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| **TECHNICAL AGREEMENT**  **between**  **XXXX & XXXX**  **SUPPLIER:**  SUPPLIER ACTIVITIES:  Document Ref Number :  Review Date: *5 YEARS FROM LAST SIGNATURE* |
| **XXXXX:**  ***\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_***  ***Signature of XXXXX Head of Quality & Compliance***  ***Print Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***  ***Position: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***  ***\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_/\_\_\_\_\_/\_\_\_\_\_***  ***Signature of XXXXX Performance & Compliance Manager***  ***Print Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***  ***Position: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*** |
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**Preamble**

This Quality Agreement defines the roles and responsibilities of XXXXX and **Supplier** in order to maintain cGDP compliance when providing services to XXXXX. This Quality Agreement shall be incorporated within and constitute a part of the Commercial Agreement by and between XXXXX and **Supplier**. In the event of inconsistencies between this Quality Agreement and the Commercial Agreement, the Commercial Agreement shall control except with respect to quality assurance requirements, which shall be controlled by this Quality Agreement.

This Quality Agreement takes the form of a detailed checklist of the activities associated with transportation of active substances, bulk and finished medicinal products, and related support activities. Responsibility for each activity is assigned to either XXXXX and/or **Supplier** in the appropriate box in the delegation Checklist. For each responsibility listed, the respective party is required to put into effect all applicable procedures and to take all necessary actions to effectuate that responsibility in accordance with cGDP’s, applicable laws, and the marketing authorisations.

No changes to the terms of this Agreement may be made unless by written amendment, mutually agreeable to both parties, attached hereto and made a part hereof. The parties will review the Quality Agreement once every two years unless required sooner to incorporate changes in services and/or Product(s) and issue a revised document or appendix, as appropriate. To facilitate routine communications between the parties, company contact individuals are provided on page 10.

XXXXX and **Supplier** contact individuals may be updated as required by notification to either party.

In the event of a conflict between any of the provisions of the Quality Agreement and the Commercial Agreement, in matters of business, financial, or legal nature, the terms of the Commercial Agreement shall override. For matters related to Quality the terms of the Quality Agreement shall govern.

**Revision History**

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| **Issue Date** | **Revision Issue No.** | **Pages Issued** | **Reason for Issue** |
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| 1. **ACCREDITATION AND LICENSURE** | |  |  |
|  | Hold and maintain accreditations/licenses as per local regulatory requirements. |  |  |
|  | Each Party will notify the other in writing in advance of impending changes, modifications, or updates to licenses and registrations required to support those activities contracted to them in the Service Level Agreement. |  |  |
| 1. **GDP STANDARDS** | | **XX** | **XX** |
|  | Comply with applicable domestic and international current good distribution practices (cGDP) as referenced in the European Guideline on Good Distribution Practice of Medicinal Products for Human Use (2013/C 343/01) and other relevant international, federal, state, and local laws, regulations and guidelines appropriate to transportation. |  |  |
|  | Maintain a high level of quality throughout the distribution network. |  |  |
|  | Comply with GMP/GDP regulations and only use GMP and GDP compliant manufacturers and distribution partners. |  |  |
|  | Verify that supplier manufacturers, importers, transporters or distributors are registered with the relevant authority. |  |  |
|  | Will inform the competent authority and/or the marketing authorisation holder if he has information that products under the scope of this agreement are, or are suspected of being falsified. |  |  |

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| 1. **COUNTERFEIT & TAMPERING** | | **XX** | **XX** |
|  | Procedures in place addressing counterfeit and tampering or suspect counterfeit products. |  |  |
|  | Have procedures in place to a) segregate the suspect counterfeit products b) communicate to XXXXX and c) material destruction- this would form part of the return process. |  |  |
|  | Inform the relevant authorities if notified of counterfeit and tampering or suspect counterfeit products. |  |  |

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| 1. **QUALITY PRESENCE** | | **XX** | **XX** |
|  | Shall work collaboratively to conduct periodic meetings to discuss transport quality-related data, future planning, and such other matters as may be requested by XXXXX and **Supplier.** |  |  |
|  | Dedicate sufficient Quality personnel to ensure good distribution practice. |  |  |
|  | XXXXX and **Supplier** will assign a QA representative as point of contact for all quality matters. |  |  |
| 1. **REGULATORY INSPECTIONS AND COMPLIANCE** | | **XX** | **XX** |
|  | Will notify XXXXX within one (1) business day of any regulatory agency action that specifically affects the contracted services and/or Products to be transported or stored pursuant to this Agreement. |  |  |
|  | Notify XXXXX of any regulatory agency inspection specifically impacting the transported or stored products covered by this Agreement within one (1) business day of the initiation of the audit by the regulatory agency. |  |  |

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| 1. **COMPLIANCE WITH MARKETING AUTHORISATION** | | **XX** | **XX** |
|  | Will ensure compliance with marketing authorisation by communicating promptly to XXXXX any change to processes, products, methods or specifications that have an impact on transportation and storage of Products. |  |  |
|  | Will implement all changes communicated by XXXXX in a promptly manner in order to prevent deviations from the marketing authorisation. These changes will be documented in the XXXXX change control system. |  |  |

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| 1. **TRAINING /QUALIFICATION** | | **XX** | **XX** |
|  | Shall maintain a program to assure that all personnel engaged in the operations have the education, training, and experience to properly perform their assigned functions in compliance with cGDP. |  |  |
|  | Training shall be in the particular operations that the employee performs and in current applicable transport and warehousing regulations, as they relate to the employee’s functions. |  |  |
|  | Training records for all personnel shall be maintained and made available upon request or pursuant to any regulatory review. |  |  |
| 1. **RECORDS** | | **XX** | **XX** |
|  | Shall maintain a program to assure electronic and hardcopy documents that support transport and storage processes adhere to defined retention requirements, security, and controlled destruction. |  |  |
|  | Will retain records for a minimum of seven (7) years from the date of transportation/storage. |  |  |
|  | Will notify XXXXX prior to destruction of any records at the completion of the XXXXX retention period. |  |  |
|  | Will provide to XXXXX for each shipment of Product the shipment documentation to demonstrate full traceability from manufacturer to final XXXXX customer and documentation supporting shipments deviations when applicable.  At the minimum the following should be provided:   * Order reference number, date of dispatch, method of shipment, identity of carrier and carrier reference number * Name and Address of Shipper and Consignee * Product Name, strength and batch number * Quantity of order * Temperature conditions for each product * Records of transportation   Where a computer system is used to maintain transportation records, the system will be validated. |  |  |
| 1. **SUB-CONTRACTING** | | **XX** | **XX** |
|  | A written Technical Agreement is in place for transportation sub-contracted to a 3rd party, ensuring the contractor is aware of all relevant conditions applicable to storage and transportation of medicinal product. |  |  |
|  | A 3rd party qualification program is in place and described in SOPs. |  |  |
|  | Will review **Supplier’s** 3rd party qualification program during regular or for-cause audits. |  |  |
| 1. **AUDITS** | | **XX** | **XX** |
|  | Will permit XXXXX to perform a minimum of one (1) standard cGDP annual compliance audit for the services contracted, upon reasonable notification from XXXXX, with actual audit dates subject to mutual agreement. Such audits shall not exceed two (2) business days and shall have no more than two (2) auditors. An extension of the audit frequency may occur at any time with written agreement from both Parties. |  |  |
|  | Will report audit findings verbally at the close of the audit and will provide a written report within thirty (30) calendar days of the audit. |  |  |
|  | Response will include root cause evaluation, corrective actions, preventative actions, and remedial actions, where appropriate, and shall include a timeline for completion of each action. The response will be sent to XXXXX within thirty (30) calendar days from report receipt or in a mutually agreed upon time period. |  |  |
|  | Will allow XXXXX to conduct for-cause audits (i.e. audits due to major regulatory issues or suspect for high quality risk to products) anytime. These audits are not part of the routine audit schedule. |  |  |
|  | Will routinely perform self-inspections in order to ensure compliance with internal GDP procedures and processes. |  |  |
| 1. **TRANSPORTATION** | | **XX** | **XX** |
|  | Will be responsible for transportation as per XXXXX’s standard operating procedures for the distribution of medicinal products ultimately intended for human use. |  |  |
|  | Maintain transportation conditions to ensure that the quality of the product is not affected; to protect against breakage, adulteration and theft; and to ensure appropriate environmental conditions are maintained during transportation. |  |  |
|  | Transport products in accordance with the storage conditions indicated & as per label claim. |  |  |
|  | Develop a risk based approach when planning transportation routes. |  |  |
|  | Have SOPs in place for operation and maintenance of vehicles. |  |  |
|  | Use dedicated vehicles where possible. |  |  |
|  | Where non dedicated vehicles are used, procedures should be in place to ensure that the quality of the Products is not compromised. |  |  |
|  | When hubs are used for temporary storage, a maximum storage time at such locations should be no longer than **XX** hours. |  |  |
|  | Unplanned storage at a hub beyond 36 hours will require pre-approval by XXXXX in writing. |  |  |
|  | Routine storage at a hub beyond 36 hours would require that the premises hold a license. |  |  |
|  | If unloading and reloading, e.g. at terminals and hubs, is necessary these premises *should* be audited and approved prior to deployment. |  |  |
|  | Products should be transported in vehicles with the capability to be continuously monitored for the temperature ranges specified and daily temperature recordings and maintained and made available to XXXXX. |  |  |
|  | Products should be transported in containers that have no adverse effect on the quality of the products and that offer adequate protection from external influences including contamination. |  |  |
|  | Have SOPs in place to describe how temperature sensitive products are distributed. |  |  |
|  | Have a contingency plan defined in SOPs for issues that may occur during transportation. |  |  |
|  | Have measures to minimise exposure of products at ambient conditions (hold times) when required by the shipping conditions. |  |  |
|  | Document and control transportation routes (safe and secure supply chain; route certification). |  |  |
|  | Have defined process for accurate communication between the carrier and the driver. |  |  |
|  | Have procedures in place to inspect vehicles prior to loading to assure no prior material or opportunities for contaminations are present. |  |  |

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|  | Have procedures in place to assure safe custody and security at stopping points during transport. |  |  |
| 1. **STORAGE** | | **XX** | **XX** |
|  | BUILDING |  |  |
|  | Have written procedures describing cleaning frequency, methods, and materials. |  |  |
|  | Have written procedures that define special handling precautions for the storage and handling of hazardous materials and substances. |  |  |
|  | Have a segregated area for the holding and storage of returned/rejected goods. |  |  |
|  | Will have and maintain back-up generators on a regular maintenance and testing schedule. |  |  |
|  | Will maintain an automated alarm system to a central station in the event the temperature control conditions are not met. |  |  |
|  | Have a regular pest control and rodenticide program described in SOPs. |  |  |
|  | Maintain a diagram that shows the location of bait boxes and electronic flying insect killers to ensure that all are serviced, cleaned and inspected per schedule. |  |  |
|  | A pallet management program is in place to ensure appropriate handling and treatment of wood pallets. |  |  |
|  | Sound stacking of product & bulk materials on pallets to avoid damages. |  |  |
|  | Will physically segregate products to prevent mixing of separate products and/or lot numbers. |  |  |
|  | Have procedures to remove outdated products and segregate from general storage. |  |  |
|  | Have written procedures to document upon receipt that supplier’s documentation is checked against purchase order to verify correct label description, product number, quantity, batch number and physical conditions. |  |  |
|  | Will retain records for each delivery to include description of the products, presentation, quantity, supplier, supplier’s lot numbers, date of receipt, expiration date and temperature requirements during transport. |  |  |
|  | TEMPERATURE CONTROL |  |  |
|  | Will monitor and control warehouse temperatures within a range to meet label claim (i.e. 15 °C to 25 °C). |  |  |
|  | Will maintain products requiring lower temperature conditions, (i.e. 2 °C to 8 °C). in a suitable storage area, (cool room or refrigerator) |  |  |
|  | All controlled temperature storage areas are equipped with calibrated recorders/devices that indicate when required temperature or relative humidity ranges have not been maintained. |  |  |
|  | Have procedures to describe what actions are to be taken in case a temperature excursion is recorded. |  |  |
|  | Map controlled temperature areas to determine high and low temperature areas within the storage area during seasonal extremes. |  |  |
|  | Conduct a review of temperature mapping as part of validation plan on a planned schedule. |  |  |
|  | Have a regular preventive maintenance schedule in place to maintain all equipment. |  |  |
|  | Perform Mean Kinetic Temperature (MKT) studies for each of the storage areas. |  |  |
|  | INVENTORY CONTROL | **XX** | **XX** |
|  | Have written procedures that define the responsibilities for the preparation, communication, and implementation of QA Hold directive and dispositions. |  |  |
|  | Have documented procedures to segregate/destroy non-conforming products. |  |  |
|  | Maintain all materials under a stock control system. |  |  |
|  | Perform periodic cycle counts and note and investigate discrepancies. |  |  |
|  | Inspect periodically the stock for obsolete, damaged or expired material. |  |  |
|  | Have procedures in place to prevent outdated or short date stock being distributed. |  |  |
| 1. **VALIDATION, QUALIFICATION AND CALIBRATION** | | **XX** | **XX** |
|  | Will be responsible for maintenance, qualification, validation and calibration of the Facility, equipment, vehicles, instruments and processes associated with the storage and transport of the Products. |  |  |
|  | Possess qualified temperature-controlled vehicles for the distribution temperature ranges, (controlled ambient & chilled). |  |  |
|  | Use validated continuous temperature monitoring devices. |  |  |
|  | Will maintain a calibration and preventative maintenance program to support the storage and transport of Products. |  |  |
|  | Will maintain and follow a procedure that documents the actions to be taken in the event of a calibration failure. |  |  |
|  | Will routinely check equipment used for temperature monitoring and calibrate it at least annually. |  |  |
|  | Utilise only validated temperature control packaging solutions. |  |  |
|  | Temperature mapping under representative conditions taking into account seasonal variations. |  |  |
| 1. **DEVIATIONS AND CAPA** | | **XX** | **XX** |
|  | Responsible for investigating deviations from established procedures such as but not limited to temperature excursions during transport, product damages, storage in hubs for a time period longer that permitted, missing documentation such as traceability, chain custody. |  |  |
|  | Will notify XXXXX within **XX** (**X**) business day of any deviation that may have occurred during the transport of Products |  |  |
|  | Will review the investigation reports provided by **Supplier**, request for more information as necessary, provide feedback and approve the final documents. |  |  |
|  | Will maintain a CAPA program aimed to prevent reoccurrence of issues and to improve the systems |  |  |
|  | Will perform a regular status review of the CAPA actions |  |  |
| 1. **CHANGE CONTROL** | | **XX** | **XX** |
|  | All changes to the transported Product related documents (i.e. transport records, validation, etc.) shall proceed through an impact assessment according to XXXXX’s change control program. |  |  |
|  | Changes with a regulatory impact will be implemented only after authorisation is received by the regulatory authorities. In these cases the **Supplier** will hold the implementation of the change until such notification is provided by XXXXX. |  |  |
| 1. **COMPLAINTS** | | **XX** | **XX** |
|  | Responsible for receiving all complaints/formally requesting investigation |  |  |
|  | Will lead the investigation for all complaints |  |  |
|  | Upon receipt of the complaint notice, will perform the investigation within five (5) working days and close out the investigation completely by twenty (20) working days. |  |  |
|  | XXXXX and **Supplier** can mutually agree to expedite complaint investigations in the event of potential regulatory-related actions or other agreed upon investigational situations. |  |  |
| 1. **RETURNS** | | **XX** | **XX** |
|  | Implemented procedures for QA inspection of returns (integrity, correct quantity). |  |  |
|  | Implemented procedures for returns physical segregation from approved warehouse stock to prevent mix-ups |  |  |
|  | Implemented procedures to prevent restock of returned materials due to customer complaints |  |  |
| 1. **RECALLS** | | **XX** | **XX** |
|  | Will maintain track & trace and sound audit trails such that faulty products can be recalled |  |  |
|  | Implemented procedures to prevent restock of recalled items |  |  |
|  | Implemented procedures to a) effectively recall products from market and b) communicate recall plans with appropriate authorities |  |  |
| 1. **BUSINESS CONTINUITY PLAN** | | **XX** | **XX** |
|  | A contingency plan is in place in the event a catastrophic situation which is compromising the continuation of business for a time that might have impact on storage and/or transportation. |  |  |

**The following table defines the Quality representatives from XXXXX & SUPPLIER**

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| **SUPPLIER Representatives** | **XXXXX Representatives** |
| **Name:**  **Title:**  **Address:**      **Phone:**  **Email:** | **Name:**  **Title:**  **Address:**    **Phone:**  **Email:** |
| **Name:**  **Title:**  **Address:**      **Phone:**  **Email:** | **Name:**  **Title:**  **Address:**  **Phone:**  **Email:** |