Title:

Document Type: Carrier Quality Agreement

Document ID:

Owner:

Approver (s):

Approval Date:

Effective Date:

# Contracting Parties

Contract Giver:

**Name: XXXXXX**

**Address:**

**(Hereafter known as ZZZZZZ)**

Contract Acceptor:

**Name: XXXXXX**

**Address:**

**(Hereafter known as XXXXXX)**

# 2. Purpose and scope of this agreement

2.1.  The purpose of this agreement is to describe the quality and service aspects of the transportation (“Services”) provided by XXXXX**.**

2.2.  The scope of this agreement defines the responsibilities of XXXX and ZZZZZZ for the handling and transportation of medicinal product (“Product”) as required under Chapter 9 of the European Commission Guidelines on Good Distribution Practice of medicinal products for human use 2013/C 343/01 (“GDP”).

2.3.  Each party will undertake not to vary anything explicit or implied in this agreement other than by consultation and will give reasonable consideration to adopting any new standards, specifications and procedures at the written request of the other.

3. Basis and responsibilities

3.1. Where applicable, XXXX and ZZZZZZ shall comply with the legal and GDP Chapter 9 regulations that apply to their area of responsibility.

3.2.  XXXXX and ZZZZZZ hold valid certification, licences/Authorisations issued by the relevant Regulatory Authorities/Agencies to provide the Services.

3.3.  XXXXX and ZZZZZZ shall maintain its systems to support its certification/licences/authorisations.

3.4.  XXXXX will adhere to all necessary rules, regulations and compliance requirements in relation to the Services.

3.5.  XXXXX shall remain fully responsible for the quality of the service provided to ZZZZZZ.

3.6.  XXXXX will comply with all applicable requirements regarding Health and Safety.

3.7.  XXXXX will ensure that persons who are performing services on its behalf in connection with the Services comply with all applicable laws, statutes, regulations and codes relating to anti-bribery and corruption.

3.8.  XXXXX has and will maintain in place throughout the term of this agreement its own policies and procedures to ensure compliance with all applicable laws, statutes, regulations and codes relating to anti-bribery and corruption and will enforce them where appropriate.

3.9.  XXXXX and ZZZZZZ shall ensure that all staff affected by this agreement shall be appropriately trained in their valid Standard Operating Procedures (SOP).

3.10.  Upon reasonable advanced notice and approval by XXXXX, ZZZZZZ shall have the right to visit a mutually agreed upon location of XXXXX in order to monitor or verify XXXXX performance under this agreement.

3.11.  ZZZZZZ reserves right to conduct an assessment of XXXXX shipping and invoice records that relate to XXXXX performance under this agreement.

3.12.  XXXXX agrees to consider any commercially reasonable steps that are requested by ZZZZZZ as a result of an assessment to remedy any deficiencies reported.

3.13.  ZZZZZZ is responsible for providing cargo in good order and free of damage.

3.14.  If either party has an issue with the quality or service aspects of the transportation, the parties agree that:

3.14.1.  ZZZZZZ will be responsible for managing any and all communication to and from the end customer;

3.14.2.  if the issue is not resolved by the locally appointed relationship managers, it will be escalated to the global account managers for resolution; and

3.14.3.  any outcome agreed as part of the escalation process will always be subject to the liability provisions as specified in the XXXXX Conditions of Carriage.

4. Handling and Transportation of Product

4.1. Product should be handled and transported in a way that:

4.1.1.  identification is not lost;

4.1.2.  it does not contaminate or is not contaminated by other materials;

4.1.3.  adequate precautions are taken against spillage, breakage or theft;

4.1.4.  it is secured and not subject to unacceptable exposure to heat, cold, light, moisture or other adverse influences;

4.1.5.  security and integrity are not in any way compromised due to planned or unplanned transits, transfers, stops or delays;

4.1.6.  it is “held at rest” in a secure and safe manner that prevents tampering, theft and contamination.

4.2.  Upon request, XXXXX shall provide ZZZZZZ with transport route(s) for a specific journey.

4.3.  The temperature conditions specified by ZZZZZZ must be maintained at all times during transport.

4.4.  XXXXX is responsible for ensuring that transportation of the Product is carried out in accordance with ZZZZZZ specific instructions and requirements (including temperature requirements).

4.5.  **Vehicle Requirements (including Road Feeder Services)**

4.5.1. Vehicles must be:

4.5.1.1. clean, fully serviceable and fully enclosed

4.5.1.2. fitted with a temperature-controlled unit

4.5.1.3 temperature controlled and pre-set at the required temperature for the Product. E.g. +20°C for controlled ambient shipment and +5°C for chilled shipment;

4.5.1.4 suitable and capable of carrying the prescribed load;

4.5.1.5 hard-sided vehicles;

4.5.1.6 securely enclosed with no access to the load compartment from the driver’s cab. They must have slam locks and/or amour plated locks and be capable of being sealed as a tamper evident measure with either seals or padlocks or both;

4.5.1.7 locked at all times when in transit and not left unoccupied at any time whilst loaded;

4.5.1.8 alarmed with an approved system;

4.5.1.9 fitted with GPS satellite tracking

4.6. ZZZZZZ shall be kept fully informed on the status of the shipment during the complete logistical route

4.7.  XXXXX shall ensure that equipment and vehicles utilised in the transportation of the Product are fit for purpose and are operated by appropriately trained staff working to documented procedures.

4.8.  XXXXX will only subcontract to a third party any of the Services entrusted under this agreement if the third party is on the XXXXX approved supplier list.

5. Documentation/booking

5.1. It is the responsibility of ZZZZZZ to supply all documentation required to accompany the shipment:

5.1.1. Any shipping or transport documents that are supplied by ZZZZZZ shall be legible, and where applicable in the required format;

5.1.2. Documentation from ZZZZZZ will be handed over prior to XXXXX handling the shipment.

5.2. ZZZZZZ will make confirmed bookings with XXXXX for all shipments. If any time restrictions for booking apply, XXXXX will communicate this in advance.

5.2.1. ZZZZZZ will deliver shipments as booked. Liability for cancellation or shipments tendered that are different to the booking will be subject to XXXXX conditions of carriage.

5.2.2. All transportation is undertaken under XXXXX conditions of carriage.

5.3.  It is the responsibility of ZZZZZZ to communicate all shipment requirements, including any security or temperature control conditions which need to be adhered to throughout the journey, and any other special instructions.

5.4.  It is the responsibility of XXXXX to handover the Product and documentation as described in 5.1 above to the receiver of the shipment as notified by ZZZZZZ.

5.5.  XXXXX is responsible for taking full control of its export or import compliance procedures to meet its legal requirements, follow EU and other appropriate compliance procedures where necessary. ZZZZZZ maintains responsibility for ensuring its own Customs compliance and other legal requirements are met.

5.6.  XXXXX should provide full tracking/movement visibility via web-based systems.

6. Damages/Shortages/Deviation Reporting

6.1.  XXXXX shall notify ZZZZZZ of any known transportation incident, problem, concern, or delay that may arise during transportation of the Product. Notification must be provided within 12 hours of the incident becoming known.

6.2.  Any deviation from approved specification, processes or SOP’s during the transportation of the Product must be reported to ZZZZZZ on the same business day that the deviation becomes known.

6.3. XXXXX will ensure that all complaints are investigated within a reasonable timescale and upon request provide a written report to ZZZZZZ within 7 days of notification.

7. Change Management and approval

7.1.  XXXXX will notify any planned changes (e.g. organisational, operational or procedural) affecting this agreement. ZZZZZZ is responsible for assessing the impact of such changes.

7.2.  Amendments to this agreement may be made only by mutual agreement between the two parties and must be in writing.

8. Training

8.1.  It is the responsibility of XXXXX to ensure that all relevant persons employed are trained to enable them to carry out their responsibilities.

8.2.  XXXXX is responsible for ensuring that all relevant persons employed, or direct contractors involved in providing the Services have successfully passed a security check.

9. Quality Assurance

9.1. XXXXX shall ensure that a documented Quality Management System is in place to ensure the effectiveness of the controls and procedures described in this agreement, addressing at least, but not limited to:

9.1.1.  monitoring appropriate transport conditions;

9.1.2.  transportation security (including staff recruitment);

9.1.3.  records retention;

9.1.4.  training;

9.1.5.  transportation of Product;

9.1.6.  notification and investigation of process deviations;

9.1.7.  corrective and preventative action (CAPA) management in relation to process deviations and complaints;

9.1.8.  theft or loss of the Product.

10. Facilities

10.1. XXXXX is responsible for ensuring its facilities and vehicles (and those of its sub- contractors) are managed in accordance with defined and recognised quality standards.

10.2.  XXXXX shall use reasonable endeavours to protect the products in its care from damaging impacts and from access by unauthorised persons.

10.3.  Damaging impacts are in particular:

10.3.1. environmental;

10.3.2. dust and smell;

10.3.3. animals and insects.

11. Document retention

11.1.  ZZZZZZ reserves the right at any time to request documentation relating to the Services.

11.2.  XXXXX will, where possible, provide documentation within 48 hours of receipt of a request from ZZZZZZ.

11.3.  XXXXX will retain all documentation relating to the Services for a minimum of 5 years.

12. Term and expiration

12.1.  This agreement shall be effective from the last date of signing by all parties, unless otherwise mutually agreed.

12.2.  This agreement shall be reviewed as necessary to ensure that the personnel, systems and responsibilities remain accurate and in compliance with regulatory requirements and all other circumstances. As a minimum, the agreement shall be reviewed by ZZZZZZ for compliance every three years.

13. Confidentiality

13.1.  Both parties shall ensure that the other’s proprietary information and documentation is controlled in order to maintain confidentiality obligations.

13.2.  Where such obligations are not documented, both parties shall treat all information required to perform the Services in the strictest confidence and shall ensure that all documents supplied by the other party are suitably controlled.

14. Responsibilities matrix

|  |  |  |
| --- | --- | --- |
| **Responsibilities** | ZZZZ | XXXX |
| Implementation and maintenance of this agreement  | X |  |
| Co-ordination of GDP with suppliers and customers  | X |  |
| Implementation and maintenance of Quality agreements with customers and suppliers  | X |  |
| Compliance with anti-bribery and anti-corruption legislation  | X  | X  |
| Maintenance and update of RP and contact list  | X  |  |
| Reporting and investigating Deviations, service complaints and enquiries  |  | X  |
| Action CAPA's in a timely manner  |  | X  |
| Quality Management System  | X  | X  |
| Anti-bribery and corruption due diligence on 3rd party service providers in the supply chain  | X  |  |
| Quality assessments  | X  | X  |
| Meeting and managing specified transportation requirements  |  | X  |
| Transport of Product in good condition and timely manner  | X  | X  |
| Compliance with stated Quality standards  | X  | X  |
| Provide Product in packaging free from damage and labelled with correct address  | X  |  |
| Communication of instances where ZZZZZZ instructed requirements cannot be met  |  | X  |
| Equipment, vehicles and facilities appropriately qualified  |  | X  |

15. Approval

This agreement shall be governed by the laws of England and Wales.
IN WITNESS whereof this Agreement has been entered into the day and year written.

SIGNED for and on behalf of **XXXXX** by its duly authorised representative in the presence of:

Name:
Title:
Date:

witnessed by:

Name:
Title:
Date:

SIGNED for and on behalf of

**ZZZZZZ**

16. Schedule 1 - Responsible Contact Persons

Contract Acceptor (XXXXX)

Position:

Name:

Phone:

Email:

Address:

Quality Assurance Contact (XXXXX)

Position:

Name:

Phone:

Email:

Address:

Contract Giver (ZZZZZZ)

Position:

Name:

Phone:

Email:

Address:

Quality related enquiries Name:

Email:

Phone: