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**Introduction**

In the field of Biotherapy partnerships, agreements with external entities to perform critical services have become more commonplace. These services can include procurement, manufacturing, testing and administration of a cell/tissue product. Such relationships are defined through the use of a Service Agreement and a Quality Agreement. Service contracts typically outline the scope of work, deliverables, timelines, budgets, and business and legal liabilities. Quality Agreements identify and describe key quality and regulatory responsibilities between the client and the service provider.

The intent of a Quality Agreement is to have clearly defined expectations between parties with emphasis on each party having a sense of ownership through mutually agreed upon language and activities. At a minimum, the Quality Assurance personnel of all entities should have input into drafting the Quality Agreement, with feedback from the respective stakeholders including but not limited to: sponsor, investigator, administration site, and procurement, processing, manufacturing facility(ies).

This Quality Agreement Template is a result of AABB and ISCT communities’ request for an interpretive tool to assist with drafting and establishing of a Quality Agreement.

This Quality Agreement template includes suggested provisions surrounding agreements based on regulatory standards regarding the safety and quality of the product and processes and Guidance on Quality Agreements. This template defines the responsibilities of relevant parties regarding Quality Assurance, Quality Control, and Quality Risk Management.

*This Quality Agreement Template is for educational purposes only. It is not intended to constitute legal advice and the content should not be relied upon for legal purposes. AABB and ISCT make no representation about the Template's completeness, accuracy, or reliability. You should consult an attorney familiar with these issues and related state and federal laws for advice specific to your circumstances. AABB and ISCT expressly disclaim any liability for any damage or loss that may arise from relying upon or using information contained in these materials. By using the Template, you agree to waive all such claims.*

**Quality Agreement**

By and Between

[Client]

and

[Manufacturer]

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**Quality Agreement**

**Purpose/ Scope**

This agreement defines the divided responsibilities of the Client, [INSERT] located at [INSERT] and Manufacturer, [INSERT] located at [INSERT] as they pertain to the collection, processing, testing, storage, transport, and/or administration of the Product to ensure that operations are conducted in accordance with the respective clinical and commercial protocols, appropriate directives, regulations, and guidelines.

For the purposes of this agreement:

Product is defined as [INSERT] (type of product or service)

Client is defined as [INSERT]

Examples may include:

Hospital Organization

Transplant Program or Administration Entity

Cell Collection or Procurement Facility

Cell Processing Facility

Sponsor

Principal Investigator

Manufacturer is defined as [INSERT]

Examples may include:

Cell Processing Facility

Sponsor

Manufacturing Entity

* The source material shall be collected at [INSERT] n/a
* The final Drug Product shall be manufactured at [INSERT] n/a

The responsibility table (xx) provides a summary of planned and/or required quality unit activities associated with the agreement. Responsibility for each activity is assigned to the respective party.

Each party is required to put necessary procedures and actions in place to fully execute the activity in accordance with applicable regulations, guidelines, and directives.

**Other Agreements**

This Quality Agreement is in addition to \_\_\_\_\_\_\_\_ Agreement(s) between the parties dated \_\_\_\_\_\_\_\_\_, if any, (the “Master Service Agreement”) regarding the subject matter hereof. If there are any direct conflicts between the terms of this Quality Agreement and the Master Service Agreement, the following will prevail:

|  |
| --- |
| Quality Agreement |
|  |
| Master Service Agreement |
|  |
| Other Agreement (materials or equipment service, licensing, Confidentiality, MOU) |
|  |

**Definitions**

|  |  |
| --- | --- |
| **TERM** | **DEFINITION** |
| Administration or Transplant Facility | Facility which infuses or injects the final Drug Product into the patient. The act of delivering the product into a recipient including but not limited to infusion, transplantation, implementation, or injection. |
| Adverse Events (AE) | Any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related. |
| BPR | Batch Production Record |
| cGMP | Current Good Manufacturing Practice |
| Chain of Custody (COC) | Process which tracks the transfer of the product from collection, manufacturing, through infusion or disposal. |
| Chain of Identity (COI) | Process which tracks the donor or product identifiers through the lifecycle of the product. |
| Change Control | A formal system by which qualified representatives of appropriate disciplines review proposed or actual changes that might affect a validated, approved, or compliant status in connection with the Lentiviral vector, manufacturing, or storage processes and/or quality systems. |
| Client or Customer | Entity who is requesting products or services. The client or customer may be internal (another department or entity within the same organization) or external (department or entity outside the organization) that receives a product, service, or information. |
| Clinical Trials Investigator | Responsible for overall conduct of the study at the clinical site, including directing the administration or dispensing of the investigational product to the subject and ensuring that data are collected and maintained in accordance with the protocol and applicable regulatory requirements. |
| COA (Certificate of Analysis) | A listing of all results for tests conducted on samples from the Product Lot compared to the specifications listed in regulatory applications. May be all or part of the product release record. |
| Collection or Procurement Facility | Entity which procures the source material or product. Obtains cell/tissue products from a donor by facility approved methods including but not limited to apheresis, marrow harvest, cord blood, gestational material collection, organ harvest or tissue harvest from a donor. |
| Complaint | Complaint – Any complaint, which indicates a potential quality issue during collection, manufacturing, packaging, release testing, stability testing, dose preparation, storage or distribution, administration of the product or delivery system. |
| Deviation (Major or Critical) | Any events that were identified to have potential impact on the quality, identity, strength, safety, efficacy, potency, or purity of the product, or on any compliance or regulatory requirement. |
| Deviation (Minor) | A Deviation that (a) has no to low potential to adversely affect product safety, identity, purity, strength, quality, efficacy, performance, reliability, or durability; and/or (b) represents a nonconformity of a quality program. |
| Disposition | The fate of the final product, critical intermediate, material, and or sample as to where it will end up, like in the human body, or used in manufacturing or discarded according to state/institutional policies |
| Distribution | The removal of a cellular therapy product that has been determined to meet release criteria or exceptional release/Urgent Medical Need requirements from quarantine. |
| Drug Product | Product is it final formulation in accordance to manufacturing specifications. Further processing may be needed to prepare for administration (e.g., thaw, dilute, or transfer to a syringe). |
| Essential Documents | Any documents (which may or may not be Source Documents) that individually and collectively permit evaluation of the performance of the manufacturing and testing and the quality of the data resulting therefrom. Such documents serve to demonstrate that the organization, individuals working under the direction of the organization, and others associated with the associated activities and/or the resulting data have complied with the GTPs and all applicable regulatory requirements. |
| Excipient | Any non-active substance used in manufacturing of a product |
| FACT | Foundation for the Accreditation of Cellular Therapy |
| GxP | General abbreviation for the “good practice” quality guidelines and regulations where “X” refers to Good Manufacturing Practice, Good Laboratory Practice, Good Documentation Practice, and or Good Clinical Practice |
| ISBT 128 | International Standard for Blood Transfusion. A global standard for the identification, Manufacturing, and information transfer of medical products of human origin across international borders and disparate health care systems. |
| ISO | International Organization for Standardization |
| JACIE | Joint Accreditation Committee International Society Cell and Gene Therapy and European Society for Bone Marrow Transplantation |
| Lot | A Batch, or a specifically identified portion of a batch, having uniform composition and quality according to specified requirements. |
| Manufacturing Facility | Entity which manufactures the final drug product. This entity can be the client, processing facility, or the sponsor’s third-party contracted facility. |
| O.R. | Operating Room |
| OOS | Out of Specification |
| Operational Continuity | The facility systems are robust to continue operations even when personnel changes or critical events have occurred. |
| Pre-distribution Shipment | Products released to a facility prior to distribution approval are obtained.  Source material for further manufacturing. |
| Principal Investigator | An individual who is responsible for the project, clinical trial, and under whose immediate direction the investigational drug is administered or dispensed. |
| Processing Facility | Entity involved in the receipt and storage of a product from a procurement and/or manufacturing facility. The processing facility may perform final formulation for administration of the product. |
| In Process Product | Tangible result of procurement and/or manufacturing. The cellular therapy product provided to an intermediate facility by the procurement facility is a product for the procurement facility, but a source material for the intermediate facility. |
| QP | Qualified Person |
| Quarantine | Storage of cellular therapy products, reagents, or materials, to prevent improper release and/or cross contamination, either in a physically separate area clearly identified for such use, or by identification of a product through the use of other procedures, including automated designation, for the same purpose. |
| Source Material | Cells, tissue, or organs procured and intended for future processing or manipulation. |
| Sponsor | Person or entity who is responsible for the project or clinical trial. The sponsor may be an individual or pharmaceutical company, governmental agency, academic institution, private organization, or other organization. The sponsor is responsible for regulatory submissions, notifications to other contracted entities, adverse event reporting, and annual reporting. |

**Amendments to Quality Agreement**

This Quality Agreement may be amended by the written consent of both parties.

The parties agree to amend the terms of this Quality Agreement in order for the Product to continue to meet the regulatory requirements of applicable regulatory agencies, as may exist from time to time.

If an amendment to this Quality Agreement is proposed, the proposing party will circulate the proposed amendment to the appropriate contact person at Manufacturer and Client for review and internal approval. The appropriate contact person(s) for the Manufacturer and Client are listed in **Appendix 1** (Contacts and Responsibilities).

**Term of Quality Agreement**

This Quality Agreement shall commence on the Effective Date defined as the date of the last signature.

The Quality Agreement shall remain in effect for [INSERT] number of years.

The parties shall agree to conduct an annual review of activities governed by this agreement.

Either party may terminate this Quality Agreement upon [INSERT] days/months written notice to the other party.

**Use of Third Parties (Note this Section as with all sections may not be applicable)**

Manufacturer or Client [SHALL OR SHALL NOT] allow a third party or subcontractor to procure, manufacture, package, label, inspect, test, store, release, and handle the Product.

When a third party or subcontractor is allowed, it shall be disclosed and approved in writing by the [INSERT  Manufacturer  Client]. See Appendix 3 for approved list of third-party or subcontractor entities. Any changes to the list of third-party entities or subcontractors must be communicated and approved by [INSERT  Manufacturer  Client]. in writing.

Use of third parties or subcontractors by any party shall not relieve such party of its obligations, responsibilities, or liability hereunder.

All third parties or subcontractors used for procurement, manufacturing, packaging, labeling, inspection, testing, storage, release, and/or handling shall be qualified. Upon request, the [INSERT  Manufacturer  Client]. will provide written qualification documentation.

**Product Specifications**

Product specifications are listed in **Appendix 2**.

Changes to the agreed upon specifications must be communicated in writing between the parties to this Quality Agreement.

See **Responsibilities Table** for release, exceptional release, quarantine, and non-conforming products notifications.

**Shipping**

The shipping of the Source Material is the responsibility of [INSERT].

The shipping of the final Drug Product is the responsibility of [INSERT].

**Resolution of Quality Issues**

Quality-related issues shall be brought to the attention of the appropriate entities in writing, as listed in **Appendix 1** (Contacts and Responsibilities). Both parties agree to work jointly to develop a strategy for resolution and the resolution shall be documented.

**Miscellaneous Provisions**

**Assignment:** Neither party shall assign or transfer its rights or duties under this Agreement without the express written consent of the other party. Any transfer or assignment made without such consent shall not relieve the transferor or assignor of its duties or obligations under this Agreement and shall be null and void.

**Entire Agreement:** This instrument contains the entire understanding of the Parties with respect to the subject matter hereof and supersedes all prior or contemporaneous representations, warranties, agreements, and understandings, and may not be amended or any provision hereof waived, except in writing signed by the party against whom enforcement is sought.

**Amendment:** This Agreement may be modified only by a written document executed by both Parties.

**Severability:** Each paragraph and provision of this Agreement is severable from the entire Agreement, and if any provision is declared invalid, the remaining provisions shall nevertheless remain in effect.

**Survival:** All covenants, warranties, ownership, indemnification, and confidentiality obligations contained herein shall survive termination of this Agreement.

**Waiver:** Waiver of breach of any provision of this Agreement shall not operate or be construed as a waiver of any other provision of this Agreement, or of any subsequent breach of the same provision of this Agreement.

**Responsibility Table**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Responsibilities** | **Not Applicable** | | | **Client** | | **Manufacturer** |
| 1.0 | Compliance Requirements | | | | | | |
| 1.1 | Comply with applicable regulations, accreditation standards, and relevant Competent Authority Requirements. Examples include GxPs (Good Manufacturing Practices /Good Tissue Practice/Good Clinical Practices), biologic product guidance, and accreditation body standards. |  | | |  | |  |
| 1.2 | Comply with local and national regulations regarding data confidentiality and patient information disclosures. |  | | |  | |  |
| 1.3 | Shall be accredited by AABB, FACT, or another accrediting or regulating body. |  | | |  | |  |
| 1.4 | Notify the other party if accreditation or licensure is no longer current or revoked. |  | | |  | |  |
| 1.5 | Donor and recipient confidentiality must be maintained in accordance with institutional policy and Competent Authority Requirements. |  | | |  | |  |
| 1.6 | Operate the procurement and manufacturing facilities in compliance with institutional policies and applicable environmental, occupational health, and safety laws and regulations. |  | | |  | |  |
| 1.7 | Maintain a quality unit that is independent of production that fulfils quality assurance and quality control responsibilities. |  | | |  | |  |
| 1.8 | Notify the other party of name change, corporate reorganization, consolidation, merger or acquisition or sale of the party’s company. Notify other party(ies) of key personnel changes. |  | | |  | |  |
| **2.0** | **Audits** | | | | | | |
| 2.1 | Maintain an Internal Audit Program |  | | |  | |  |
| 2.2 | Maintain External Audit Program for manufacturers of raw materials and components, or other suitable qualification program. |  | | |  | |  |
| 2.3 | Client has the right to audit Manufacturer’s facilities and quality systems and review documents as they relate to the manufacture of Product.  Such audits and document reviews shall be conducted at a time, date, frequency, and duration mutually agreeable to the Manufacturer and Client. |  | | |  | |  |
| 2.4 | Retain the right to conduct "for cause" audits.  Specific goals/scope of the audit, proposed dates, and names of the auditors will be agreed upon mutually by the Client and the Manufacturer. |  | | |  | |  |
| 2.5 | Manufacturer has the right to audit Client’s facilities and quality systems and review documents as they relate to the quality systems associated with the responsibilities of the Client.  Such audits and document reviews shall be conducted by the Manufacturer at a time, date, frequency, and duration mutually agreeable to the Manufacturer and Client. |  | | |  | |  |
| 2.6 | Issue a confidential audit report summarizing audit observations within [INSERT] days. |  | | |  | |  |
| 2.7 | Respond in writing to audit observations documented in the audit report to Quality Assurance within [INSERT] days. |  | | |  | |  |
| **3.0** | **Regulatory Inspections and Exchanges** | | | | | | |
| 3.1 | Notify the other entity when there is a regulatory inspection that directly involves the Product. | |  |  | |  | |
| 3.2 | Allow the other entity to be present and observe at regulatory inspections which directly involve the Product. | |  |  | |  | |
| 3.3 | Notify within [INSERT] business days of a Regulatory Authority inspection report which contains finding(s) that relate to the Drug Product or the facilities used to procure, manufacture, test, ship, or store the Drug Product. | |  |  | |  | |
| **4.0** | Regulatory Filings and Regulatory Status | | | | | | |
| 4.1 | Provide pertinent information and documentation to facilitate regulatory filings including but not limited to procurement, materials, manufacturing processes, assays, procedures, equipment, shipping methods, labeling, facility operations, product release, distribution, and adverse reactions. | |  |  | |  | |
| 4.2 | Communicate all relevant submissions, amendments, or updates from regulatory agencies as it applies to the Product to the other entity. | |  |  | |  | |
| 4.3 | Responsible for all regulatory filings. | |  |  | |  | |
| 4.4 | Provide the following information regarding the use of the Product and obtain approval from:   * Institutional Review Board (IRB) or Competent Authority * Applicable Regulatory Agency | |  |  | |  | |
| **5.0** | **Documentation and Records** | | | | | | |
| 5.1 | Have a document control system to initiate, review, revise, approve, retain, obsolete, and archive all documentation and records according to relevant accreditation standards and competent authority requirements. | |  |  | |  | |
| 5.2 | Implement SOPs, BPRs (Batch Production Record), and documents necessary to meet obligations under this Agreement. | |  |  | |  | |
| 5.3 | Maintain policies and procedures that at a minimum address the following:   * Product unique identifier/numbering * Product Labeling * Chain of Identity * Equipment Management * Supply Management * Donor Evaluation * Quality Control * Process Control * Facility Control and Environmental Monitoring * Product Storage and Transport * Product Administration * Deviations, Nonconforming Products and Corrective Actions * Safety * Data Confidentiality * Adverse Events * Training | |  |  | |  | |
| 5.4 | Where applicable, electronic signatures used on the certificate of analysis or other controlled documents should be authenticated and secure. | |  |  | |  | |
| 5.5 | Maintain a record retention program for the identification, accessing, filing, storage and disposition of original records. | |  |  | |  | |
| 5.6 | Maintain records associated with this Agreement for [X] years or in accordance to accrediting bodies or Applicable Laws whichever is longer. | |  |  | |  | |
| **6.0** | **Change Control** | | | | | | |
| 6.1 | Changes to the procedures shall go through change control system. The change control system will include maintenance of a revision history file and justification for changes initiated by both parties | |  |  | |  | |
| 6.2 | Have established written procedures for control of changes impacting the Product including manufacturing components or process, computer hardware/software, Product specifications, test methods, vendors, and subcontractors, if applicable. | |  |  | |  | |
| 6.3 | Notify in writing either entity about making changes which could impact the product identity, strength, safety, potency, stability, purity, or regulatory status prior to implementation of the change. | |  |  | |  | |
| **7.0** | Events and Deviations | | | | | | |
| 7.1 | Have a system to manage events and deviations. | |  |  | |  | |
| 7.2 | Document and investigate events and deviations as it relates to the Product, process, or procedure. | |  |  | |  | |
| 7.3 | Conduct the risk assessment for events and deviations to determine impact upon the product, Identify and implement associated corrective and preventive actions. | |  |  | |  | |
| 7.4 | Notify the other entity of events and deviations with potential clinical impact within [INSERT] business days. | |  |  | |  | |
| **8.0** | Complaints and Recalls | | | | | | |
| 8.1 | Have written policies and procedures to document, investigate, evaluate, and respond to all quality related complaints. | |  |  | |  | |
| 8.2 | Monitor and track complaints. Implement corrective and preventive actions, as necessary. | |  |  | |  | |
| 8.3 | Have written policies and procedures to issue and to respond to a product recall. | |  |  | |  | |
| 8.4 | In the event that either entity determines that an event or circumstance has occurred relating to the manufacture or stability of the Drug Product which may result in the need for a recall of the Product, the Manufacturer, and Client shall consult with each other in a timely manner to determine the disposition of the Drug Product. | |  |  | |  | |
| 8.5 | Responsible for the notification of the recall to the regulatory authorities, distributors, and customers of the Product. | |  |  | |  | |
| **9.0** | **Personnel Training** | | | | | | |
| 9.1 | Maintain adequate training, and competency records of all personnel involved in the procurement, processing, manufacturing, storage and handling, and administration of Product(s), as per product specific requirements, competent authority, local regulations, and accrediting agency. | |  |  | |  | |
| **10.0** | **Materials** | | | | | | |
| 10.1 | Qualify applicable raw materials used for product procurement, manufacturing, storage, and transport. | |  |  | |  | |
| 10.2 | Establish specifications for supplies, labels, packaging materials, and other materials that would likely affect product quality. | |  |  | |  | |
| 10.3 | Have processes of quarantined, rejected, or recalled materials. | |  |  | |  | |
| 10.4 | Store materials in accordance with product insert or vendor recommendations. | |  |  | |  | |
| 10.5 | Document storage temperature excursions for materials. | |  |  | |  | |
| 10.6 | Evaluate and control the risk of using non-human derived raw materials and components. | |  |  | |  | |
| 10.7 | Where required by government regulations, ensure that the country-of-origin information will be maintained. | |  |  | |  | |
| 10.8 | Maintain appropriate records, such as a Certificate of Analysis, for each lot of animal derived material or component to ensure traceability. | |  |  | |  | |
| 10.9 | Procure, inspect, test, and release labels and supplies used in procurement and or manufacturing of the Drug Product. | |  |  | |  | |
| **11.0** | Validation/Qualification | | | | | | |
| 11.1 | Have written validation/qualification plans for the facilities, materials, equipment, procurement, manufacturing processes, cleaning procedures, quality control assays, and computerized systems as appropriate and approved by a Quality Unit. | |  |  | |  | |
| 11.2 | Provide evidence that processes associated with procurement, manufacturing and testing of the source material and or Product have been validated or qualified. | |  |  | |  | |
| **12.0** | **Donor Eligibility Screening and Source Product Procurement** | |  |  | |  | |
| 12.1 | Procure, test, labeling, and cryopreserve (as applicable) the source material in accordance with:  Sponsor specifications  Institutional SOPs  Both | |  |  | |  | |
| 12.2 | Establish acceptance and release criteria for source material. | |  |  | |  | |
| 12.3 | Establish conditions and duration for transport/shipping of source material to Manufacturer. | |  |  | |  | |
| 12.4 | Obtain donor informed consent prior to procurement in accordance with institutional policies and regulations | |  |  | |  | |
| 12.5 | Perform donor eligibility assessment according to applicable laws and regulations. | |  |  | |  | |
| 12.6 | Ensure infectious disease testing is performed in a laboratory that is accredited, registered, or licensed in accordance with Applicable Laws and Regulations; the assays used must be validated for their intended purpose. | |  |  | |  | |
| 12.7 | Ensure appropriate required records and labeling, such as donor eligibility, are affixed, attached, and/or accompany the source material at the time of transfer. | |  |  | |  | |
| **13.0** | Manufacturing Controls and Labeling | | | | | | |
| 13.1 | Manufacture Drug Product in accordance with batch production record and Drug Product specifications. | |  |  | |  | |
| 13.2 | Record supplies, product labeling, equipment, and other materials used in Drug Product production. | |  |  | |  | |
| 13.3 | Maintain Chain of Custody and Chain of Identity throughout Drug Product Lifecycle. | |  |  | |  | |
| 13.4 | Manufacture Product to prevent contamination by other materials, including carryovers. | |  |  | |  | |
| 13.5 | Perform environmental monitoring pre-, during, and post manufacturing operations. | |  |  | |  | |
| 13.6 | Utilize ISBT 128 or Eurocode labeling practices throughout the lifecycle of the Drug Product.  <https://www.isbt128.org/>  [https://www.eurocode.org/](https://health.ec.europa.eu/blood-tissues-cells-and-organs/implementation/single-european-code-sec-tissues-and-cells_en) | |  |  | |  | |
| 13.7 | Release Drug Product by [INSERT] Quality Unit or Responsible entity. | |  |  | |  | |
| 13.8 | Notify the Sponsor, Primary Investigator, or recipient’s physician of a nonconforming Drug Product. | |  |  | |  | |
| 13.9 | Obtain approval for exceptional release to use a non-conforming product or to dispose of the product. | |  |  | |  | |
| **14.0** | **QC Sample and Testing Assay Management** | | | | | | |
| 14.1 | Have procedures for sample management, testing, approval, disposition, recording, storage, retention, and disposal of manufacturing data. | |  |  | |  | |
| 14.2 | Retain stability and assays samples as required by regulatory agencies. | |  |  | |  | |
| 14.3 | Have procedures and appropriately document the preparation, use and management of reagents, solutions, and calibration standards. | |  |  | |  | |
| 14.4 | Have a program for qualification, calibration, and preventive maintenance of all analytical equipment. | |  |  | |  | |
| 14.5 | Test Drug Product and source material in accordance with approved validated methods and with protocol specifications. | |  |  | |  | |
| 15.0 | **Storage and Distribution** | | | | | | |
| 15.1 | Source Material/ Drug Product shall be stored in devices or equipment appropriate for maintaining storage conditions. | |  |  | |  | |
| 15.2 | Maintain storage conditions to prevent mix-up, contamination, or damage. | |  |  | |  | |
| 15.3 | Have processes of quarantined, rejected, or recalled products. | |  |  | |  | |
| 15.4 | Provide Safety Data Sheet or equivalent for product storage i.e., donor viral markers, biohazard, genetically modified product, as applicable. | |  |  | |  | |
| 15.5 | Notify the other entity when a quality issue related to storage was identified. | |  |  | |  | |
| 15.6 | Monitor storage conditions. Maintain records of temperature monitoring and alarms. Maintain records of actions taken for alarm excursions. | |  |  | |  | |
| **16.0** | **Stability** | | | | | | |
| 16.1 | Maintain an ongoing stability program to monitor the stability of the Drug Product including determination of suitable containers to ensure the integrity of the product. | |  |  | |  | |
| **17.0** | **Distribution of Drug Product** | |  |  | |  | |
| 17.1 | Ensure appropriate documents, records, and labeling, such as donor eligibility, IDM testing results, and blood group compatibility assessment as applicable, are affixed, attached, and/or accompany the final Drug Product at the time of distribution. | |  |  | |  | |
| 17.2 | Provide distribution records and documents including all that apply:   * Certificate of Analysis * Summary of Donor Eligibility Records as per section 12.0 * Instructions for product storage, preparation, and use. * Instructions for reporting serious adverse events. * Other documents in accordance with applicable laws and accreditation agencies. | |  |  | |  | |
| **18.0** | **Receipt and Administration of Drug Product** | |  |  | |  | |
| 18.1 | Define receipt and storage requirements for Drug Product at the administration facility. | |  |  | |  | |
| 18.2 | Notify Manufacturer and Sponsor of nonconforming events during transport or receipt of the Drug Product. | |  |  | |  | |
| 18.3 | Prepare Drug Product for administration in accordance to defined instructions. | |  |  | |  | |
| 18.4 | Notify Manufacturer and Sponsor of events related to the administration of Drug Product. | |  |  | |  | |

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**APPENDIX 1: Contacts and Responsibilities**

|  |  |  |
| --- | --- | --- |
| **Contact Persons**  *(including Notices of Amendment, Assignment, Termination, Resolution of Quality Issues)* | | |
|  | **Contact Person for Manufacturer** | **Contact Person for Client** |
| **Name:** |  |  |
| **Title:** |  |  |
| **Phone/Fax:** |  |  |
| **Address**  ***(mail/delivery):*** |  |  |
| **E-mail Address:** |  |  |
| **With a Copy to:** |  | |
| **Name:** |  |  |
| **Title:** |  |  |
| **Phone/Fax:** |  |  |
| **Address**  ***(mail/delivery):*** |  |  |
| **E-mail Address:** |  |  |

**Duplicate page above for additional information**

**APPENDIX 2: Drug Product Specifications Example: THIS IS AN EXAMPLE. MAKE ADJUSTMENTS AS PER source material or product specifications.**

|  |  |  |
| --- | --- | --- |
| Release Criteria for Drug Product | | |
| **Tests** | **Specifications** | **Assay Method** |
| Visual Inspection |  |  |
| Storage condition |  |  |
| Gram Stain |  |  |
| Endotoxin |  |  |
| Mycoplasma |  |  |
| Viability |  |  |
| Immunophenotyping |  |  |
|  |  |
| Cell Dose |  |  |

**Appendix 3: Approved Vendors/Service Providers**

In consideration of the parties’ agreement to perform the activities provided in this Quality Agreement and for other valuable consideration the receipt and sufficiency of which is hereby acknowledged, and intending to be legally bound, Manufacturer and Client agree as provided in this Quality Agreement as follows:

|  |  |
| --- | --- |
| **Client** | **Manufacturer** |
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| Signature |  | Signature |
| Name |  | Name |
| Title |  | Title |
| **Signed the \_\_\_\_ day of \_\_\_\_\_\_\_\_\_\_\_\_**  **in the year 20\_\_\_\_** |  | **Signed the \_\_\_\_ day of \_\_\_\_\_\_\_\_\_\_\_\_**  **in the year 20\_\_\_\_** |

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