Title: Non-Transport Supplier

Document Type: Quality Agreement

# Contracting Parties

Contract Giver:

**Name: ZZZZZZ**

**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 XXXXXXX (“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 regulations that apply to their area of responsibility.

3.2.  XXXXX holds a valid certification in the (insert country) and Authorisations issued by the relevant Regulatory Authorities/Agencies. XXXXX shall maintain it systems to support its certification/licenses/authorisations.

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

3.4. XXXXX and ZZZZZZ shall implement and update their own effective Quality Management System (QMS), including the performance of internal audits and the implementation of the resulting corrective actions.

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

3.6. ZZZZZZ holds a valid licence or accreditation issued by a competent authority. ZZZZZZ shall maintain its systems to support its licence.

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

3.8.  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.

3.9.  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.

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

3.11.  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.

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

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

4. Handling and Transportation of Product

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

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

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

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.

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

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.

5.3.  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.

5.4.  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 shall designate persons responsible for information flow to ZZZZZZ regarding day to day operational logistical instructions.

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 2 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. ZZZZZZ may, if required, be actively involved in the resolution of major deviations at XXXXX.

6.3. XXXXX will ensure that all complaints are investigated within a reasonable timescale and upon request provide a written report to ZZZZZZ within 5 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 ensures that transportation of the Product is carried out in accordance with GDP and ZZZZZZ specific instructions and requirements.

9. Audits

9.1. XXXXX will permit ZZZZZZ, its representatives or any officer from a competent authority, for the purposes of carrying out quality or security audits, all reasonable access to its facilities upon reasonable notice and within working hours.

9.1.1.  equipment calibration and maintenance

9.1.2.  records retention;

9.1.3.  training;

9.1.4.  notification and investigation of process deviations;

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

9.1.6.  self-inspection

10. Quality Assurance

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

10.1.1.  equipment calibration and maintenance

10.1.2.  records retention;

10.1.3.  training;

10.1.4.  notification and investigation of process deviations;

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

10.1.6.  self-inspection

11. Facilities

11.1. XXXXX is responsible for ensuring its facilities are managed in accordance with defined and recognised quality standards.

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

11.3.  Damaging impacts are in particular:

11.3.1. environmental;

11.3.2. dust and smell;

11.3.3. animals and insects.

11.4 XXXXX is responsible for ensuring that the facility is kept in an orderly and tidy condition. Cleaning will be carried out in accordance with a written cleaning program.

11.5 XXXXX shall ensure reliable personnel have been appointed, who have the required documented theoretical and technical qualifications, supported by procedures.

12. Invoicing, payment and document retention

12.1. ZZZZZZ will only accept invoices that reflect agreed Product charges or pre-approved written rate quotations.

12.2. Payment of approved charges by ZZZZZZ shall be remitted thirty (30) days from the date of invoice.

12.3. ZZZZZZ reserves the right at any time to request back-up documentation to any statement/individual invoice they have been charged with. XXXXX will have all backups of invoices to NPPON EXPRESS UK available in hardcopy for inspection at the XXXXX facility within 48 hours of a request. All files are kept for a minimum of x (insert country document retention requirement) years.

13. Insurance

13.1. XXXXX will provide evidence of all relevant insurance arrangements, if requested by ZZZZZZ, including but not limited to:

13.1.1. Employers liability insurance;

13.1.2. Public liability insurance.

14. Term and expiration

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

14.2.  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.

15. Confidentiality

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

15.2.  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.

16. 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  |
| Implementation and maintenance of Quality Agreements with other 3rd party service providers  | X  | X |
| Maintenance and update of RP and contact list  | X |   |
| Service complaints and enquiries  | X | X  |
| Action complaint investigations and CAPA's in a timely manner  |  | X  |
| Negotiation with the national competent authority  | X  |  |
| Co-ordination of regulatory changes to WDA | X  |  |
| Quality Management System  | X | X  |
| Anti-bribery and corruption due diligence on 3rd party service providers in the supply chain  | X  | X  |
| Quality Audits | X  | X  |
| Customer approval activities | X  |  |
| Supplier and 3rd party service providers Quality Management System | X | X  |
| Transport of product in a timely manner |  | X  |
| Compliance with stated Quality standards |  | X |
| Provide product in packaging free from damage |  | X |
| Delivery of product to correct address |  | X |

17. 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**

18. 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: