DECAHEDRON Ltd, Unit 14, The Spire Green Centre, Merring Way, Harlow, CM19 5TR, United Kingdom
Telephone: +44 (0) 1279 435 591 www.decahedron.com

QUALITY TECHNICAL AGREEMENT

For the Purchase and Transportation of Medicinal Products within GB

between

DECAHEDRON LIMITED

And

(Please delete and enter name of your Company)

Valid for 3 years from the date of signing
(DD/MMM/YYYY)

DECAHEDRON Ltd, Unit 14, The Spire Green Centre, Merring Way, Harlow, CM19 5TR, United Kingdom
Telephone: +44 (0) 1279 435 591 www.decahedron.com

This agreement is made between:-

DECAHEDRON LIMITED, of Unit 14, The Spire Green Centre, Merring Way, Harlow, CM19 5TR,

Hereinafter called "Supplier" and

Your Company Name ……..

Of Address ……...

Delivery address if different from above

…….....

Hereinafter called "Customer"

1. OBJECT

The object of this agreement is to set out the arrangements and responsibilities between Supplier and Customer, as required under current EU Good Distribution Practice (hereinafter referred to as 'cGDP') guidance (2013/C343/01), and as set out in Directive 2001/83/EC, as amended, for the purchase, storage and transportation of pharmaceutical products for parallel distribution within the European Economic Area.

EU GDP Guidance (2013/C343/01), Chapter 9 (Transportation) states, in principle, that '*it is the responsibility of the Supplying wholesaler to protect medicinal products against breakage, adulteration and theft, and to ensure that temperature conditions are maintained within acceptable limits during transport'.*

It is, however, a generally accepted principle in the pharmaceutical distribution industry that customers purchase goods on an 'ex-factory' or 'ex-works' basis, that is to say, that all responsibility for the condition of the goods concerned passes immediately they are collected, or loaded for transport by the supplier, (completion of the sale), and that this modifies the nature of the cGDP relationship between supplier and customer. However, Decahedron will supply goods under the minimum of FCA incoterms, i.e. through their approved transportation company at the cost to the customer.

Nevertheless, cGDP places differing burdens of responsibility on both parties in these transactions, and this technical agreement, therefore, addresses the respective responsibilities of the parties in this modified perspective.

2. RESPONSIBILITIES

a) Of the Supplier

(i) Quality Management: the supplier confirms that they operate the requisite quality system demanded by cGDP. They further confirm that goods provided to the customer have been

placed in free circulation onto the EEA market, and that such sale complies with all relevant national pharmaceutical regulations with regard to their legal sale.

(ii) Personnel: the supplier confirms their observance of cGDP and they employ sufficient competent personnel to carry out the task required, and that the Responsible Person is suitably qualified.

(iii) Premises and Equipment: the supplier confirms that they maintain suitable and adequate premises, installations and equipment, so as to ensure proper storage and distribution of medicinal products. In particular, the premises should be clean, dry and maintained within acceptable temperature limits, in accordance with cGDP.

(iv) Documentation: the supplier confirms that they maintain an adequate documentation system to record all written procedures, instructions, contracts, records and data, in paper or electronic form, and in accordance with cGDP.

(v) Operations: the customer confirms that their operations are in accordance with the requirements of cGDP.

(vi) Complaints, Returns, suspected Falsified Medicinal Products and medicinal product Recalls: the supplier confirms their adherence to the principle and practice of cGDP.
The supplier confirms that they will notify the customer immediately of any recall notice issued in their national market, which affects the medicinal products supplied under this agreement.

(vii) Outsourced activities: the supplier confirms that any activity which is outsourced beyond their immediate company should be correctly defined, agreed and controlled under a written agreement, in accordance with cGDP.

(viii) Self-Inspections: the supplier confirms that self-inspections are undertaken within a defined timeframe in order to monitor implementation and compliance with cGDP principles.

(ix) Transportation: The supplier will notify the Customer of the manufacturers recommended storage conditions for each product. As set out in section 1 of this agreement all responsibilities regarding the condition of the medicinal products pass to the customer after they loaded for transport by the supplier (completion of the sale). The supplier will notify the Customer of the manufacturers recommended storage conditions for each product.

(x) Audit: The supplier accepts the requirements of GDP Chapter 7.

b) Of the Customer:

(i) Quality Management: the customer confirms that they operate the requisite quality system demanded by their National Competent Authority.

(ii) Personnel: the customer confirms their observance of the requirements of their National Competent Authority and they employ sufficient competent personnel to carry out the task required, and that the Responsible Person is suitably qualified.

(iii) Premises and Equipment: the customer confirms that they maintain suitable and adequate premises, installations and equipment, so as to ensure proper storage and distribution of medicinal products. In particular, the premises should be clean, dry and maintained within acceptable temperature limits, in accordance with the requirements of their National Competent Authority.

(iv) Documentation: the customer confirms that they maintain an adequate documentation system to record all written procedures, instructions, contracts, records and data, in paper or electronic form, and in accordance with the requirements of their National Competent Authority.

(v) Operations: the customer confirms that their operations are in accordance with the requirements of their National Competent Authority. The customer agrees that all exported products, that are covered by a marketing authorisation granted by the EU, or by a Member State, are not allowed back into the EU either directly or via a third party.

(vi) Complaints, Returns, suspected Falsified Medicinal Products and medicinal product recalls: the customer confirms their adherence to the principle and practice of the requirements of their National Competent Authority.

(vii) Outsourced activities: the customer confirms that any activity which is outsourced beyond their immediate company should be correctly defined, agreed and controlled under a written agreement, in accordance with National Competent Authority.

(viii) Self-Inspections: the customer confirms that self-inspections are undertaken within a defined timeframe in order to monitor implementation and compliance within the requirements of their National Competent Authority principles.

(ix) Transportation: The customer confirms the use of supplier transport operation i.e. DHL medical, and that all products will be transported within the storage conditions recommended by the manufacturers. As set out in section 1 of this agreement that all responsibilities regarding the condition of the medicinal products pass to the customer after they have been loaded for transport by the supplier (completion of the sale).

(x) Audit: The customer accepts the requirements of GDP Chapter 7.

(xi) Consignee: The Customer confirms that, as the consignee, they are authorized or entitled to receive medicinal products for wholesale distribution or supply to the public in accordance with the applicable legal and administrative provisions of their competent authority. Products purchased from the Supplier will only be delivered to Customers licensed premises.

(xii) Documentation: Proof of safe delivery to Customers address will be provided to Supplier; and, for export sales, customs documentation to include Bill of Lading, CMR consignment notes, C88/Single Administrative Documents (SAD) etc will be completed, fully and legibly, and provided to the supplier.

Approval by Customer

Company Name: ……..

Print Name: …….

Title: …….

Signature: …….

Date: ……

Approval by Decahedron Limited

Name: ……..

Title: ……

Signature: ……

Date: ……