end of life care\*\* [B3.8.1.17]

*\*The transfusion medicine requirement is separate from the pathology requirement.\*\*Pediatric Specialty: If not submitting documentation of pediatric specific subspecialty, then submit documentation of general pediatrics with specialty.*

**Clinical Quality Manager**

[ ]  Documentation of at least ten (10) hours of participation annually of continuing education since the previous accreditation date (at a minimum 2 years) for each Clinical Quality Manager in educational activities related to cellular therapy and/or quality management. For initial applicants submit documentation of at least ten (10) hours of continuing education for the previous 12 months. Complete and upload the [Educational Activities Form](https://www.factglobal.org/files?a=EducationalActivitiesForm/) or submit other documentation that contains the equivalent information for each activity: [B3.9.3] (Meeting names and topics must be defined).

[ ]  Date of activity

[ ]  Title of activity

[ ]  Type of activity (e.g., webinar, meeting, grand rounds)

[ ]  Topic of activity (e.g., hematology, cell administration)

[ ]  Approximate number of hours of activity

**Data Management Staff**

[ ]  Documentation of participation in educational activities for each defined data management staff. Complete and upload the [Educational Activities Form](https://www.factglobal.org/standards/hct-standards/) or submit other documentation that contains the equivalent information for each activity: [B3.10.2] (Meeting names and topics must be defined).

[ ]  Date of activity

[ ]  Title of activity

[ ]  Type of activity (e.g., webinar, meeting, grand rounds)

[ ]  Topic of activity (e.g., hematology, cell administration)

[ ]  Approximate number of hours of activity

**Other Clinical Documentation**

[ ]  A completed [Clinical Facility Grid](https://www.factglobal.org/files?a=clinicalfacilitygrid/), which includes new patient numbers. For initial accreditation, enter data for the previous 12 months. For renewal accreditation, enter data from the start of the current accreditation cycle. [B1.1]

[ ]  Complete and upload the [IEC List](https://www.factglobal.org/files?a=IECList). [B1.1]

[ ]  General physical floor plan of all program facilities (clinical, collection, processing). Label all floors of the building(s) that are used for cellular therapy activities. If the floor plan or diagram is labeled in a language other than English, include a general description of the floor plan or diagram in English. [B1.1]

[ ]  A map of the overall organization that includes all facilities. If the map is labeled in a language other than English, include a general description of the map in English. [B1.1]

[ ]  If the Clinical Program or intermediary facility receives cellular therapy products directly from a third-party provider, an example or template of a written agreement that defines the following responsibilities at a minimum for each applicable cellular therapy product: [B1.2.1]

[ ]  Traceability and chain of custody of cellular therapy products. [B1.2.1.1]

[ ]  Cellular therapy product storage and distribution. [B1.2.1.2]

[ ]  Verification of cellular therapy product identity. [B1.2.1.3]

[ ]  Review and verification of product specifications provided by the manufacturer, if applicable. [B1.2.1.4]

[ ]  Readily available access to a summary of documents used to determine allogeneic donor eligibility. [B1.2.1.5]

[ ]  Documented evidence of donor eligibility screening and testing in accordance with Applicable Law. [B1.2.1.6]

[ ]  A copy of the certificate for each licensure, registration, or accreditation required by the appropriate governmental authorities. Include, as appropriate, certificates for accreditation of in-patient facilities such as the Joint Commission, American Osteopathic Association, DNV, Australian Council on Healthcare Standards, Canadian Council on Health Services Accreditation, or other certification required by the appropriate governmental authority. If the licensure, registration, or accreditation is in a language other than English, include a general description of the document in English. [B1.3.1]

[ ]  A complete recipient list, in Excel or similar format from the previous twelve months. Include unique patient identifier, year only of cellular therapy, diagnosis, source of cells (marrow, apheresis, tissue, cord blood, etc.), type of donor (autologous, allogeneic), type of recipient (adult, pediatric), and CIBMTR ID (if applicable). Per United States HIPAA guidelines, do not include protected health information (PHI), e.g., patient names, medical record numbers, birthdate, or others. [B1.5]

[ ]  For programs requesting allogeneic accreditation of cellular therapies requiring HLA matching, submit a copy of the HLA laboratory's current ASHI, EFI, CAP, or other appropriate accreditation certificate, including documentation of certification for DNA-based typing. If the certificate is in a language other than English, include a general description of the document in English. [B2.13]

[ ]  For ASHI accreditation:

[ ]  Include the accreditation letter in addition to the certificate.

[ ]  If the laboratory is not ASHI-accredited for HSC/BM transplantation, include documentation of HLA expertise available within the Clinical Program for selecting the best matched donor for the recipient.

[ ]  Copy of the Clinical Program’s Quality Management Plan that includes all requirements listed in B4. [B4.2]

[ ]  Organizational chart of key positions and functions within the cellular therapy program, including clinical, collection, and processing, as applicable. [B4.3]

[ ]  Copies of policies and Standard Operating Procedures referenced in the Quality Management Plan that address the following:

[ ]  Personnel requirements for each key position in the Clinical Program. [B4.4]

[ ]  Development, approval, implementation, distribution, review, revision, and archival of all critical documents. [B4.5, B4.5.2]

[ ]  A standardized format for critical documents, and the required elements of each Standard Operating Procedure. [B4.5.3.1 and B5.3]

[ ]  The establishment and maintenance of written agreements. [B4.6]

[ ]  Documentation and review of safety and efficacy of the cellular therapy product, and outcome analysis to verify that the procedures in use consistently provide a safe and effective product. [B4.7]

[ ]  Audits of the Clinical Program’s activities to verify compliance. [B4.8]

[ ]  The management of external audits. [B4.8.4]

[ ]  The management of cellular therapy products with positive microbial culture results. [B4.9]

[ ]  Occurrences (errors, accidents, deviations, adverse events, adverse reactions, and complaints). [B4.10]

[ ]  Cellular therapy product chain of identity and chain of custody that allow tracking from the donor to the recipient or final disposition and tracing from the recipient or final disposition to the donor. [B4.11]

[ ]  Actions to take in the event the Clinical Program’s operations are interrupted. [B4.12]

[ ]  Qualification of critical manufacturers, vendors, equipment, software, supplies, reagents, facilities, and services. [B4.13]

[ ]  Validation or verification of critical procedures. [B4.14]

[ ]  Management of critical supplies including drugs and supplies. [B4.15]

[ ]  Evaluation of risk in changes to a process to assess the effect of the change elsewhere in the organization. [B4.16]

[ ]  Obtaining feedback. [B4.17]

[ ]  Evidence of a completed outcome analysis, e.g., a report of conclusions, meeting minutes, or completed forms. [B4.7]

[ ]  Schedule of audits that includes dates and subjects of audits already performed and audits planned for the future. Audits listed under B4.8.3 must be included. [B4.8]

[ ]  An audit report from a recently completed audit listed under B4.8.3. (This must be a different audit than the audit of the accuracy of clinical data). [B4.8]

[ ]  A validation of a critical procedure of the Clinical Program (marrow or other cellular collection procedures, labeling, storage, distribution, preparation for administration, and infusion) that includes: [B4.14, B4.14.3]

[ ]  An approved plan, including conditions to be assessed.

[ ]  Acceptance criteria.

[ ]  Data collection.

[ ]  Evaluation of Data.

[ ]  Summary of results.

[ ]  References, if applicable.

[ ]  Review and approval of the plan, report, and conclusion by the Quality Manager and the Clinical Program Director.

[ ]  Copy of the most recently completed Annual Report on the Effectiveness of the Quality Management Program. [B4.19]

[ ]  The Clinical Program list of controlled documents, including title and identifier. [B5.2]

[ ]  Standard Operating Procedure(s) for consenting allogenic and autologous cellular therapy product donors. [B6.2]

[ ]  Unsigned samples of all allogeneic and autologous donor consent forms. [B6.2.1]

[ ]  Standard Operating Procedure(s) for consenting cellular therapy recipients. [B7.1]

[ ]  Unsigned samples of recipient consent forms for consenting to receive cellular therapy. [B7.1]

[ ]  Policies for determining the appropriate volume and the appropriate dose of cryoprotectants, and other additives. [B7.6.1]

[ ]  Documentation of staff training on content and location of a Circular of Information or Investigator’s Brochure for cellular therapy products. [B7.6.5]

[ ]  Policies or Standard Operating Procedures addressing the appropriate follow-up of recipients after administration of preparative regimens and cellular therapy products. [B7.7]

[ ]  Policies or Standard Operating Procedures addressing the management of complications. [B7.8]

[ ]  Data management [B9]:

[ ]  The most recent CIBMTR Cellular Therapy Audit Results Report.

[ ]  Programs with a CIBMTR Cellular Therapy Audit that resulted in >5.0% critical field error rate.

[ ]  Corrective Action Plan (CAP) developed in response to the Cellular Therapy audit.

[ ]  Summary of current progress on implementation of the CAP.

[ ]  An audit report from a recent internal data accuracy audit (performed within the last 12 months on current cellular therapy data) addressing the effectiveness of the CAP.

[ ]  Programs not audited by CIBMTR for cellular therapy data: [B9]

[ ]  An audit report from a recent internal data accuracy audit (performed within the past 12 months on current cellular therapy data).

**Electronic Record Systems:**

[ ]  Current list of critical electronic record systems under the control of the Clinical Program. Complete and upload the [Critical Electronic Record Systems](https://www.factglobal.org/files?a=CriticalElectronicRecordSystems/) form or submit other documentation that contains the equivalent information for each critical record system. [B10.6.1]

For critical electronic record systems used for record keeping, documentation of validation of the systems must be available at inspection as well as a qualified individual to review the documentation with the inspector. Documentation should demonstrate compliance with the following Standards:

[ ]  Validated procedures for and documentation of: [B10.6.9]

[ ]  Systems development. [B10.6.9.1]

[ ]  Numerical designation of system versions, if applicable. [B10.6.9.2]

[ ]  Prospective validation of systems, including hardware, software, and databases. [B10.6.9.3]

[ ]  Installation of the system. [B10.6.9.4]

[ ]  Training and continued competency of personnel in systems use. [B10.6.9.5]

[ ]  Monitoring of data integrity. [B10.6.9.6]

[ ]  Back-up of the electronic records system on a regular schedule. [B10.6.9.7]

[ ]  System maintenance and operations. [B10.6.9.8]

[ ]  System assignment of unique identifiers. [B10.6.9.9]

**COLLECTION DOCUMENTATION**

**Medical Director of Collection Activities**

[ ]  Copy of the current license to practice medicine in the jurisdiction in which the program is located for each Medical Director. If the license is in a language other than English, include a general description in English. [C3.1.1]

[ ]  Curriculum vitae for each Medical Director. If one individual serves as a director for multiple facilities, submit this individual’s curriculum vitae whenever applicable. If the curriculum vitae is in a language other than English, include a summary in English. [C3.1, C3.1.3]

[ ]  Documentation of at least ten (10) hours of participation annually of continuing education since the previous accreditation date (at a minimum 2 years) for each Medical Director in educational activities related to cellular therapy and/or the therapeutic disease area. For initial applicants submit documentation of at least ten (10) hours of continuing education for the previous 12 months. Complete and upload the [Educational Activities Form](https://www.factglobal.org/files?a=EducationalActivitiesForm/) or submit other documentation that contains the equivalent information for each activity: [C3.1.4] (Meeting names and topics must be defined).

[ ]  Date of activity

[ ]  Title of activity

[ ]  Type of activity (e.g., webinar, meeting, grand rounds)

[ ]  Topic of activity (e.g., cell collection)

[ ]  Approximate number of hours of activity

**Collection Quality Manager**

[ ]  Documentation of at least ten (10) hours of participation annually of continuing education since the previous accreditation date (at a minimum 2 years) for each Collection Facility Quality Manager in educational activities related to cellular therapy, cell collection, and/or quality management. For initial applicants submit documentation of at least ten (10) hours of continuing education for the previous 12 months. Complete and upload the [Educational Activities Form](https://www.factglobal.org/files?a=EducationalActivitiesForm/) or submit other documentation that contains the equivalent information for each activity: [C3.2.3] (Meeting names and topics must be defined).

[ ]  Date of activity

[ ]  Title of activity

[ ]  Type of activity (e.g., webinar, meeting, grand rounds)

[ ]  Topic of activity (e.g., cell collection)

[ ]  Approximate number of hours of activity

**Other Collection Documentation**

[ ]  A completed [Collection Facility Grid](https://www.factglobal.org/files?a=clinicalfacilitygrid/). For initial accreditation, enter data for the previous 12 months. For renewal accreditation, enter data from the start of the current accreditation cycle. [C1.1]

[ ]  A map of the overall organization that includes all facilities. If the map is labeled in a language other than English, include a general description of the map in English. [C1.1]

[ ]  Physical floor plans of all facilities. Label all floors of the building(s) that are used for cellular therapy related activities. If the floor plan(s) or diagram is labeled in a language other than English, include a general description of the floor plan or diagram in English. [C1.1]

[ ]  Certificate of licensure, registration, or accreditation required by the appropriate governmental authority for the activities performed. U.S. apheresis collection facilities must submit a copy of the validated FDA registration for Human Cells, Tissues, and Cellular and Tissue Based Products. U.S. surgical collection facilities must submit documentation of accreditation by the Joint Commission, DNV, HFAP, or other appropriate accrediting body as required by Applicable Law. Facilities in other countries must submit certification required by the appropriate governmental authority. If the licensure, registration, or accreditation is in a language other than English, include a general description of the document in English. [C1.3.1, C1.5.1, C11.1.1]

[ ]  Collection Facility’s Quality Management Plan that includes all requirements listed in C4. [C4.2]

[ ]  Organizational chart of key personnel and functions required for collection. [C4.3]

[ ]  Copies of all policies and Standard Operating Procedures referenced in the Quality Management Plan that address the following:

[ ]  Personnel requirements for each key position required for cellular therapy product collection. [C4.4]

[ ]  Development, approval, implementation, distribution, review, revision, and archival of all critical documents. [C4.5, C4.5.2]

[ ]  A standardized format for critical documents, and the required elements of each Standard Operating Procedure. [C4.5.3.1 and C5.3]

[ ]  The establishment and maintenance of written agreements. [C4.6]

[ ]  Documentation and review of safety and efficacy of the cellular therapy product, and outcome analysis to verify that the procedures in use consistently provide a safe and effective product. [C4.7]

[ ]  Audits of the collection facility activities to verify compliance. [C4.8]

[ ]  Management of external audits requested by the commercial manufacturer or applicable regulatory agency. [C4.8.4]

[ ]  The management of cellular therapy products with positive microbial culture results. [C4.9]

[ ]  Occurrences (errors, accidents, deviations, adverse events, adverse reactions, and complaints. [C4.10]

[ ]  Cellular therapy product chain of identity and chain of custody that allow tracking from the donor to the recipient or final disposition and tracing from the recipient or final disposition to the donor. [C4.11]

[ ]  Actions to take in the event collection operations are interrupted. [C4.12]

[ ]  Qualification of critical manufacturers, vendors, equipment, software, supplies, reagents, facilities, and services. [C4.13]

[ ]  Validation or verification of critical procedures. [C4.14]

[ ]  Management of critical supplies including supplies, reagents, and equipment. [C4.15]

[ ]  Evaluation of risk in changes to a process to assess the effect of the change elsewhere in the organization. [C4.16]

[ ]  Obtaining feedback. [C4.17]

[ ]  Evidence of a completed outcome analysis e.g., a report of conclusions, meeting minutes, or completed forms. [C4.7]

[ ]  Schedule of audits that includes dates and subjects of audits already performed and audits planned for the future. The audits listed in C4.8.3 must be included. [C4.8]

[ ]  An audit report from a recently completed audit listed under C4.8.3.

[ ]  A validation or verification study of a critical collection procedure other than ISBT 128 labeling of the collection facility (Collection by Apheresis, Marrow, or Tissue, as applicable), that includes: [C4.14, C4.14.2]

[ ]  An approved plan, including conditions to be assessed.

[ ]  Acceptance criteria.

[ ]  Data collection.

[ ]  Evaluation of data.

[ ]  Summary of results.

[ ]  References, if applicable.

[ ]  Review and approval of the plan, report, and conclusion by the Medical Director and the Quality Manager.

[ ]  Copy of the most recently completed Annual Report on the Effectiveness of the Quality Management Program. [C4.19]

[ ]  The Collection Facility’s list of controlled documents, including title and identifier. [C5.2]

[ ]  Unsigned samples of all allogeneic and autologous donor consent forms. [C6.2.1]

[ ]  The Standard Operating Procedure for consenting donors for the collection procedure that includes all required elements. [C6.2.1]

[ ]  A summary of one completed validation of the ISBT 128 labeling system that includes [C7.1.2]:

[ ]  An approved plan, including conditions to be assessed.

[ ]  Acceptance criteria.

[ ]  Data collection.

[ ]  Evaluation of Data.

[ ]  Summary of results.

[ ]  References, if applicable.

[ ]  Review and approval of the plan, report, and conclusion by the Quality Manager and the Medical Director.

[ ]  Completed examples of each type of label used by the Collection Facility. Do not include protected health information (PHI), e.g., patient names, medical record numbers, birthdate, or others. Mock identifiers and names must be used. [C7.4.1, C7.4.3, C7.4.8]

[ ]  In-process collection label used by the Collection Facility from each type of cell source. [C7.4.1]

[ ]  Primary product container label, applied on completion of collection of products for allogeneic use from each type of cell source. [C7.4.3, Appendix I]

[ ]  Primary collection container label, applied on completion of collection of products for autologous use from each type of cell source. [C7.4.3, Appendix I]

[ ]  Any partial labels applied at distribution for administration by the Collection Facility. [C7.4.3, Appendix I]

[ ]  Inner container document and outer shipping container label for products shipped or transported on public roads. [C7.4.3, Appendix IIA]

[ ]  Cellular therapy products distributed for nonclinical purposes, labeled with the statement, “For Nonclinical Use Only.” [C7.4.8]

[ ]  A Standard Operating Procedure for labeling that includes when biohazard and/or warning labels are used, including: [C7.4.4, Appendix I]

[ ]  Biohazard legend

[ ]  Statement “NOT EVALUATED FOR INFECTIOUS SUBSTANCES”

[ ]  Statement “WARNING: Advise Patient of Communicable Disease Risks”

[ ]  Statement “WARNING: Reactive Test Results for [name of disease agent or disease]”

[ ]  Statement “FOR AUTOLOGOUS USE ONLY”

[ ]  Documentation that accompanies the cellular therapy product at distribution and a policy or Standard Operating Procedure that discusses the documentation that is distributed with the product. [C7.4.5, Immune Effector Cells Standards Appendix III]

[ ]  Completed examples of documentation of the visual examination of supplies and reagents used to collect cellular therapy products. [C8.2.2]

**Electronic Record Systems:**

[ ]  Current list of critical electronic record systems under the control of the program performing collection. Complete and upload the [Critical Electronic Record Systems](https://www.factglobal.org/files?a=CriticalElectronicRecordSystems/) form or submit other documentation that contains the equivalent information for each critical record system. [C14.6.1]

For critical electronic record systems used for record keeping, documentation of validation of the systems must be available at inspection as well as a qualified individual to review the documentation with the inspector. Documentation should demonstrate compliance with the following Standards:

[ ]  Validated procedures for and documentation of: [C14.6.9]

[ ]  Systems development. [C14.6.9.1]

[ ]  Numerical designation of system versions, if applicable. [C14.6.9.2]

[ ]  Prospective validation of systems, including hardware, software, and databases. [C14.6.9.3]

[ ]  Installation of the system. [C14.6.9.4]

[ ]  Training and continued competency of personnel in systems use. [C14.6.9.5]

[ ]  Monitoring of data integrity. [C14.6.9.6]

[ ]  Back-up of the electronic records system on a regular schedule. [C14.6.9.7]

[ ]  System maintenance and operations. [C14.6.9.8]

[ ]  System assignment of unique identifiers. [C14.6.9.9]

**PROCESSING FACILITY DOCUMENTATION**

**Processing Facility Director**

[ ]  Curriculum vitae for each Processing Facility Director. If one individual serves as a director for multiple facilities, submit this individual’s curriculum vitae whenever applicable. If the documentation is in a language other than English, include a summary in English. [D3.1.1]

[ ]  Documentation of at least ten (10) hours of participation annually of continuing education since the previous accreditation date (at a minimum 2 years) for each Processing Facility Director in educational activities related to cellular therapy. For initial applicants submit documentation of at least ten (10) hours of continuing education for the previous 12 months. Complete and upload the [Educational Activities Form](https://www.factglobal.org/files?a=EducationalActivitiesForm/) or submit other documentation that contains the equivalent information for each activity: [D3.1.3] (Meeting names and topics must be defined).

[ ]  Date of activity

[ ]  Title of activity

[ ]  Type of activity (e.g., webinar, meeting, grand rounds)

[ ]  Topic of activity (e.g., hematology, cell processing)

[ ]  Approximate number of hours of activity

**Processing Facility Medical Director**

[ ]  Copy of the current license to practice medicine in the jurisdiction in which the program is located for each Processing Facility Medical Director. If the license is in a language other than English, include a general description in English. [D3.2.1]

[ ]  Curriculum vitae for each Processing Facility Medical Director. If one individual serves as a director for multiple facilities, submit this individual’s curriculum vitae whenever applicable. If the curriculum vitae is in a language other than English, include a summary in English. [D3.2.1]

[ ]  Documentation of at least ten (10) hours of participation annually of continuing education since the previous accreditation date (at a minimum 2 years) for each Processing Facility Medical Director in educational activities related to cellular therapy. For initial applicants submit documentation of at least ten (10) hours of continuing education for the previous 12 months. Complete and upload the [Educational Activities Form](https://www.factglobal.org/files?a=EducationalActivitiesForm/) or submit other documentation that contains the equivalent information for each activity: [D3.2.3] (Meeting names and topics must be defined).

[ ]  Date of activity

[ ]  Title of activity

[ ]  Type of activity (e.g., webinar, meeting, grand rounds)

[ ]  Topic of activity (e.g., hematology, cell processing)

[ ]  Approximate number of hours of activity

**Processing Facility Quality Manager**

[ ]  Documentation of at least ten (10) hours of participation annually of continuing education since the previous accreditation date (at a minimum 2 years) for each Quality Manager in educational activities related to cellular therapy processing and/or quality management. For initial applicants submit documentation of at least ten (10) hours of continuing education for the previous 12 months. Complete and upload the [Educational Activities Form](https://www.factglobal.org/files?a=EducationalActivitiesForm/) or submit other documentation that contains the equivalent information for each activity: [D3.3.3] (Meeting names and topics must be defined).

[ ]  Date of activity

[ ]  Title of activity

[ ]  Type of activity (e.g., webinar, meeting, grand rounds)

[ ]  Topic of activity (e.g., hematology, cell processing)

[ ]  Approximate number of hours of activity

**Other Processing Documentation**

[ ]  A completed [Processing Facility Grid](https://www.factglobal.org/files?a=processingfacilitygrid/). For initial accreditation, enter data for the previous 12 months. For renewal accreditation, from the start of the accreditation cycle. [D1.1]

[ ]  A map of the overall organization that includes all facilities. If the map is labeled in a language other than English, include a general description of the map in English. [D1.1]

[ ]  Physical floor plans of all facilities. Label all floors of the building(s) that are used for cellular therapy related activities. If the floor plan(s) or diagram is labeled in a language other than English, include a general description of the floor plan or diagram in English. [D1.1]

[ ]  Documentation of licensure, registration, and/or accreditation required by the appropriate governmental authority for the activities performed. U.S. facilities must submit a copy of the validated FDA registration for Human Cells, Tissues, and Cellular and Tissue Based Products Facilities in other countries must submit certification required by the appropriate governmental authority. If the licensure, registration, or accreditation is in a language other than English, include a general description of the document in English. [D1.2.1]

[ ]  Processing Facility’s Quality Management Plan that includes all requirements listed in D4. [D4.2]

[ ]  Organizational chart of key positions and functions within the Processing Facility. [D4.3]

[ ]  Copies of all policies and Standard Operating Procedures referenced in the Quality Management Plan that address the following:

[ ]  Personnel requirements for each key position in the Processing Facility. [D4.4]

[ ]  Development, approval, implementation, distribution, review, revision, and archival of all critical documents. [D4.5, D4.5.2]

[ ]  A standardized format for critical documents, and the required elements of each Standard Operating Procedure. [D5.3 and D4.5.3.1]

[ ]  The establishment and maintenance of written agreements. [D4.6]

[ ]  Documentation and review of safety and efficacy of the cellular therapy product, and outcome analysis to verify that the procedures in use consistently provide a safe and effective product. [D4.7]

[ ]  Audits of the Processing Facility’s activities to verify compliance. [D4.8]

[ ]  Management of external audits requested by the commercial manufacturer or applicable regulatory agency. [D4.8.4]

[ ]  The management of cellular therapy products with positive microbial culture results. [D4.9]

[ ]  Occurrences (errors, accidents, deviations, adverse events, adverse reactions, and complaints). [D4.10]

[ ]  Cellular therapy product chain of identity and chain of custody that allow tracking from the donor to the recipient or final disposition and tracing from the recipient or final disposition to the donor. [D4.11]

[ ]  Actions to take in the event the Processing Facility’s operations are interrupted. [D4.12]

[ ]  Qualification of critical manufacturers, vendors, equipment, software, supplies, reagents, facilities, and services. [D4.13]

[ ]  Validation or verification of critical procedures in both minimally and more than minimally manipulated products. [D4.14]

[ ]  Management of critical supplies including supplies, reagents, and equipment. [D4.15]

[ ]  Evaluation of risk in changes to a process to assess the effect of the change elsewhere in the organization. [D4.16]

[ ]  Obtaining feedback. [D4.17]

[ ]  Evidence of a completed outcome analysis, e.g., a report of conclusions, meeting minutes, or completed forms. [D4.7]

[ ]  Schedule of audits that includes dates and subjects of audits already performed and audits planned for the future. The audits listed in D4.8.3 must be included. [D4.8]

[ ]  An audit report from a recently completed audit listed under D4.8.3.

[ ]  A validation study of a critical processing procedure other than ISBT 128 labeling, e.g., the cryopreservation procedure, or microbial culture assay, that includes: [D4.14, D4.14.2]

[ ]  An approved plan, including conditions to be assessed.

[ ]  Acceptance criteria.

[ ]  Data collection.

[ ]  Evaluation of data.

[ ]  Summary of results.

[ ]  References, if applicable.

[ ]  Review and approval of the plan, report, and conclusion by the Processing Facility Director and the Quality Manager.

[ ]  Copy of the most recently completed Annual Report on the Effectiveness of the Quality Management Program. [D4.19]

[ ]  Complete cryopreservation and thawing Standard Operating Procedure(s) that includes the directions for cryopreservation and preparation of the cryoprotectant solution. [D5.1.3.1]

[ ]  If the Processing Facility performs processing with more-than-minimal manipulation, a Standard Operating Procedure(s) for release and exceptional release. [D5.1, D5.1.9]

[ ]  The Processing Facility’s list of controlled documents, including the title and identifier. [D5.2]

[ ]  Completed examples of documentation of the visual examination of supplies and reagents used to manufacture cellular therapy products. [D6.3.1]

[ ]  A policy or SOP for cleaning, sanitation, calibration, and maintenance of equipment used in cellular therapy product processing, testing, cryopreservation, storage, and distribution. [D6.5]

[ ]  A summary of one completed validation of the ISBT 128 labeling system that includes [D7.1.2]:

[ ]  An approved plan, including conditions to be assessed.

[ ]  Acceptance criteria.

[ ]  Data collection.

[ ]  Evaluation of Data.

[ ]  Summary of results.

[ ]  References, if applicable.

[ ]  Review and approval of the plan, report, and conclusion by the Quality Manager and the Processing Facility Director.

[ ]  Completed examples of each type of label used by the Processing Facility. Do not include protected health information (PHI), e.g., patient names, medical record numbers, birthdate, or others. Mock identifiers and names must be used. [D7.4.1, D7.4.3, D7.4.10]

[ ]  Any partial labels applied at distribution for administration by the Processing Facility. [Immune Effector Cells Standards Appendix I]

[ ]  Labels applied at completion of processing of allogeneic products collected from each type of cell source. [D7.4.3, Appendix I]

[ ]  Labels applied at completion of processing of autologous products collected from each type of cell source. [D7.4.3, Appendix I]

[ ]  Labels applied prior to distribution for allogeneic products collected from each type of cell source. [D7.4.3, Appendix I]

[ ]  Labels applied prior to distribution for autologous products collected from each type of cell source. [D7.4.3, Appendix I]

[ ]  Inner container document and outer shipping container label for products shipped or transported on public roads. [D4.7.3, Appendix IIA]

[ ]  Cellular therapy products distributed for nonclinical purposes, labeled with the statement, “For Nonclinical Use Only.” [D7.4.10]

[ ]  If processing personnel apply labels to cellular therapy products at completion of collection, submit: Do not include protected health information (PHI), e.g., patient names, medical record numbers, birthdate, or others. Mock identifiers and names must be used. [C7.4.3]

[ ]  Completed example of a primary collection container label applied on completion of allogeneic cellular therapy product collection from each type of cell source. [C7.4.3, Appendix I]

[ ]  Completed example of a primary collection container label applied on completion of autologous cellular therapy product collection from each type of cell source. [C7.4.3, Appendix I]

[ ]  Completed examples of labels applied prior to transport or shipping of cellular therapy products, including inner and outer container labels. [C7.4.3, Appendix IIA]

[ ]  A Standard Operating Procedure for labeling that includes when biohazard and/or warning labels are used, including: [D7.4.4, Appendix I]

[ ]  Biohazard legend

[ ]  Statement “NOT EVALUATED FOR INFECTIOUS SUBSTANCES”

[ ]  Statement “WARNING: Advise Patient of Communicable Disease Risks”

[ ]  Statement “WARNING: Reactive Test Results for [name of disease agent or disease]”

[ ]  Statement “FOR AUTOLOGOUS USE ONLY”

[ ]  Documentation that accompanies the cellular therapy product at distribution and a policy or Standard Operating Procedure that discusses the documentation that is distributed with the product. [D7.4.6, Immune Effector Cells Standards Appendix III]

[ ]  The Standard Operating Procedure and associated worksheet(s) for cellular therapy product processing, testing, cryopreservation, storage, and administration or disposal/disposition/distribution. [D8.9]

[ ]  A written stability program that annually evaluates the viability and potency of cryopreserved cellular therapy products, and the results of the last annual assessment. [D9.2.3]

[ ]  If a document other than the current version of the inter-organizational *Circular of Information for the Use of Cellular Therapy Products* is used, submit the document made available to clinical staff containing the following information: [D11.2.4]

[ ]  Use of the cellular therapy product, indications, contraindications, side effects and hazards, dosage, and administration recommendations. [D11.2.4.1]

[ ]  Instructions for handling the cellular therapy product to minimize the risk of contamination or cross-contamination. [D11.2.4.2]

[ ]  Appropriate warnings related to the prevention of the transmission or spread of communicable diseases. [D11.2.4.3]

[ ]  A pre-collection written agreement between the storage facility and the designated recipient or the donor that includes the length of storage, circumstances for disposal, and option to transfer the cellular therapy product to another facility. [D12.1.1 and D12.1.2]

**Electronic Record Systems:**

[ ]  Current list of critical electronic record systems under the control of the Processing Facility. Complete and upload the [Critical Electronic Record Systems](https://www.factglobal.org/files?a=CriticalElectronicRecordSystems/) form or submit other documentation that contains the equivalent information for each critical record system. [D13.3.1]

For critical electronic record systems used for record keeping, documentation of validation of the systems must be available at inspection as well as a qualified individual to review the documentation with the inspector. Documentation should demonstrate compliance with the following Standards:

[ ]  Validated procedures for and documentation of: [D13.3.9]

[ ]  Systems development [D13.3.9.1]

[ ]  Numerical designation of system versions if applicable [D13.3.9.2]

[ ]  Prospective validation of systems, including hardware, software, and databases [D13.3.9.3]

[ ]  Installation of the system [D13.3.9.4]

[ ]  Training and continued competency of personnel in systems use [D13.3.9.5]

[ ]  Monitoring of data integrity [D13.3.9.6]

[ ]  Back-up of the electronic records system on a regular schedule [D13.3.9.7]

[ ]  System maintenance and operations [D13.3.9.8]

[ ]  System assignment of unique identifiers [D13.3.9.9]