CHAPPER healthcare IRELAND	Ref:	Issue:
TECHNICAL AGREEMENT		

This Technical Agreement is to establish the obligation and responsibilities of:

CHAPPER healthcare Ireland Limited, a company registered in the Republic of Ireland whose address is 38 Main Street, Swords, County Dublin, Ireland, K67 E0A2 ("**Supplier**");

and

…….. a company registered in ……..……

whose registered office is ……

("**Client**")

Now therefore, the Parties hereto have adopted and are bound by the provisions of this Agreement.

AGREED BY:

Name: Jonathan Chapper
……..…
Title: Director and RP
On behalf of CHAPPER healthcare Ireland Limited:
……

Signature:

Date:

Name: ……
……
Title: ……
On behalf of: ……..……..
……

Signature:

Date:

The Agreement will be reviewed no later than 3 years after the date of its signature.

Confidentiality

Neither party is entitled to use the knowledge the other has disclosed to it under this Agreement after the cessation of this Agreement or without consent of the other party. Exclusions are given when information is requested by regulatory bodies or is required by law. Both parties undertake to maintain strict confidentiality which shall also apply after the Agreement has ceased.

GENERAL REQUIREMENTS AND RESPONSIBILITIES

Variations to Agreement

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

This Agreement shall be reviewed as a result of any significant changes in the scope or working arrangements between CHAPPER healthcare and Client.

This technical agreement is to be read in conjunction with the legal terms and conditions applying to any specific order.

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Sr No	Technical Requirements	Client	Supplier (CHAPPER healthcare)
1.	Compliance with Wholesale Distribution Authorisation requirements of the HPRA (or other applicable regulatory authority) and EU GDP (where applicable).	✓	✓
2.	Quality System Quality System must be established & maintained to fulfil GDP requirements in compliance with EU GDP 20013/C 343/01 (if applicable) or other applicable GDP	✓	✓
3.	Personnel Ensures a Responsible Person and competent personnel are appointed to fulfil all GDP requirements	✓	✓
4.	Maintenance of Premises and Equipment	✓	✓
5.	The responsible Person will ensure a system is in place to regularly review all Standard Operating Procedures (SOPs)	✓	✓
6.	Maintenance of Records The following data for each receipt or despatch will be recorded: 1. Date 2. Product description 3. Batch number 4. Quantity supplied These records will be retained for a minimum of 5 yrs.	✓	✓
7.	Receipt of Goods Supplier ensures to provide prior notification with storage condition of goods.		✓
8.	Storage Conditions Supplier is responsible for the storage of all packaged finished Products under appropriate conditions in compliance with current GDP guidelines whilst the Products are in Supplier's possession.		✓
9.	Security Ensures storage and distribution of all medicinal products under secure conditions. When the legal status of a medicine requires special storage conditions it is the responsibility of Supplier to inform Client of these conditions.	✓	✓
10.	Transportation Except in the case of an ex works shipment, Supplier is responsible for arranging transportation of stock using approved couriers or other approved logistics providers to agreed point of delivery, from which point Client is responsible for any further transportation. Where an ex works shipment, Client is responsible for all transportation.		✓

11.	Falsified Medicines Will ensure systems are in place ensuring medicines are not falsified in accordance with 2011/62/EC (if applicable) or other relevant regulation (where nonEU).	✓	✓
12.	Ensures entitlement to Distribute Medicines is maintained and Client will be informed in case of any issues that may affect product quality or efficacy.		✓
13.	Order Receipt To verify orders received. Any discrepancies in orders or damage to materials will be notified to the Supplier.	✓	
14.	Deliveries Where deliveries are not ex works, confirmation of deliveries will be emailed to Client by Supplier. Supplier will ensure that goods are transported so that identification is not lost; they are not likely to contaminate other goods and nor are they likely to be contaminated by other products or materials, that reasonable precautions are taken against spillage, breakage or theft and to ensure that they are secure and are not subjected to unacceptable degrees of heat, cold, light, moisture or other adverse influence. Supplier will take precautions to ensure that product(s) are safely and securely loaded onto vehicles for transport and can be safely unloaded at the point of delivery so as to avoid injury to people and damage to product(s). Where deliveries are ex works, confirmation of availability for Client to pick up will be emailed to Client by Supplier. Supplier will ensure that goods are packed so that: identification is not lost, nor are they likely to contaminate other goods nor be likely to be contaminated by other products or materials, that reasonable precautions are taken against spillage, breakage or theft and that they are packed so as to be secure and not be subjected to unacceptable degrees of heat, cold, light, moisture or other adverse influence. Supplier will take precautions to ensure that product(s) are available to be safely loaded onto vehicles for transport.		✓
15.	Deviations Will inform Client of any significant deviations that have the potential to affect products supplied.		✓
16.	Complaints Complaints received for the products supplied to Client will be promptly informed to Client.		✓

17.	Product Recall In case of any product recall, Supplier will advise promptly Client of the need for any further action. Client will provide all necessary support to facilitate recall	✓	✓
18.	Returns Client RP will examine and assess returned Product(s) which have been placed into quarantine. Where return to the Supplier is appropriate, they will then be placed in a suitably labelled area for their collection by Supplier.	✓	
19.	Self-Inspection Ensures self-inspections of the quality system at appropriate intervals are conducted and recorded. The inspection records will be made available upon request from and for the purpose of any regulatory inspection/competent authority.	✓	✓
20.	Sub-Contracting No work will be subcontracted relating to GDP activities without the prior permission of the other party.	✓	✓
21.	Training Both parties will ensure that all staff engaged in GDP activities are trained in the principles of GDP	✓	✓
22.	Bona Fide checks Will ensure that regular bona fide checks are carried out to ensure the ongoing validity of suppliers and customers	✓	✓
23.	Health & Safety Any Products supplied to Client that are subject to the requirements of the Control of Substances Hazardous to Health Regulations will be supported with appropriate hazard data sheets.		✓
24.	Communication All communication between parties will be made in an accurate and timely manner to ensure the commercial efficiency and continuity of supply.	✓	✓

Change history		
Version No	**Date**	**Reason for Change**