

STANDARD TERMS AND CONDITIONS OF PURCHASE (US)

1. Interpretation

- 1.1 The rules of interpretation and definitions that apply to this Contract are as set out in Appendix 1.

2. Basis of contract

- 2.1 These Conditions apply to the Contract to the exclusion of any other terms that the Supplier seeks to impose or incorporate contained or referenced in any document issued by the Supplier to the Customer (including any acknowledgement or other form of acceptance, quotation, delivery note) or which may be implied by law, trade custom, practice or course of dealing. Without prejudice to the foregoing, where the Supplier and the Customer enter into a written agreement, signed by both parties for the supply of the Goods such agreement will supersede and extinguish all previous and contemporaneous agreements and understandings between them, including the Contract.

- 2.2 The Order constitutes an offer by the Customer to purchase the Goods in accordance with these Conditions.

- 2.3 The Order shall be deemed to be accepted on the earlier of:

- (a) the Supplier issuing a written acceptance of the Order; and
- (b) the Supplier doing any act consistent with fulfilling the Order

at which point the Contract shall come into existence.

3. Goods

- 3.1 The Supplier shall ensure that the Goods shall:

- (a) correspond with their description and any applicable Specification and QTA;

- (b) be of satisfactory quality and fit for any purpose held out by the Supplier or made known to the Supplier by the Customer expressly or by implication;
- (c) be free from defects in design, material and workmanship;
- (d) comply with all Applicable Laws including statutory and regulatory requirements relating to the Manufacture and supply of the Goods; and
- (e) comply in full with any and all quality requirements set out in or referenced in the Order, the QTA and any other reasonable quality requirements as notified by the Customer to the Supplier from time to time.

3.2 The Supplier shall ensure that at all times:

- (a) it has and maintains all the licenses, permissions, authorizations, consents and permits that it needs to Manufacture (if the Supplier is the Manufacturer of the Goods) and supply the Goods (including the storage and handling of Materials) and to carry out its obligations under the Contract; and
- (b) it handles and stores Materials and Goods in accordance with: (i) any temperature and storage requirements set out in the Order, the QTA or as otherwise agreed by the parties in writing; (ii) best practice and quality standards in the Supplier's industry; and (iii) as per relevant and current quality standards.

3.3 The Customer may inspect and test the Goods at any time before delivery. The Supplier shall remain fully responsible for the Goods despite any such inspection or testing and any such inspection or testing shall not reduce or otherwise affect the Supplier's obligations or liability under the Contract.

3.4 If following such inspection or testing the Customer considers that the Goods do not conform or are unlikely to comply with the Supplier's undertakings at clause 3.1 or 3.2, the Customer shall inform the Supplier and the Supplier shall immediately take such remedial action as is necessary to ensure compliance.

3.5 The Customer may conduct further inspections and tests after the Supplier has carried out its remedial actions.

4. Delivery

4.1 The Supplier shall deliver the Goods in accordance with the Incoterms 2020 rule stated in the Order, to the location specified in the Order together with a delivery note specifying the date of the Order, the Order number (if any), the type and quantity of the

Goods (including the code number of the Goods, where applicable), special storage instructions (if any) and any other documentation or information required by the Contract or otherwise by the Customer:

- (a) on the Delivery Date;
- (b) at the Delivery Location; and
- (c) during the Customer's normal business hours, or as instructed by or otherwise agreed in writing by the Customer.

4.2 Delivery of the Goods shall occur on the completion of unloading the Goods at the Delivery Location.

4.3 The Customer may require the Supplier to delay delivery of the Goods or suspend performance under the Contract for a period of up to three months.

4.4 If the Supplier requires the Customer to return any packaging material to the Supplier, that fact must be clearly stated on the delivery note and any such packaging material shall be returned to the Supplier at the cost of the Supplier.

4.5 The Supplier shall not deliver the Goods in installments without the Customer's prior written consent. Where it is agreed by the Customer that the Goods are to be delivered in installments, each installment may be invoiced and paid for separately. Any failure by the Supplier to deliver any one installment in accordance with delivery dates agreed in advance and in writing by the Customer, or at all, or any defect in an installment shall entitle the Customer to the remedies set out in clause 5.

4.6 The Customer shall not be required to accept delivery of any Goods prior to the Delivery Date.

5. Customer remedies

5.1 If the Goods are not delivered on the Delivery Date, or do not comply with the undertakings set out in clause 3.1, then, without limiting any of its other rights or remedies, and whether or not it has accepted the Goods, the Customer may exercise any one or more of the following rights and remedies:

- (a) terminate the Contract;
- (b) reject the Goods (in whole or in part) and return them to the Supplier at the Supplier's own risk and expense;

- (c) require the Supplier to replace the rejected Goods, or to provide a full refund of the price of the rejected Goods (if paid);
- (d) refuse to accept any subsequent delivery of the Goods which the Supplier attempts to make;
- (e) recover from the Supplier any costs incurred by the Customer in obtaining substitute goods from a third party; and
- (f) claim damages for any other costs, losses or expenses incurred by the Customer which are in any way attributable to the Supplier's failure to carry out its obligations under the Contract.

5.2 If the Goods are not delivered on the Delivery Date the Customer may, at its option, claim or deduct by way of liquidated damages 2% of the price of the Goods for each week's delay in delivery until the earlier of delivery by the Supplier or termination or abandonment of the Contract by the Customer, up to a maximum of 50% of the total price of the Goods. Such liquidated damages have been calculated, and are a genuine pre-estimate of the loss likely to be suffered by the Customer.

5.3 These Conditions shall apply to any replacement Goods supplied by the Supplier.

5.4 The Customer's rights and remedies under these Conditions are in addition to its rights and remedies implied by statute and common law.

6. Title and risk

Title to and risk in the Goods shall pass to the Customer on completion of delivery.

7. Price and payment

7.1 The price of the Goods and the currency for payment will be set out in the Order. If no price is quoted in the Order, the price will be the last price quoted in writing by the Supplier to the Customer, and if the Supplier has not quoted a price in writing, it will be the price as set out in the Supplier's published price list in force as at the date the Contract comes into existence.

7.2 The price of the Goods:

- (a) excludes amounts in respect of value added tax or any other similar tax (**VAT**) payable in the Customer's jurisdiction of incorporation, which the

Customer shall additionally be liable to pay to the Supplier at the prevailing rate, subject to the receipt of a valid VAT invoice; and

- (b) unless stated otherwise in the Order, includes the costs of packaging, insurance and carriage of the Goods.

7.3 No extra charges shall be effective unless agreed in writing with the Customer.

7.4 The Supplier may invoice the Customer for price of the Goods plus VAT at the prevailing rate (if applicable) on or at any time after the completion of delivery. The Supplier shall ensure that the invoice includes the date of the Order, the invoice number, the Supplier's VAT registration number and any supporting documents that the Customer may reasonably require.

7.5 Provided the Goods are free from defects, the Customer shall pay undisputed, correctly rendered invoices within 60 days' of receipt by the Customer of the undisputed invoice. Payment shall be made to the bank account nominated in writing by the Supplier.

7.6 If the Customer fails to make any payment due to the Supplier under the Contract by the due date for payment, the Supplier will be entitled to charge interest on all undisputed overdue amounts at a rate of 3% per annum above the Bank of England's base rate from time to time, but at 3% a year for any period when the base rate is below 0%, accruing on a simple basis from the day the amount became overdue and ending on the day payment is received in full by the Supplier.

7.7 The Customer may at any time, set off any liability of the Supplier to the Customer against any liability of the Customer to the Supplier, whether either liability is present or future, liquidated or unliquidated, and whether or not either liability arises under the Contract. If the liabilities to be set off are expressed in different currencies, the Customer may convert either liability at a market rate of exchange for the purpose of set-off. Any exercise by the Customer of its rights under this clause shall not limit or affect any other rights or remedies available to it under the Contract or otherwise.

8. Customer Materials

The Supplier acknowledges that all materials, equipment, tools, drawings, Specifications and data supplied by or on behalf of the Customer to the Supplier, including the Customer's Background IP (**Customer Materials**) and all rights in and to the Customer Materials are and shall remain the exclusive property of the Customer. The Supplier shall keep the Customer Materials in safe custody and at its own risk, maintain them in good condition until returned to the Customer and not dispose or use the same other

than in accordance with the Customer's written instructions and the terms of the Contract.

9. Recall and complaints

9.1 Subject to the terms of the QTA, if the Customer decides to recall any Goods or is the subject of a request, court order or other directive of a Regulatory Authority to withdraw any Goods from the market, it shall promptly notify the Supplier in writing and the parties agree that the Customer's recall procedures, as notified to the Supplier from time to time, shall apply and be followed. Without limiting the generality of the foregoing, the parties will cooperate with each other, including by providing information on track and traceability in connection with any such recall. In the event that a recall results from a failure by the Supplier to Manufacture or supply the Goods in accordance with the terms of the Contract, the Supplier shall be responsible for all expenses and costs arising out of the recall. In the event that a recall results from any reason other than the Supplier's failure to Manufacture or supply the Goods in accordance with the terms of the Contract, the Customer shall be responsible for all expenses and costs arising out of the recall and will indemnify the Supplier for any direct losses suffered by the Supplier arising out of or resulting from such recall, which in all cases shall be limited to the loss of actual direct costs and expenses of the Supplier (excluding any incidental, consequential, loss of revenue or other types of damages or costs).

10. Subject to the terms of the QTA, in relation to any complaint relating to the Goods from customers, patients, doctors and/or any Regulatory Authority (each a **Complaint**), the Supplier shall cooperate with the Customer in all activities relating to investigations of a Complaint, to the extent reasonably requested by the Customer. For the avoidance of doubt, the Customer shall have the sole responsibility for handling all Complaints.

11. Indemnity

11.1 The Supplier shall indemnify the Customer, its Affiliates, their respective officers, directors, employees, representatives and agents (**Indemnified Party**) against all liabilities, costs, expenses, damages and losses (including any direct, indirect or consequential losses, loss of profit, loss of reputation and all interest, penalties and legal costs (calculated on a full indemnity basis) and all other reasonable professional costs and expenses) suffered or incurred by an Indemnified Party as a result of or in connection with:

- (a) any claim made against an Indemnified Party for actual or alleged infringement of a third party's Intellectual Property Rights arising out of or in connection with the Manufacture, supply or use of the Goods, to the extent

that the claim is attributable to the acts or omissions of the Supplier, its employees, agents or subcontractors;

- (b) any claim made against an Indemnified Party by a third party for death, personal injury or damage to property arising out of or in connection with defects in Goods, to the extent that the defects in the Goods are attributable to the acts or omissions of the Supplier, its employees, agents or subcontractors; and
- (c) any claim made against an Indemnified Party by a third party arising out of or in connection with the Manufacture or supply of the Goods, to the extent that such claim arises out of the breach, negligent performance or failure or delay in performance of the Contract by the Supplier, its employees, agents or subcontractors.

11.2 This clause 11 shall survive termination of the Contract.

12. Intellectual Property Rights

12.1 All Background IP is and shall remain the exclusive property of the party owning it (or, where applicable, the third party from whom its right to use the Background IP has derived).

12.2 Save in relation to Manufacturing Improvements which shall vest in and be owned by the Supplier, all other New IP shall vest in and be owned absolutely by the Customer and shall be the Confidential Information of the Customer (**Customer New IP**). The Supplier shall promptly inform the Customer in writing of the creation of any New IP and at the Customer's request do everything reasonably necessary to assign and transfer such Customer New IP (including a written irrevocable waiver of all Supplier's employees, agents, officers, advisers and other representatives' statutory moral rights in the Customer New IP, to the fullest extent permissible by law,) absolutely to the Customer. To the extent that any Customer New IP is capable of prospective assignment, the Supplier hereby assigns such Customer New IP to the Customer and to the extent any such Customer New IP cannot be so assigned, the Supplier will assign that Customer New IP to the Customer as and when it is created, at the request of the Customer.

12.3 All Confidential Information of the Customer and Customer Materials are and shall remain the exclusive property of the Customer.

12.4 Save as expressly provided in the Contract, nothing under the Contract constitutes a grant of a license of any Intellectual Property Rights of one party to the other party.

- 12.5 Neither party shall do or omit to do, any act or thing to prejudice or otherwise adversely affect the other party's Intellectual Property Rights.
- 12.6 To the extent that the Supplier sub-contracts performance of any of its obligations under the Contract, in accordance with the terms of the Contract, the Supplier shall ensure that any New IP arising from services performed by its subcontractors shall be assigned to it absolutely.
- 12.7 The Supplier undertakes to the Customer:
- (a) not to register nor attempt to register any of the Customer Background IP or Customer New IP; and
 - (b) to execute all documents, make all applications, give all assistance and do all acts and things, at any time either during or after termination of the Contract, as may in the opinion of the Customer, be necessary or desirable to vest the Intellectual Property Rights in, and register or obtain patents or registered designs in, the name of the Customer.
- 12.8 The Supplier warrants to the Customer that it has not given and will not give permission to any third party to use any of the Customer New IP.
- 12.9 The Supplier acknowledges that no further remuneration or compensation other than provided for in the Contract is or may become due to the Supplier in respect of the performance of its obligations under this clause 12.
- 12.10 The Customer grants to the Supplier a royalty-free, non-exclusive, non transferable, non-sublicensable license for the term of the Contract: (a) to its Background IP; and (b) the Customer New IP for the sole purpose of Manufacturing and supplying the Goods.
- 12.11 The Supplier grants to the Customer a royalty-free, non-exclusive license to its Manufacturing Know-How and to the Manufacturing Improvements for the purpose of receiving the Goods and where applicable the resale of the Goods and to the extent reasonably required to enable the Customer to independently Manufacture or have Manufactured the Goods in the event that the Supplier is unable to Manufacture and supply the Goods in accordance with the terms of this Contract.

13. Insurance

During the term of the Contract and for a period of three (3) years thereafter, the Supplier shall maintain in force, with a reputable insurance company, professional

indemnity insurance, product liability insurance and public liability insurance to cover the liabilities that may arise under or in connection with the Contract, and shall, on the Customer's request, produce both the insurance certificate giving details of cover and the receipt for the current year's premium in respect of each insurance.

14. Confidentiality

- 14.1 Each party shall keep the other party's Confidential Information confidential and shall not: (a) use such Confidential Information except for the purpose of exercising or performing its rights and obligations under or in connection with the Contract; or (b) disclose such Confidential Information in whole or in part to any third party, except as expressly permitted by this clause 14.
- 14.2 Each party may disclose the other party's Confidential Information: (a) to its employees, officers, agents, consultants or permitted subcontractors (**Representatives**) who need to know this information for the purposes of carrying out the party's obligations under the Contract, provided that the disclosing party takes all reasonable steps to ensure that its Representatives comply with the confidentiality obligations contained in this clause 14 as though they were a party to the Contract. The disclosing party shall be responsible for its Representatives' compliance with the confidentiality obligations set out in this clause 14; and (b) as may be required by law, a court of competent jurisdiction, or any governmental or Regulatory Authority, provided that, where permissible, it takes into account the reasonable requests of the other party in relation to the content of such disclosure.
- 14.3 Each party reserves all rights in its Confidential Information. No rights or obligations in respect of a party's Confidential Information other than those expressly stated in the Contract are granted to the other party or to be implied from the Contract.
- 14.4 The provisions of this clause shall not apply to any Confidential Information that the receiving party can prove to the reasonable satisfaction of the disclosing party from written records or other substantive evidence: (a) is or becomes generally available to the public (other than as a result of its disclosure by the receiving party or its Representatives in breach of this clause); (b) was available to the receiving party on a non-confidential basis before disclosure by the disclosing party; (c) was, is or becomes available to the receiving party on a non-confidential basis from a person who is not bound by a confidentiality agreement with the disclosing party or otherwise prohibited from disclosing the information to the receiving party; or (d) the parties agree in writing is not confidential or may be disclosed.

- 14.5 Except as expressly stated in the Contract, no party makes any express or implied warranty or representation concerning its Confidential Information.
- 14.6 The provisions of this clause 14 shall continue to apply after termination of the Contract.
- 14.7 Supplier may not use, in advertising or publicity, the Customer's name without Customer's prior written approval for each instance of use.

15. Compliance with relevant laws and policies

- 15.1 In performing its obligations under the Contract, the Supplier shall:
- (a) comply with all Applicable Laws; and
 - (b) comply with the Mandatory Policies.
- 15.2 The Customer may immediately terminate the Contract for any breach of clause 15.

16. Termination

- 16.1 The Customer may terminate the Contract in whole or in part up to one month before the Delivery Date with immediate effect by giving the Supplier written notice, whereupon the Supplier shall discontinue all work on the Contract. The Customer shall pay the Supplier fair and reasonable compensation on a pro-rated basis for any work in progress on the Goods at the time of termination, but such compensation shall not include loss of anticipated profits or any consequential loss.
- 16.2 Without limiting its other rights or remedies, including its other rights of termination in the Contract, the Customer may terminate the Contract with immediate effect by giving written notice to the Supplier if:
- (a) the Supplier commits a material breach of any term of the Contract and (if such a breach is remediable) fails to remedy that breach within 15 days of being notified in writing to do so;
 - (b) the Supplier takes any step or action in connection with its entering administration, provisional liquidation or any composition or arrangement with its creditors (other than in relation to a solvent restructuring), obtaining a moratorium, being wound up (whether voluntarily or by order of the court, unless for the purpose of a solvent restructuring), having a receiver appointed to any of its assets or ceasing to carry on business or, if the step

or action is taken in another jurisdiction, in connection with any analogous procedure in the relevant jurisdiction;

- (c) the Supplier takes any step or action in connection with the Supplier being made bankrupt, entering any composition or arrangement with its creditors, having a receiver appointed to any of its assets, or ceasing to carry on business or if the step or action is taken in another jurisdiction, in connection with any analogous procedure in the relevant jurisdiction;
- (d) the Supplier suspends, or threatens to suspend, or ceases or threatens to cease to carry on all or a substantial part of its business; or
- (e) the Supplier's financial position deteriorates so far as to reasonably justify the opinion that its ability to give effect to the terms of this agreement is in jeopardy.

16.3 On termination or expiry of the Contract, the Supplier shall immediately return all Customer Materials and any and all documents and materials containing, reflecting, incorporating, or based on any Confidential Information of the Customer. If the Supplier fails to do so, then the Customer may enter the Supplier's premises and take possession of them. Until they have been returned or delivered, the Supplier shall be solely responsible for their safe keeping and will not use them for any purpose not connected with the Contract.

16.4 Termination or expiry of the Contract, however arising, shall not affect any of the parties' rights and remedies that have accrued as at termination or expiry, including the right to claim damages in respect of any breach of the Contract which existed at or before the date of termination or expiry.

16.5 The provisions of clauses 1, 5, 9, 11,12, 14, 16, 18 and 19 will survive termination or expiry of the Contract.

17. Force majeure

Neither party shall be in breach of the Contract nor liable for delay in performing, or failure to perform, any of its obligations under the Contract if such delay or failure result from a Force Majeure Event. The affected party will use all reasonable endeavors to mitigate the effect of a Force Majeure Event. In such circumstances the affected party shall be entitled to a reasonable extension of the time for performing such obligations. If the period of delay or non-performance continues for four (4) weeks, the party not affected may terminate the Contract by giving five (5) days' written notice to the affected party.

18. Limitation of liability

18.1 Without prejudice to clause 18.3 and 18.4, the Customer's total liability arising under or in connection with this Contract/an Order, whether arising in contract, tort (including negligence), for breach of statutory duty, misrepresentation, restitution or otherwise, shall in all circumstances be limited to 200% of the amount paid by the Customer under the Order.

18.2 Without prejudice to clause 18.3 and 18.4, the Supplier's total liability arising under or in connection with this Contract/an Order, whether arising in contract, tort (including negligence), for breach of statutory duty, misrepresentation, restitution or otherwise, shall in all circumstances be limited to the higher of (i) \$1 million or (ii) an amount equal to the value of the Orders placed by the Customer with Supplier during the twelve (12) Month period prior to the date that the act giving rise to the liability has taken place and for the avoidance of doubt shall include the value of the Order which has given rise the liability even if it has not been paid for by the Customer.

18.3 Without prejudice to clause 18.4, neither party shall under any circumstances whatsoever be liable to the other, whether in contract, tort (including negligence) or restitution, or for breach of statutory duty or misrepresentation, or otherwise, for any:

loss of profit; or

loss of goodwill; or

loss of business; or

loss of business opportunity; or

loss of anticipated saving; or

loss or corruption of data or information; or

special, indirect or consequential damage

suffered by the other party that arises under or in connection with the Goods and/or this agreement.

18.4 Nothing in this Contract shall limit or exclude the liability of either party:

(a) for death or personal injury resulting from negligence;

(b) for fraud or fraudulent misrepresentation; or

(c) that may not otherwise be excluded by law.

19. General

19.1 Assignment and other dealings

- (a) The Customer may at any time assign, transfer, mortgage, charge, subcontract, delegate, declare a trust over or deal in any other manner with any or all of its rights or obligations under the Contract.
- (b) The Supplier may not assign, transfer, mortgage, charge, delegate, declare a trust over or deal in any other manner with any or all of its rights or obligations under the Contract without the prior written consent of the Customer.

19.2 Entire agreement. The Contract constitutes the entire agreement between the parties and supersedes and extinguishes all previous agreements, promises, assurances, warranties, representations and understandings between them, whether written or oral, relating to its subject matter.

19.3 Variation. Except as set out in these Conditions, no variation of the Contract, including the introduction of any additional terms and conditions, shall be effective unless it is agreed in writing and signed by the Customer.

19.4 Waiver. No failure or delay by a party to exercise any right or remedy provided under the Contract or by law shall constitute a waiver of that or any other right or remedy, nor shall it prevent or restrict the further exercise of that or any other right or remedy. No single or partial exercise of such right or remedy shall prevent or restrict the further exercise of that or any other right or remedy.

19.5 Severance. If any provision or part-provision of the Contract is or becomes invalid, illegal or unenforceable, it shall be deemed deleted, but that shall not affect the validity and enforceability of the rest of this agreement. If any provision of the Contract is deemed deleted under this clause 19.5 the parties shall negotiate in good faith to agree a replacement provision that, to the greatest extent possible, achieves the intended commercial result of the original provision.

19.6 Notices.

- (a) Any notice or other communication given to a party under or in connection with the Contract shall be in writing and shall be:
 - (i) delivered by hand or by pre-paid first-class post or other next working day delivery service at its registered office (if a company) or its principal place of business (in any other case); or

- (ii) sent by email to the address specified in the Order.
- (b) Any notice or communication shall be deemed to have been received:
 - (i) if delivered by hand, at the time the notice is left at the proper address;
 - (ii) if sent by pre-paid first-class post next working day delivery service, at 9:00 am on the second Business Day after posting; or
 - (iii) if sent by email at the time of transmission, or, if this time falls outside business hours in the place of receipt, when business hours resume. In this clause 19.6(b)(iii), business hours means 9:00 am to 5:00 pm Monday to Friday on a day that is not a public holiday in the place of receipt.
- (c) This clause does not apply to the service of any proceedings or other documents in any legal action or, where applicable, any arbitration or other method of dispute resolution.

19.7 Third party rights. Unless it expressly states otherwise, the Contract shall not confer any rights or remedies upon any person or entity other than the parties named herein and their respective successors and permitted assigns..

19.8 Governing law. The Contract, and any dispute or claim (including non-contractual disputes or claims) arising out of or in connection with it or its subject matter or formation, shall be governed by and construed in accordance with the law of the State of North Carolina.

19.9 Jurisdiction. Each party irrevocably agrees that the courts of North Carolina shall have exclusive jurisdiction to settle any dispute or claim (including non-contractual disputes or claims) arising out of or in connection with the Contract or its subject matter or formation.

Appendix 1

1. Definitions:

Affiliates: means as to any person, any other person that is in Control of, is Controlled by, or is under common Control with such person.

Applicable Law: all applicable local, foreign and international laws, common laws, judicial or administrative decisions, statutes, ordinances, regulations and rules and published guidelines or pronouncements governing the Manufacture, supply, marketing, advertising, distribution and sale of the Goods including GMP, GDP and all relevant anti-corruption laws and laws relating to the processing of personal data and all regulations, rules or published guidelines or pronouncements having the effect of law promulgated by any Regulatory Authority.

Background IP: Intellectual Property Rights owned or controlled by a party prior to the date of the Contract or generated or acquired by either party at any time other than in the course of Manufacturing or supplying the Goods.

Business Day: a day other than a Saturday, Sunday or public holiday in the United States of America, when banks are open for business.

Conditions: the terms and conditions set out in this document as amended from time to time in accordance with clause 19.3.

Contract: the contract between the Customer and the Supplier for the sale and purchase of the Goods in accordance with these Conditions.

Confidential Information: any and all information of a confidential nature (however recorded or preserved) disclosed by a party or its Representatives to the other party and/or that party's Representatives whether before or after the date of the Contract, in connection with the Contract, including (i) the existence and terms of the Contract; and (ii) any information that would be regarded as confidential by a reasonable business person, including information relating to: (a) the business, affairs, customers, clients or suppliers of the disclosing party or of any of its Affiliates; (b) the operations, processes, plans, product information, know-how, designs, trade secrets, software and market opportunities of the disclosing party or of any of its Affiliates. For the avoidance of doubt, the Customer Materials, Customer's Background IP and the Customer New IP are the Confidential Information of Customer.

Control: having sufficient power through voting shares of a company or otherwise to direct the corporate activities and guide and/or make the decisions on its behalf..

Customer: Alliance Pharma Inc., a Delaware corporation with its principal place of business located at 11000 Regency Pkwy, Ste 106, Cary, NC 27518 or any Affiliate company of the Customer which is detailed on the Order.

Customer Materials: has the meaning set out in clause 8.

Delivery Date: the date specified in the Order, or, if none is specified, as agreed by the parties in writing.

Delivery Location: the address for delivery of Goods as set out in the Order.

Goods: goods or products (or any part of them) set out in the Order.

GDP: means all applicable then-current standards for the distribution of Goods, including the Applicable Laws in any relevant state, region or country, each as may be amended and applicable from time to time.

GMP: means all applicable then-current standards for Manufacturing, including, as applicable, (a) the principles detailed in the U.S. Current Good Manufacturing Practices, 21 C.F.R. §§ 111 and 117, and all applicable FDA guidelines and requirements and (b) the equivalent Applicable Laws in any relevant state, region or country, each as may be amended and applicable from time to time.

GXP: the good practice quality guidelines and regulations.

Force Majeure: means any circumstance not in a party's reasonable control and which a party cannot prevent by taking reasonable measures and precautions including, acts of God, flood, drought, earthquake or other natural disaster, epidemic or pandemic, terrorist attack, civil war, civil commotion or riots, war, threat of or preparation for war, armed conflict, imposition of sanctions, embargo or breaking off of diplomatic relations, nuclear, chemical or biological contamination, or sonic boom, any law or any action taken by a government or public authority, including imposing an export or import restriction, quota or prohibition, collapse of buildings, fire, explosion or accident and interruption or failure of utility service.

Intellectual Property Rights: patents, utility models, rights to inventions, copyright and neighboring and related rights, trademarks and service marks, business names and domain names, rights in get-up and trade dress, goodwill and the right to sue for passing off or unfair competition, rights in designs, rights in computer software, database rights, rights to use, and protect the confidentiality of, confidential information (including know-how and trade secrets), and all other intellectual property rights, in each case whether registered or unregistered and including all applications and rights to apply for and be granted, renewals or extensions of, and rights to claim priority from, such rights and all similar or equivalent rights or forms of protection that subsist or will subsist now or in the future in any part of the world.

Mandatory Policies: the Customer's business policies on Ethical Standards and Human Rights, Sanctions, Anti-bribery, Corruption and Anti-Facilitation of Tax Evasion, Data

Privacy and Security as provided to the Supplier by the Customer and as amended by notification to the Supplier from time to time.

Manufacture: all operations involved in the planning, production, packaging, labelling, storage, sample retention, testing, release and dispatch and other handling of the Goods.

Manufacturing Know-How: means the Intellectual Property Rights owned or controlled by the Supplier prior to the date of the Contract or generated or acquired by the Supplier at any time other than in the course of Manufacturing and supplying the Goods which relate to the process or method of manufacture of products such as the Goods which is not Customer Background Intellectual Property.

Manufacturing Improvements: means any and all improvements, modifications or enhancements to Manufacturing Know-How that have been conceived, created, developed, and/or otherwise invented in relation to or as a result of the Manufacture and supply of the Goods.

Materials: all ingredients and components required to Manufacture and supply the Goods, including active ingredients, excipients, blends, printed and unprinted packaging, labels, leaflets, printed materials and any additional components included as part of the Goods e.g., measuring cups or droppers, but excluding any Packaging.

New IP: all Intellectual Property Rights created, generated, or identified by or on behalf of either party alone or jointly in relation to or as a result of the provision of the Manufacture or supply of the Goods.

Order: the Customer's order for the Goods, as set out in the Customer's purchase order form, the Customer's written acceptance of the Supplier's quotation, as the case may be.

Packaging: the packaging materials required to store and transport the Goods, details of which are set out in the Specification.

QTA: the quality agreement entered into by the parties, setting forth the responsibilities of Supplier and the Customer with respect to certain technical and quality activities required in connection with the Manufacture and supply of the Goods, as such agreement may be amended, supplemented or otherwise modified from time to time by the parties in writing and if no such agreement is in place, the quality agreement at Appendix 2.

Regulatory Authority: any local, state, federal, foreign or international governmental or regulatory body, court, agency, commission, official or arbitrator.

Representative: shall have the meaning as set out in clause 14.2.

Specification: any specification for the Goods, including any related plans and drawings, that is agreed in writing by the Customer and the Supplier.

Supplier: the person identified in the Order, from whom the Customer purchases the Goods.

2. Interpretation:

- (a) A **person** includes a natural person, corporate or unincorporated body (whether or not having separate legal personality).
- (b) The Contract shall be binding on, and inure to the benefit of, the parties to this Contract and their respective personal representatives, successors and permitted assigns, and a reference to a party includes its personal representatives, successors and permitted assigns.
- (a) A reference to legislation or a legislative provision is a reference to it as amended or re-enacted. A reference to legislation or a legislative provision includes all subordinate legislation made under that legislation or legislative provision.
- (b) Any words following the terms **including, include, in particular, for example** or any similar expression shall be construed as illustrative and shall not limit the sense of the words, description, definition, phrase or term preceding those terms.
- (c) A reference to **writing** or **written** includes emails.
- (d) Clause, Appendix and paragraph headings shall not affect the interpretation of the Contract.
- (e) The Appendices form part of the Contract and shall have effect as if set out in full in the body of the Contract. Any reference to the Contract includes the Appendices.
- (f) Unless the context otherwise requires, words in the singular shall include the plural and in the plural shall include the singular.
- (g) Any obligation on a party not to do something includes an obligation not to allow that thing to be done.

1.14 References to a document in agreed form are to that document in the form

Appendix 2 – Quality Agreement

1. Supplier shall Manufacture and supply the Goods using the highest level of skill, care and diligence in accordance with: (i) the applicable Specification as supplied by Customer; (ii) the terms of the Contract, and (iii) all Applicable Law, including GXP, all generally accepted and applicable industry standards and practices, and all manufacturing protocols agreed to by the parties.
2. The Goods supplied by Supplier under the Contract shall:
 - 2.1. conform to the Specification in full, including all Packaging, labelling and leaflets;
 - 2.2. be: (i) of satisfactory quality and fit for the purpose for which they are to be sold; and (ii) fit for any purpose held out by Supplier or made known to Supplier by Customer;
 - 2.3. be free from defects in design, material and workmanship and remain so for the stated shelf life of the Goods; and
 - 2.4. comply with all Applicable Law.
3. Supplier shall ensure that the Goods are properly packed, in the agreed Packaging as set out in the Specification and secured in a manner to enable them to reach their Delivery Location in good condition and that the Packaging is itself of satisfactory quality and fit for its purpose and free from any defects in design, material and workmanship.
4. Supplier shall store the Goods in accordance with: (i) GDP; (ii) any written instructions provided by Customer; and (iii) the applicable Specification, in each case (i) through (iii), until delivery to Customer.
5. Supplier shall obtain and maintain in force for the Term all licenses, permissions, authorizations, consents and permits needed to Manufacture and supply the Goods in accordance with the terms of the Contract.
6. Customer shall have the right to receive from Supplier upon written request lot specific Manufacturing records.
7. Customer shall have the right to receive from Supplier upon written request evidence of established Standard Operating Procedures and validated processes.
8. Customer and its Representatives shall have the right to enter the Supplier's facility and any other premises used by Supplier in relation to the Manufacture and/or supply of the Goods to:
 - 8.1. inspect the facility and such other premises and the equipment used by Supplier in the Manufacture and supply of the Goods:
 - 8.2. inspect and take samples of the Materials, Packaging and the Goods; and
 - 8.3. inspect stock levels of Materials, Packaging and Goods.

Inspections shall be carried out during business hours on reasonable notice to Supplier, provided that in the event of emergency, Supplier shall grant Customer expedited access to its premises.
9. If following an inspection Customer reasonably considers that the Goods are not or are not likely to meet the applicable Specification, Customer shall inform Supplier and Supplier shall immediately take any action as is necessary to ensure that the Goods are or will comply with the applicable Specification. Customer shall have the right to reconduct inspections and take further samples after Supplier has carried out its remedial actions.
10. Supplier shall provide reasonable cooperation in relation to Customer's efforts to obtain marketing authorization of each of the Goods.
11. Each party shall keep the other informed of any formal or informal inquiry from any Regulatory Authority relating to any Goods, in accordance with Applicable Law. Without

limiting the foregoing, if a Regulatory Authority makes an inquiry or otherwise requests information or assistance relating to any Goods, whether to Supplier or Customer, Supplier shall provide access to, and coordinate and make available, applicable personnel, facilities, materials, and documents as necessary to respond to such inquiries. Supplier shall promptly notify Customer in writing after learning of any proposed visit or inspection initiated or performed by any Regulatory Authority that would have a material impact on any Goods. Supplier shall cooperate with each such Regulatory Authority in connection with any such visit or inspection and shall permit Customer or its agents to be present and participate in such visit or inspection, unless prohibited by Applicable Law. Upon Customer's written request, Supplier shall provide to Customer a copy of any report and other written communications received from such Regulatory Authority in connection with such visit or inspection, and any written communications received from such Regulatory Authority relating to any Goods Manufactured in accordance with the Contract. Supplier shall review Customer's comments in good faith, if any, concerning the response of Supplier to each such communication to those responses made to those Regulatory Authorities. Supplier shall provide Customer with a copy of all final responses sent to such Regulatory Authority.

12. The supplier shall provide Alliance with an emergency contact on entering into this agreement.