

SHARP STERILE MANUFACTURING, LLC
TERMS AND CONDITIONS

1. **PARTIES.** Whenever "SSM" is used in these Terms and Conditions, it refers to Sharp Sterile Manufacturing, LLC, as applicable, and whenever "Buyer" 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"). Subject to the terms and conditions below and set forth elsewhere in the Proposal/Scope of Work package (the "Quotation"), Berkshire Sterile Manufacturing, LLC ("SSM") will provide the services described in the Quotation ("Services").
2. **ACCEPTANCE OF PURCHASE ORDERS.** The Quotation terms are offered only to the entity to whom it is addressed ("Buyer") and only until the date stated, or 180 days from submission to Buyer, whichever is earlier. These Terms and Conditions shall be deemed accepted upon either: (i) acceptance of this Quote or (ii) payment of any part of the services. Notwithstanding that Buyer's purchase order shall include different or additional terms, whether or not such terms are material, the Terms and Conditions shall take precedence over such Purchase Order and any such terms of Buyer's Purchase Order shall be null and void. **SSM HEREBY NOTIFIES BUYER THAT THE TERMS AND CONDITIONS INCLUDED HEREIN ARE THE ONLY TERMS AND CONDITIONS UNDER WHICH SSM AGREES TO BE BOUND**
3. **ENTIRE AGREEMENT.** These Terms and the Quotation, when signed by both parties, constitute the entire agreement between the parties with respect to the subject matter thereof, and supersedes and replaces all other understandings or agreements, written or oral, regarding such subject matter. No additions or modifications to such agreement or the Services shall be binding unless in writing and signed by a duly authorized representative of both parties
4. **PROVISION OF GOODS AND SERVICES.** SSM shall provide the goods and services set forth in the applicable Quote or Purchase Order and with these Terms and Conditions. If Buyer engages SSM for processing services or development work, then, beginning on the first month of each calendar quarter, Buyer shall provide SSM with a written forecast of its processing requirements for the next four quarters (a "Rolling Forecast"). The first six (6) months of each Rolling Forecast shall constitute a firm order ("Firm Order"). For work to be performed Buyer shall provide SSM with a Purchase Order for the value of the six (6) month Firm Order period at least ninety (90) days prior to the requested manufacturing date. Every Firm Order shall specify the quantities, delivery dates, and shipping information for the products for the applicable Firm Order period. So long as the quantity and delivery date requirements set forth in each six (6) month Firm Order period is achievable, SSM shall respond with the expected date of manufacture. Buyer acknowledges and agrees any expected date of manufacture and actual date of manufacture will not be so great as to effect SSM's ability to meet the delivery date specified in the Purchase Order. The expected date of manufacture is conditional upon Buyer providing the Technology Transfer Documentation and approval of the Master Batch Record, including, but not limited to, approval of final Product Specifications within the SSM directed timing requirements applicable to each item for each lot within each Firm Order.
5. **PRICE, TAXES, SHIPPING.** Buyer shall pay the price stated in the Quotation for the Services. Prices are good for the dates/schedule stated or one (1) year, whichever is less. The prices stated are exclusive of any taxes, imposts, stamp duties, consular or other fees, duties, licenses, or levies ("Taxes"), now or hereinafter imposed upon the Services. Buyer shall pay any Taxes related to the Services and reimburse SSM for any such Taxes which SSM is required to pay. Buyer shall provide an exemption certificate acceptable to the authorities responsible for any such Taxes. All such Taxes shall be billed as a separate item on the invoice. The prices stated are also exclusive of shipping charges which shall be paid by Buyer. Any shipments are made FCA (Incoterms 2010) SSM's facility. Title and risk of loss for materials produced hereunder shall pass to Buyer on the earlier of a) 30 days after Buyer's receipt of released executed batch records or b) shipment of such materials to Buyer. Storage fees as set forth in the Quotation apply after such 30 days. Buyer shall maintain adequate insurance during all periods for which title and risk of loss of materials or components belongs Buyer.
6. **PAYMENT TERMS.** Payment terms are net 30 days from the date of SSM's invoice to Buyer or as otherwise stated in the Terms and Conditions. Unless otherwise stated in the Terms and Conditions, Buyer shall prepay 50% of the total fees upon signing the Quotation or issuing the first purchase order number, and the balance of the fees will be due net 30 days from the date of SSM's invoices for completed Service(s). If payment is not received by the due date, a service charge will be added at the rate of 1.5% per month (18% per year) or the maximum legal rate, whichever is less.
7. **MATERIALS, SUPPLIES, INFORMATION & PAYMENTS.** Buyer shall be fully responsible for all materials and their associated testing unless otherwise agreed upon in writing by SSM. Unless mutually agreed upon by the parties otherwise, all materials and supplies to be provided by the Buyer or any supplier not validated by SSM must be delivered to SSM in sufficient quantity at least four (4) weeks prior to the scheduled commencement date of task execution. Buyer will promptly provide to SSM any information pertinent to the project that may be known to the Buyer. Buyer will provide written approval of the project GANTT, which will be generated and sent for review by SSM at the start of a project, that pertain to the dates required for receipt of information and materials, review and approval of documentation, and other tasks for which the Buyer is responsible. Upon written approval of the project GANTT by Buyer, any delay or departure from the dates to any task in the project GANTT caused by Buyer shall result in the assessment of rescheduling fees per Section VI herein. Buyer will promptly provide safety and toxicology data and information (both known and suspected, including a MSDS) for any compound prior to project initiation, as well as updates as information becomes available. Buyer understands that failure to make payments on a timely basis or provide materials, supplies, documentation, or information to SSM with sufficient notice as set forth herein will result in expediting/rescheduling/cancellation fees as detailed below. Unless otherwise specified in the Proposal, the Buyer will be invoiced at SSM's cost plus 10% for all materials, supplies, outside services and equipment necessary to complete the project. Notwithstanding this, Buyer agrees to pay SSM costs in advance for special purchase items which either individually or in the aggregate exceed \$10,000.00. Buyer is responsible for waste disposal costs directly associated with Buyer's product which will be billed to Buyer at SSM's cost plus 10%.
8. **DOCUMENTATION.** Buyer agrees that any document submission associated with work performed by SSM which is submitted to the FDA, domestic or international regulatory agencies, or any third parties, shall not be altered from the original form as originally provided by SSM. For commercial products, Buyer will provide SSM with documentation that the product to be produced by SSM is approved by the US FDA for its intended use. For clinical products, Buyer will provide SSM with documentation that the product to be produced by SSM is approved by the US FDA for use in clinical trials. This may be an NDA, IND, IDE, PMA, ANDA, NADA, 510K or other appropriate reference to a filing with the US FDA.
9. **INSURANCE.** Buyer agrees that it is responsible for providing adequate insurance coverage for its Product and other materials it supplies while in transit and at SSMSSM facilities and that it has title at all times for its Product, as well as for any excipient(s) from suppliers that are not validated by SSM.
10. **ASSUMPTION OF COSTS.** Buyer assumes responsibility and shall pay SSMSSM for all fees and costs associated with batch failure(s) until such time as there exists a Validated Manufacturing Process for a particular Product. For purposes of this Agreement, a "Validated Manufacturing Process" means successful execution of a mutually agreed validation protocol or manufacture of three consecutive GMP Grade batches at scale and at the same specification for a particular Product. Changes to specifications may require a new validation.
11. **BUYER DOCUMENT REVIEW. MASTER BATCH RECORD (MBR):** Buyer will transfer to SSM all appropriate information including methods, manufacturing directions and/or process descriptions, and in-process assays for manufacturing the Product, MSDS, etc., with all such information to be received by SSM with ample advance notice such that said information can be signed off in the Master Batch Record [MBR] by Buyer at least four days prior to the date that services are to commence. All information necessary to complete the **Master Batch Record (MBR)** must be provided to SSM no later than six (6) weeks prior to the date of manufacture. This includes technical information for processing, comprehensive and final in-process sampling plan, specifications for release, storage conditions, and a clear and definitive recipe for formulation, if applicable. Any queries submitted by SSMSSM to the Buyer within four (4) weeks of the scheduled task execution date must be addressed within two (2) business days. Additionally, all of Buyer's queries/responses must be

SHARP STERILE MANUFACTURING, LLC
TERMS AND CONDITIONS

submitted such that the MBR is signed off at least five (5) business days prior to the scheduled commencement of task execution.

Master Protocol (MP) and Master Standard Operating Procedure (MSOP): All information necessary to complete the **Master Protocol (MP)** and/or the **Master Standard Operating Procedure (MSOP)** must be provided to SSM no later than six (6) weeks prior to the date of manufacture. Any queries submitted by SSM to the Buyer within four weeks of the scheduled task execution date must be addressed within two (2) business days. Additionally, all of Buyer's queries/responses must be submitted such that the MP and/or MSOP are complete at least five (5) business days prior to the scheduled commencement of task execution.

Production Batch Record (PBR) and Executed Protocol (EP): Buyer must review and submit comments on the Production Batch Record (PBR) and the Executed Protocol (EP) within ten (10) business days of receipt from SSM. SSM will review Buyer's PBR and EP comments received within the ten (10) business day period and make changes as appropriate at no additional charge. Additional review and changes made by SSM related to batch records or protocols received by SSM after the above-mentioned timeframes will be charged to the Buyer at a rate effective at the time of review.

Stability Data: Buyer must review and submit comments on Stability Data within five (5) business days of receipt from SSM.

Task Completion and Storage, Shipping & Handling: With respect to filling services for the manufacture of clinical or commercial product, the completion of this task is deemed to have taken place when SSM releases the PBR or Certificate of Analysis and the manufactured product is ready for delivery to the Buyer. This task will also be deemed to be complete if the product and PBR is complete except for outstanding items required from the Buyer to complete this task such as packaging materials, material test results or other information. Title vests in Buyer upon completion.

All other tasks specified in the Proposal shall be deemed to have been completed when the task has been completed and specified deliverables for that particular task has been sent to the Buyer.

Buyer may reject a Batch of Product if such Batch does not comply with the Product Specifications, or was not processed in compliance with the specifications and master batch record, except to the extent such failure was caused by defective, adulterated or misbranded Product (including, but not limited to failure of Product to meet applicable Specifications or to have been manufactured in accordance with cGMP) or is caused during shipment of such Product to Buyer or Buyer's designee. Buyer shall notify SSM in writing of its rejection of any Batch by the earlier to occur of the end of a thirty day Batch Record review period or thirty (30) days from notification of the availability for testing of quality control samples (the "Notice Period"). Said notice of rejection by Buyer shall specify Buyer's reasons for rejection and be accompanied by any supporting analyses or documentation. If written notice of rejection is not received by SSM during the end of the Notice Period, the Batch shall be deemed accepted.

12. **NOTICE OF REJECTION; INDEPENDENT LABORATORY; EXCLUSIVE REMEDY.** Within thirty (30) days of receiving a notice of rejection, SSM shall respond stating whether (i) it accepts the rejection or (ii) it disputes the rejection, in which case the parties shall, after good faith negotiation as to whether the rejection is justified, refer such dispute to a mutually acceptable independent third party with the appropriate expertise to assess the conformity or non-conformity of the rejected Product to Product Specifications and the master batch record. Such independent third party shall test the applicable Product and shall determine whether such Product met or did not meet the applicable Product Specifications and/or shall review the relevant Batch Records and other relevant documentation to determine whether such Product was processed in accordance with the master batch record and shall also make a determination as to whether any failure was caused by defective, adulterated or misbranded Product or other Buyer-supplied Materials (including, but not limited to failure of Product or other Buyer-supplied Materials to meet applicable Specifications or to have been manufactured in accordance with cGMP) or was caused during shipment of such Product to Buyer or Buyer's designee. The parties agree that such third party's determination shall be final and binding upon the parties. The party against whom the independent third party rules shall bear the costs of testing and review by such independent third party. If such third party determines that Buyer's rejection of Product was incorrect, Buyer shall purchase and pay for both the initially rejected Product and any replacement Product produced at

Buyer's request. In the event that Buyer rightfully rejects a Batch after a Validated Manufacturing Process has been established, SSM shall have, in its sole discretion, the right to either replace as soon as possible the rejected portion of the Batch at no further cost to Buyer (other than the cost of Product and other Buyer-supplied Materials which shall continue to be Buyer's costs), or to refund a pro rata portion of the amount paid by Buyer with respect to such Batch based on the percentage of such Batch that is unusable. The remedy under the foregoing sentence shall be Buyer's sole remedy for failure of Product to meet Product Specifications or to have been processed in accordance with the master batch record and the other terms of this Agreement.

SSM has limited storage facilities for Buyer products, materials, and equipment. Buyer shall take delivery of product within two (2) weeks of the SSM batch release date. Buyer shall arrange for pickup of all Buyer owned materials and equipment within two (2) weeks of the completion of Buyer's project or planned suspension of project for more than 4 (four) weeks, unless otherwise authorized by SSM. If Buyer requests SSM to store product longer than two (2) weeks past the SSM batch release date or if the Buyer does not take delivery of product within two (2) weeks past the end of the SSM batch release date, SSM may, at its option, ship the product to Buyer's address at Buyer's expense, or space permitting, and upon mutual written agreement of the parties, SSM may store such product at SSM or third-party storage location.

Buyer is responsible for all shipping, packaging, and handling costs.

13. **TERMINATION.** Buyer or SSM may terminate this Agreement by mutual agreement at any time; with thirty (30) days' notice in the event the other party has breached any representation, warranty, or obligation contained in this Agreement and/or has defaulted in the performance of any of its duties or obligations in any material respect and such breach or default has not been remedied within 30 days after written notice of such breach; If a voluntary petition in bankruptcy is filed by a party under the United States Bankruptcy Code, if an involuntary petition under the United States Bankruptcy Code is filed against the other party, or if a receiver is appointed for the other party or its property; or for convenience by either party effective ninety (90) days following receipt of written notice to the other party. SSM will cease all further work and activity with respect to the Services, other than reasonable and necessary wind-down and cleanup activities. Buyer shall compensate SSM for the costs of labor, materials and non-cancellable commitments that have been incurred for that portion of the Services undertaken but not completed and the Quotation price for Services completed up to the effective date of termination. If such amounts plus any cancellation fees owed are less than the prepayment made by Buyer, SSM shall reimburse Buyer the difference. Except for any lyophilization service, any Services cancelled will be subject to a cancellation fee of 50% of the total contract amount in addition to SSM's incurred costs up to the effective date of cancellation. Any Services cancelled with less than 90 day notice prior to scheduled initiation will be subject to a cancellation fee of 100% of the total contract amount. In the case of lyophilization services, Buyer shall pay 100% of the costs and fees for such services contained in any signed Quotation, any cancellation notwithstanding.
14. **RESCHEDULING.** Buyer may reschedule the Services or production by written notice with no penalty provided that such notice is received at least 90 days prior to the scheduled commencement of activity(ies) and the rescheduled date is within two (2) calendar quarters of the original date. If the rescheduled date is beyond two (2) calendar quarters then the Services will be considered cancelled and subject to the cancellation charges noted in the above paragraph. If notice of rescheduling is received less than 90 days but at least 30 days prior to scheduled commencement, then a surcharge of 50% of the amounts payable for the rescheduled Services will apply. If the rescheduling notice is received less than 30 days prior to the scheduled commencement then a 75% rescheduling surcharge will be applied. All rescheduling requires a signed change order. Buyer shall also compensate SSM for any costs, materials and non-cancellable commitments that have been incurred for that portion of the Services undertaken but not completed due to rescheduling. Tasks rescheduled, delayed or put on hold more than once or rescheduled, delayed, or put on hold beyond thirty (30) days of the initial scheduled date shall be deemed to have been cancelled.
15. **EXPEDITING COSTS.** SSM requires a fully executed Terms and Conditions or change order, Purchase Order and prepayment a minimum of sixty days prior

SHARP STERILE MANUFACTURING, LLC
TERMS AND CONDITIONS

- to scheduled initiation of the relevant manufacturing or engineering Services. If the relevant signed documents or prepayment are received less than 90 days prior to the scheduled initiation date, and provided SSM nevertheless agrees to such date, Buyer will pay a 50% expediting fee. Any expedited Services requiring work to be performed outside of regular business hours (e.g. overtime) will be charged an additional 30%. Buyer's failure to provide payments, information, materials, supplies, or equipment according to the timeframes stated in these Terms or the Terms and Conditions shall result in expediting, rescheduling, or cancellation fees.
16. **CREDIT TERMS AND COLLECTION COSTS.** If SSM determines, at any time and in its sole discretion, that Buyer may not pay the price in full when due, SSM may demand reasonable assurances from Buyer, including, without limitation, a letter of credit for payment of the price or payment in cash before performing all or a portion of the Services. Upon making such demand, SSM may suspend work and shipments until such demand is satisfied. If within 30 days of SSM's making such demand, Buyer fails to agree and comply with such different terms of payment and/or fails to give adequate assurance of performance, SSM may treat such failure as a repudiation by Buyer of its agreement with SSM with respect to the portion of the agreement still to be performed and terminate such agreement. Prepayments or other funds held by SSM shall be automatically applied to any invoice(s) more than 60 days past due. Buyer's acceptance of this Quotation and performance by SSM of its agreement with Buyer shall constitute a representation that Buyer is solvent. SSM shall be entitled to recover all costs of enforcing its agreements or collecting amounts due hereunder, including its reasonable attorney's fees.
17. **CONFIDENTIAL INFORMATION.** Neither SSM nor Buyer shall disclose to third parties, or use for any purpose other than performing this contract, any proprietary data and other information received from the other party ("Disclosing Party") concerning the Services (the foregoing to be referred to as "Confidential Information"), without prior express written approval from the Disclosing Party unless (i) such Confidential Information is or becomes public other than through breach of an obligation (ii) is learned by the other party ("Receiving Party") from a third party who was under no obligation to the Disclosing Party to keep confidential such Confidential Information, (iii) was already in Receiving Party's possession prior to receipt from Disclosing Party (iv) Receiving Party's written records demonstrate that such information was developed by the Receiving Party's employee's, consultants or advisors without reference to any Confidential Information of the Disclosing Party, (v) the Receiving Party is required by law to disclose such Confidential Information, or (vi) the Receiving Party must disclose such Confidential Information in connection with any claim or proceeding arising under this Agreement.
18. **OWNERSHIP OF MATERIALS.** Materials provided to SSM by Buyer shall at all times be the property of, and the risk of loss with respect thereto shall remain with, Buyer. SSM will not, without prior written approval from Buyer, transfer or transmit the Materials or any portion thereof to a third party.
19. **SSM WARRANTY.** SSM warrants only that the Services will be performed in a workmanlike manner in accordance with the Terms and Conditions. SSM MAKES NO OTHER REPRESENTATION OR WARRANTY CONCERNING THE SERVICE OR THE RESULTS THEREOF AND DISCLAIMS ALL WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.
20. **LIMITATION OF INCIDENTAL DAMAGES.** In no event will either party be liable to the other party for lost profits, loss of use, loss of business, business interruption, loss of data, cost of cover or any indirect, special, consequential, incidental, or punitive damages of any nature whatsoever, however caused and under any theory of liability whether based in contract, warranty, tort (including without limitation, negligence), strict liability, statutory or otherwise, arising out of or in connection with this agreement even if such party has been advised of the possibility of such damages.
21. **LIMIT ON SSM'S AGGREGATE LIABILITY.** In no event shall SSM's aggregate liability under this agreement exceed the fees paid by Buyer to SSM for the service(s) at issue under the applicable proposal in the year in which the claim arises less any other amounts previously paid by Buyer to SSM with respect to claims under such proposal arising in the same year. These limitations shall apply notwithstanding any failure of essential purpose of any limited remedy. In no event shall the reference to an aggregate liability under this paragraph be deemed to expand SSM's liability under any section of this agreement.
22. **LOSS OF BUYER-SUPPLIED MATERIALS.** Notwithstanding anything to the contrary in this agreement, SSM shall have no liability for loss or damage to Buyer-supplied materials, including API, at any time except in the event of SSM's gross negligence or willful misconduct, provided that SSM's liability for loss or damage due to SSM's gross negligence and/or willful misconduct shall in no event exceed a maximum liability of \$25,000 in the aggregate.
23. **INDEMNITY.** Buyer shall indemnify, defend and hold SSM harmless against all costs and liabilities which arise from Buyer's use of the Services or its use or transfer of any deliverables, including, without limitation, any claim, action, proceeding or investigation initiated against SSM with respect to the Services, or Buyer's release, discharge, use, testing, storage, sale, marketing, labeling or transfer of the data or products produced from the Services, except if any such cost or liability results solely from SSMs gross negligence or willful misconduct.
24. **CHOICE OF LAW AND JURISDICTION.** This Terms and Conditions shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts. Each party hereby submits to the exclusive jurisdiction and venue of the state and federal courts of Middlesex, Massachusetts for all actions related to the Services.