

Sharp Clinical Services, LLC
Sharp Clinical Services (UK) Ltd.
Terms and Conditions



1. **Parties.** Whenever “Sharp” is used in these Terms and Conditions, it refers to Sharp Clinical Services, LLC and/or Sharp Clinical Services (UK) Ltd., and whenever “Customer” is used in these Terms and Conditions, it refers to the other contracting party to the Quote, whether the Quote be for the purchase of goods, performance of services, or both (collectively, the Quote and these Terms and Conditions, the “Agreement”).
2. **Acceptance; Entire Agreement.** These Terms and Conditions are for the purchase and sale of goods and services described in the Quote and constitute the sole terms and conditions of any Quote between the parties. Acceptance of these Terms and Conditions will be limited to the terms and conditions contained herein and incorporated by reference. These Terms and Conditions shall be deemed accepted upon either: (i) acceptance of this Quote, (ii) payment of any part of the services, or (iii) after 10 days’ receipt of the Quote, without objection. Further, Customer’s agreement to any Quote is expressly made conditional upon Customer’s agreement to these Terms and Conditions and Customer agrees that these are the only Terms and Conditions that the parties shall be bound. Sharp rejects any additional or inconsistent terms and conditions offered by Customer at any time, whether or not such terms or conditions materially alter the Terms and Conditions and irrespective of Sharp’s acceptance of or payment for goods or services. Sharp hereby notifies Customer that these Terms and Conditions are the only terms and conditions that Sharp agrees to be bound.
3. **Provision of Goods/Services.** Sharp shall provide the goods and services set forth in the applicable Quote or other written agreement in accordance with the specifications and with these Terms and Conditions. Sharp’s liability for failure to comply with the Agreement, and Customer’s sole remedy, shall be, at Sharp’s discretion, to replace or repair the goods and/or services not in conformity with the Agreement, in which case any non-conforming goods shall be returned to Sharp’s facilities for the purpose of replacement or repair. Customer shall give Sharp written notice of rejection of goods or services that fail to meet the specifications, or breaches Sharp’s warranties, covenants, and obligations under this Agreement, within thirty (30) days of delivery. Sharp, at its sole cost and expense, shall provide Customer with any missing quantities and replace as soon as commercially reasonable packaging for any non-conforming packaged products and Customer, at its sole cost and expense, shall replace applicable products and components for such non-conforming packaged products. Any claim of non-conforming goods or services must be made in writing to Sharp within the thirty (30) day period set forth above or it shall be deemed to have been waived by Customer. The obligation of Sharp set forth above to repair or replace non-conforming goods or services shall be Customer’s sole and exclusive remedy for non-conforming goods and services.
4. **Changes.** These Terms and Conditions may not be modified or cancelled without the written consent of Sharp, and these Terms and Conditions may not be modified or cancelled with respect to any portion of the Quote already in process, except upon terms satisfactory to Sharp, in its sole discretion. Despite the foregoing, Sharp may revise the price of the goods and services: (i) if Customer’s requirements or any Customer-provided information is inaccurate or incomplete; (ii) Customer and Sharp agree in writing to any changes in Sharp’s responsibilities or the project specifications, instructions, procedures, assumptions, processes, test protocols, test methods, or analytical requirements; or (iii) for such other reasons set forth in this Terms and Conditions or any agreement between Sharp and Customer.
5. **Payments.** Sharp shall invoice Customer as set forth in the Quote or a subsequent written agreement by the parties and Customer shall pay invoices within 30 days of the invoice date. Sharp will be entitled to charge a late payment fee of 1½% of all unpaid amounts per month. Failure to bill for interest due shall not constitute a waiver of Sharp’s right to charge interest. Sharp shall have, and Customer hereby grants to Sharp, a security interest in all of Customer’s products, packaged products and in any proceeds thereof, to secure payment of the purchase price for the goods and services provided by Sharp. Sharp shall have all of the rights and remedies in force and available to it as a matter of law in the jurisdiction where Sharp seeks to enforce any of such rights or remedies, including the rights and remedies available under the Uniform Commercial Code. If Sharp requests, Customer shall sign and deliver to Sharp such documents, in a form acceptable to Sharp, as Sharp may require to confirm or perfect its security interest in the products, packaged products, and proceeds thereof.
6. **Taxes.** Customer shall be responsible for all sales, use, gross receipts, compensating, value-added, or other taxes, duties, licenses, or fees, excluding Sharp’s net income and franchise taxes, assessed by any tax jurisdiction arising from the sale of goods and services, whether paid by Sharp or Customer.
7. **Hazardous Materials.** Customer warrants to Sharp that no specific safe handling instructions are applicable to any Customer-supplied materials, except as disclosed to Sharp in writing by Customer in sufficient time for review and training by Sharp prior to delivery. Customer will provide a Material Safety Data Sheet for all Customer-supplied materials and finished product.
8. **Title; Risk of Loss.** Title to all products, packaged products, all work in process to produce packaged products, and any other Customer-owned property shall remain with Customer at all times. Sharp shall not be liable for risk of loss to any of the foregoing or any other Customer-owned property, except for Sharp’s gross negligence or willful acts or omissions, in which case Sharp’s liability shall not exceed the fees paid to Sharp by Customer for such services as described in this Terms and Conditions, excluding pass through costs, during the 12 month period immediately preceding the event giving rise to the claim.
9. **Shipment.** Customer may arrange for Sharp to ship Customer’s products and materials in the Agreement. Despite the foregoing sentence, all products and materials shipped by Sharp will be made Ex-Works, Sharp’s loading docks at its facilities (Incoterms 2020). Customer shall arrange the shipment of any Customer supplied product and components to Sharp and such shipments will be made Delivered Duty Paid (Incoterms 2020).
10. **Limitation of Liability.** Sharp shall have no liability for any exemplary, punitive, incidental, indirect, special, or consequential damages, whether based on contract, tort, strict liability, or any other theory in connection with these Terms and Conditions. In addition, despite anything to the contrary in these Terms and Conditions, in no event shall Sharp’s liability exceed the fees paid to Sharp by Customer for such services as described in these Terms and Conditions, excluding pass through costs, during the 12 month period immediately preceding the event giving rise to the claim.
11. **Confidentiality.** Sharp and Customer shall not disclose any and all trade secrets, confidential or proprietary business information and any other confidential or proprietary information disclosed by a party (the “Discloser”) to the other party (the “Recipient”) or developed and/or discovered by either party as a result of the performance of services or using confidential or proprietary information of the other party (collectively, “Confidential Information”) to any person or entity, except: (i) to affiliates that are made aware of the confidential nature of the Confidential Information and agree to comply with the terms of this Agreement; (ii) to employees and authorized representatives of each party having a need to know the information in Terms and Conditions to fulfill such party’s obligations hereunder; or (iii) as required by applicable law. The parties shall use the Confidential Information solely for the purpose of carrying out the obligations contained in the Agreement. The obligations of Recipient specified above shall not apply to any Confidential Information to the extent that such Confidential Information: (a) is in the public domain at the time of disclosure or becomes part of the public domain after disclosure other than by breach of this Agreement; (b) was in the Recipient’s possession at the time of disclosure as established by reasonable proof; (c) is received by Recipient from a third party which had, to the knowledge of the Recipient, the right to disclose the information; (d) is subsequently and independently developed by Recipient without reference to or reliance upon the Discloser’s Proprietary Information; or (e) is required to be disclosed by Recipient to comply with applicable law, regulation, or legal process.



12. **Intellectual Property.** “Customer Property” means all intellectual property and embodiments thereof owned by or licensed to Customer as of the Effective Date or developed by Customer other than in connection with the goods and services performed by Sharp. “Sharp Property” means all intellectual property and embodiments thereof owned by or licensed to Sharp as of the Effective Date or developed by Sharp prior to or independent of any intellectual property specifically developed for Customer as part of the goods and services provided by Sharp under this Agreement. “Invention” means any intellectual property developed by either party in connection with the Agreement. “API Inventions” means any Invention that relates exclusively to the Customer IP or Customer’s patented active pharmaceutical ingredient (“API”). “Process Inventions” means any Invention, other than an API Invention, that relates exclusively to the Sharp IP or relates to developing, formulating, manufacturing, filling, processing, packaging, analyzing, or testing pharmaceutical products generally. Customer exclusively owns all Customer Property and API Inventions and no right therein is granted to Sharp under this Agreement except for use in performing the services. Sharp exclusively owns all Sharp IP and Process Inventions and no right therein is granted to Customer under this Agreement. All Inventions to generic API (other than API Inventions and Process Inventions), if any, shall be owned jointly by Sharp and Customer. The parties will cooperate to achieve the allocation of rights to Inventions anticipated herein. Each party shall be solely responsible for costs associated with the protection of its intellectual property.

13. **Warranties.** Sharp will provide goods and perform services in accordance with the written specifications and instructions expressly set forth or referenced in the Quote and in accordance with United States current Good Manufacturing Practices or current Good Laboratory Practices, as applicable. The warranties set forth in this section are the sole and exclusive warranties made by Sharp to Customer, and Sharp makes no other representations, warranties or guarantees of any kind whatsoever, including implied warranties of merchantability, non-infringement, or fitness for a particular purpose.

14. **Customer Obligations.** Unless otherwise agreed to by the parties in writing, it is solely Customer’s responsibility to (i) provide complete and accurate scientific data and specifications for the goods and/or services; (ii) if applicable, review and approve all in-process and finished product test results to ensure conformity of such results with the product specifications, regardless of which party is responsible for finished product release; (iii) prepare all submissions to regulatory authorities; and (iv) perform such other obligations of Customer set forth in the Agreement.

15. **Indemnification.** Customer will indemnify, defend and hold harmless, Sharp, its affiliates, and their respective directors, officers, employees, and agents against any claim arising directly or indirectly from (i) the manufacture, promotion, marketing, distribution, possession, sale, consumption or use of, or exposure to, the product, API and/or Customer-supplied materials; (ii) the negligence or willful misconduct of Customer; (iii) the breach of any representation, warranty, covenant or other provision of this Agreement by Customer; or (iv) the permitted use of Customer’s intellectual property. Sharp will indemnify, defend and hold harmless, Customer against any third-party claim arising directly or indirectly from the gross negligence or willful misconduct of Sharp. This provision will survive termination of this Agreement.

16. **Force Majeure.** Sharp shall not be liable for any failure to perform or for delay in performance resulting from any cause beyond its reasonable control, including without limitation, acts of God, fires, floods or weather, strikes or lockouts, factory shutdowns, embargoes, wars, riots, or shortages in transportation (each, a “Force Majeure”). If the Force Majeure continues unabated for more than 30 days, then the parties will discuss and negotiate in good faith what modifications to this Agreement should result from such Force Majeure.

17. **Use and Disposal.** Customer represents and warrants to Sharp that Customer will hold, use, and dispose of products and other materials

provided by Sharp in accordance with all applicable laws, rules, and regulations. Customer grants Sharp full authority to use any Customer-supplied materials for purposes of this Agreement.

18. **Record Retention; Regulatory Inspections.** Unless the parties otherwise agree in writing, Sharp will retain batch, laboratory, and other technical records for the minimum period required by applicable law. Sharp will promptly notify Customer of any regulatory inspections directly relating to this Agreement. Customer shall pay reasonable and documented costs charged by a regulatory authority for such inspections.

19. **Independent Contractor.** Sharp is an independent contractor in the performance of this Agreement and nothing herein may be construed to create a joint venture, co-partners, employer and employee, agent, or any other relationship.

20. **Publicity.** Neither party may make any press release or other public disclosure regarding this Agreement or the contemplated transactions without the other party's express prior written consent, except as required by applicable law, any governmental agency, or the rules of any stock exchange on which the shares of the other party are listed, in which case the party required to make the press release or public disclosure shall redact commercially sensitive information and use commercially reasonable efforts to obtain the approval of the other party as to the form, nature, and extent of the press release or public disclosure prior to issuing the press release or public disclosure.

21. **Precedence.** These Terms and Conditions supersede any conflicting terms and conditions set forth in the Quote. This Agreement constitutes the entire understanding between the parties and supersedes any contracts, agreements, purchase orders, or other understandings by the parties, with respect to the goods and services, but does not supersede a confidentiality agreement or a master services agreement between the parties, which agreements shall take precedence over any conflicting terms and conditions set forth in this Agreement. The parties agree this Agreement may only be amended in a signed written amendment.

22. **Governing Law.** The laws of the Commonwealth of Pennsylvania shall apply, without reference to principles of conflicts of laws, if this Agreement, is entered into by Sharp Clinical Services, LLC, solely, or together with Sharp Clinical Services (UK) Ltd and Customer. The Parties agree a suit may only be instituted at any federal court in the Eastern District of Pennsylvania or in state court in the Commonwealth of Pennsylvania. Each party waives any objection based on the venue of any action, suit, or proceeding, and irrevocably submits to the personal jurisdiction of any such court. If this Agreement is entered into by Sharp Clinical Services (UK) Ltd. and not Sharp Clinical Services, LLC, shall be construed and enforced in accordance with the laws of England and Wales and shall be subject to the exclusive jurisdiction of the English courts. When this Agreement is entered into by Sharp Clinical Services (UK) Ltd., Enestia Belgium NV, and/or EPC Production BV, and/or European Packaging Center BV, the laws of England and Wales shall apply. The United National Convention on the International Sale of Goods shall not apply to this Agreement. This Agreement is a joint product of both parties and shall not be construed for or against either party based on the principles of *contra proferentem* or any other presumption as to inequality of bargaining power.