

Technical Agreement

For the supply of products between

Contract Giver

Avana Healthcare Ltd
Unit 2 Eddington Lane,
Eddington Business Park,
Herne Bay
Kent
CT6 5TG

WDA

AND

Contract Acceptor

WDA

DATED

The object of this Agreement is to set out the arrangements and responsibilities between both parties, required under current Good Manufacturing Practice legislation and Good Distribution Practice (GDP), and as detailed in the Rules and Guidance for Pharmaceutical Manufacturers and Distributors, The Falsified Medicines Directive, to cover the supply, storage and distribution of medicinal products, as set out in the EU GDP directive 2001/83/EC.

Responsibilities

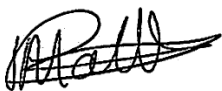
Storage and Distribution		Contract Giver	Contract Acceptor
	Hold and maintain a valid authorisation / license from the local competent authority for the storage and distribution of pharmaceutical products.	X	X
	Contract Acceptor shall inform Contract Giver about any change or withdrawal of such authorisation / license without undue delay. Contract Acceptor is responsible for providing Contract Giver with an updated copy of the license / authorisation once it becomes available.		X
	Store and distribute products in accordance with EU/EEA legislation: Directive 2004/27/EC on human products; Directive 2001/83/EC Articles 76-85; EU Good Distribution Practice (GDP) Guidelines (2013/C 343/01) and local regulations. Distribute products under appropriate transportation conditions (i.e. temperature, time, packaging etc) as agreed to by the parties and handle and store all products so they remain fit and effective for their intended use.	X	X
Personnel		Contract Giver	Contract Acceptor
	Ensure that personnel involved in GDP activities are competent and have appropriate, periodic training on GDP activities relevant to their job description.	X	X
	Inform each other of changes to the nominated contact list.	X	X
Storage		Contract Giver	Contract Acceptor
	Premises designed to ensure the conservation, security and distribution of pharmaceutical products and to prevent contamination by rodents and insects.	X	X
	Storage facilities maintained in a clean and well organised manner. Schedule, verify and document cleaning activities.	X	X
	Perform temperature mapping studies of product storage areas at appropriate time intervals or after changes to storage areas.	X	X
	Monitor and record storage conditions using calibrated devices. Review records weekly.	X	X
	Products stored in accordance with current guidelines on Good Distribution Practice and according to the product's specific storage conditions.	X	X

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Documentation		
	Contract Giver	Contract Acceptor
Construct and maintain written procedures, approved by the Responsible Person, that describe all the GDP related activities undertaken by the company.	X	X
Retention of all records relating to the storage and distribution of products for a period of at least 5 years.	X	X
Both parties must maintain batch tracking records for all medicines supplied to customers.	X	X
Contract Acceptor will verify that its suppliers are authorised to supply appropriately licenced medicinal products.		X
Contract Acceptor is responsible for maintaining a list of approved EU wholesalers which have been authorised as sources to supply products. Products must not be sourced from an unauthorised supplier.	X	X
Operations		
	Contract Giver	Contract Acceptor
Contract Giver to provide Contract Acceptor with the purchase order number, product licence number, minimum batch quantity & expiry, how long the PO remains open for and other relevant details for products ordered.	X	
In advance of the purchase order, Contract Giver must ensure that Contract Acceptor WDA authorises the receipt of product type under enquiry.	X	
Ensure that all products are distributed in accordance with GDP.	X	X
Ensure products are transported to designated delivery point, under any special product storage conditions required, using own vehicles or approved carriers, who have been audited and approved.	X	X
Delivery paperwork to be supplied with all deliveries and clearly state the following: Customer name & address, delivery address, delivery date, purchase order number, product description, quantity, batch numbers, expiry dates, date of collection, and signature of driver upon collection.	X	X
Contract Acceptor takes full responsibility for the collection and transportation of Cold-Chain goods. Avana Healthcare will only hand over goods to couriers that are approved and inspected vehicles prior to hand over of goods. Avana Healthcare reserves the right not to hand over consignments.		X

Avana Healthcare have GDP responsibility only up to the collection of goods if the goods are collected by the Contract Acceptor. Hence the moment the goods leave the premises the GDP responsibility passes over to the Contract Acceptor.		X
Both parties must remain vigilant of falsified medicinal products. If one party suspects products are falsified, they must notify the other party immediately. Stock suspected of being falsified must be quarantined immediately. The relevant regulatory body and the Manufacturing Authorisation Holder (MAH) must be contacted.	X	X
Deviations		
	Contract Giver	Contract Acceptor
Provide Contract Giver with a nominated contact for notifying any quality/service issues in relation to a delivery		X
Notify Contract Giver by email within 48 hours of significant deviations, including but not limited to: Any significant delivery quantity inaccuracy, any issues relating to the expiry date of product ,any damaged stock received , any suspicions that stock may be falsified or tampered with .		X
Returns		
	Contract Giver	Contract Acceptor
Products should be returned to the Contract Giver in line with the Contract Givers return procedure and it should not exceed 5 days for ambient between despatch and return. Cold chain lines are only to have authorised return by the Contract Givers RP, Controlled Drugs are non-returnable. Also, ensure relevant paperwork accompanies each returned product.		X
Inform Contract Giver of any product quality complaints or adverse events brought to its attention in a timely manner. Maintain a record of these complaints.		X
Contract Giver to investigate complaints raised by the Contract Acceptor in a timely manner and according to the Contract Givers procedure.	X	
If the Contract Acceptor receives an adverse or suspected adverse drug reaction report in relation to a product supplied by the Contract Giver, the Contract Acceptor is to communicate this information to the CG or directly to the MAH within 24 hours.		X

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Product Recalls		Contract Giver	Contract Acceptor
Contract Giver will notify the Contract Acceptor of any MHRA Product recalls in relation to stock they have supplied.		X	
Contract Acceptor must inform the Contract Giver if they have any of the affected batches in stock that have been supplied by the Contract Giver.			X
Contract Giver will send relevant returns paperwork to the Contract Acceptor to approve before returning.		X	
Inspections		Contract Giver	Contract Acceptor
Contract Giver will give Contract Acceptor and the relevant regulatory agencies all possible assistance to satisfy themselves, by way of an audit if necessary, that Contract Giver is GDP compliant. Any areas requiring attention/improvement will be rectified within 60 days of these being raised by the Contract Giver or regulatory agencies, unless Contract Acceptor can satisfactorily justify these being unnecessary.		X	
Contract Giver		Contract Acceptor	
Avana Healthcare LTD			
Name	Maya Patel	Name	
Signature		Signature	
Date		Date	
Position	RP	Position	