

Terms and Conditions

AMRI Burlington, Inc.

1. **AGREEMENT AND ACCEPTANCE:** The entire agreement (the “Agreement”) between AMRI Burlington, Inc. (“AMRI”), and the Customer consists of: (i) AMRI’s proposal for the products, materials, services, goods (collectively “Proposal”), and (ii) these Terms and Conditions provided by AMRI. For purposes of this Agreement, any documentation, report, product, material or good provided to Customer in the performance of Services shall be referred to as “Deliverables” or “Deliverable” and AMRI’s performance of any services, including but not limited to providing process scale-up development and aseptic filling services and related scientific or manufacturing services shall be generally referred to as “Services”. The Agreement shall become binding when accepted by Customer either by acknowledgment or at the time performance of the services begins. Any terms and conditions proposed by the Customer which are additional to or inconsistent with the Terms and Conditions contained in the Agreement shall be void. In the event a Services and Supply Agreement is in place between the parties, the Services and Supply Agreement will govern over any Terms and Conditions. Customer acknowledges that these Terms and Conditions are incorporated into the Proposal and govern over any Customer purchase orders.

2. **CUSTOMER API, MATERIALS, SUPPLIES & INFORMATION:** Customer shall be fully responsible for all materials and their associated testing unless otherwise agreed upon in writing by AMRI. All materials and supplies to be provided by the Customer or any supplier not validated by AMRI must be delivered to AMRI in sufficient quantity at least four (4) weeks prior to the scheduled commencement date of task execution. Customer shall promptly provide to AMRI any information pertinent to the Services that may be known to the Customer. Customer will provide written approval of the project GANTT, which will be generated and sent for review by AMRI at the start of Services that pertain to the dates required for receipt of information and materials, review and approval of documentation, and other tasks for which the Customer is responsible. Upon written approval of the project GANTT by Customer, any delay or departure from the dates to any task in the project GANTT caused by Customer shall result in the assessment of rescheduling fees outlined herein. Customer will promptly provide safety and toxicology data and information (both known and suspected, including a SDS) for any compound prior to project initiation, as well as updates as information becomes available. Customer agrees that it is responsible for providing adequate insurance coverage for its active pharmaceutical ingredient (API) and other materials it supplies while in transit and while physically located at AMRI facilities and that it has legal title and risk of loss at all times for its API, as well as for any excipient(s) from suppliers that are not validated by AMRI. Any samples of final product or API required to be retained by cGMP or other regulatory requirements shall be the responsibility of the Customer with the Customer retaining title and risk of loss at all times.

3. **DOCUMENTATION:** Customer agrees that any document submission associated with work performed by AMRI 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 AMRI Burlington. For commercial products, Customer will provide AMRI with documentation that the product to be produced by AMRI is approved by the US FDA for its intended use. For clinical products, Customer will provide AMRI with documentation that the product to be produced by AMRI is approved by the US FDA for use in clinical trials. This may be an NDA, INDA, IDE, PMA, ANDA, NADA, 510K or other appropriate reference to a filing with the US FDA.

4. **ASSUMPTION OF COSTS:** Notwithstanding anything in this Agreement to the contrary, Customer shall pay for all failed batches of product in accordance with the applicable Proposal and assumes responsibility for all costs, including but not limited to the cost of API or other Customer materials, associated with batch failures 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 and manufacture of such number of batches as agreed in the validation protocol, at scale, that have been processed in accordance with the agreed upon manufacturing standards to meet product specifications. Customer acknowledges that a change in product specifications, manufacturing process or Master Batch Records may require a new Validated Manufacturing Process using the new product specifications, manufacturing process or Master Batch Records.

5. **INTELLECTUAL PROPERTY:** Customer agrees that its intellectual property shall remain its own, and AMRI's intellectual property shall remain AMRI's. In the event Customer directs or requires use of third-party intellectual property provided by or through Customer, then Customer hereby indemnifies AMRI in the event that AMRI's use of such intellectual property as directed infringes on any third party intellectual property rights

6. **AUDITS:** AMRI allows the Customer an annual one-day audit or a one-day visit to the facility during development. Additional audits or visits will be charged to the Customer at a rate of \$2,000 per day per auditor. Audits and visits must be scheduled in advance at a mutually agreeable time.

7. **CUSTOMER DOCUMENT REVIEW:** **Master Batch Record (MBR):** Customer will transfer to AMRI 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 AMRI with ample advance notice such that said information can be signed off in the MBR by Customer at least four days prior to the date that services are to commence. All information necessary to complete the MBR must be provided to AMRI 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 AMRI to the Customer within four (4) weeks of the scheduled task execution date must be addressed within two (2) business days. Additionally, all of Customer's queries/responses must be 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 MP and/or the MSOP must be provided to AMRI no later than six (6) weeks prior to the date of manufacture. Any queries submitted by AMRI to the Customer within four weeks of the scheduled task execution date must be addressed within two (2) business days. Additionally, all of Customer'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):** Customer must review and submit comments on the PBR and the EP within ten (10) business days of receipt from AMRI. AMRI will review Customer'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 AMRI related to batch records or protocols received by AMRI after the above mentioned timeframes will be charged to the Customer at a rate of \$250/hour. **Stability Data:** Customer must review and submit comments on Stability Data within five (5) business days of receipt from AMRI.

FAILURE TO COMPLY with these information and review timeframes will result in expediting, rescheduling or cancellation fees as detailed herein.

8. **SERVICES AND TASK COMPLETION:** 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 AMRI releases the PBR or Certificate of Analysis and the manufactured product is ready for delivery to the Customer. 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 have been sent to the Customer.

9. **DELIVERY:**

Title and risk of loss of product shall transfer from AMRI to Customer upon the delivery of product EXW AMRI's facilities (Incoterms 2010) ("Delivery"). Evidence of Delivery will be through the issuance of the completed Batch Record or a Certificate of Analysis to the Customer. Customer is responsible for transportation of the product to the Customer's final destination, at the sole risk and expense of the Customer. For avoidance of doubt, the Customer is responsible for arranging pick up by the carrier and all shipping costs and risks. Should the Customer request the AMRI to assist with any arrangements with the carrier, such arrangements will be made by the AMRI on behalf of Customer in accordance with Customer's applicable instructions and at the sole risk and expense of the Customer.

10. **STORAGE:**

If Customer does not pick up product upon Delivery by AMRI, AMRI shall store such product at the AMRI's facilities or third-party storage location for 30 days at no cost and, thereafter, at a monthly storage charge to

Customer for the duration of storage, billed at AMRI's (or third-party's as applicable) then current standard monthly storage fees and minimums, pro-rated for any partial month. For all Product stored by the AMRI, Customer agrees that: (i) Customer has title and risk of ownership; (ii) Customer has made a fixed commitment to purchase such product; (iii) Customer is responsible for any decrease in market value of such product that relates to factors and circumstances outside of AMRI's control; (iv) Customer is responsible for obtaining insurance for such product during the storage period, if desired; and (v) Customer is responsible for transportation of the product to the Customer's final destination, at the sole risk and expense of the Customer. Notwithstanding the above provisions related to Delivery and product storage, in the event that Customer does not intend to take delivery of product from AMRI's facilities, as may be the case with certain development-stage Services, the parties agree that AMRI will store the product until such time that Customer notifies AMRI in writing with a request for AMRI to destroy the product on behalf of Customer, in no case will the storage period be greater than one year, unless specifically agreed to by AMRI. If Customer has not arranged to pick-up the product by one year from the date of Delivery, AMRI will ship the product to Customer's facilities at the cost of the Customer. The storage fees stated above are applicable until such notification is received by Customer. Fees for product destruction and disposal will be outlined in the applicable Quotation. In the event fees for product destruction and disposal are not outlined in the Quotation, the then current standard fees will apply.

11. **INVOICING AND PAYMENT TERMS:** Customer is responsible to make payments in accordance with this section. Customer understands that failure to make payments on a timely basis or provide materials, supplies, documentation or information to AMRI with sufficient notice as set forth herein will result in expediting/rescheduling/cancellation fees as detailed herein. **Engineering, Laboratory and Manufacturing Services:** Fifty percent (50%) of the amount specified in the applicable Proposal or Purchase Order for each task will be invoiced upon the earlier of signing of the Proposal or the issuance of a Purchase Order and payment will be due upon invoice but in no event later than thirty (30) days before the start of work on the project; Forty percent (40%) is invoiced upon completion of the filling operation for engineering, clinical or commercial manufacturing services and due within 10 days; the balance remaining for manufacturing services is invoiced upon the release of the PBR or certificate of analysis (if applicable) or delivery of manufactured product (whichever is first to occur) and due within 10 days; the balance remaining for all other tasks is invoiced upon completion of task and delivery of specified documentation and due within 10 days. **Equipment, Supplies and Outside Services:** One-Hundred percent (100%) is invoiced upon AMRI placement of vendor purchase order or issuance from AMRI inventory and due within 10 days. All freight charges shall be billed collect to Customer. **Stability Studies:** Fifty percent (50%) of the stability chamber and protocol pricing is invoiced upon acceptance of Proposal or issuance of purchase order and due within 10 days; the remaining Fifty percent (50%) of the stability chamber and protocol price is invoiced upon delivery of the protocol and due within 10 days; all testing and related documentation will be invoiced after testing is performed and due within 10 days. **Analytical Testing:** AMRI Burlington in house analytical testing will be invoiced at rates published in AMRI Burlington's most current Analytical Testing Services Rate Sheet unless otherwise indicated. The cost of testing materials and outsourced testing will be billed to Customer at AMRI Burlington's cost plus Fifteen percent (15%). **Miscellaneous Terms:** Fees for Services shall be as set forth in the Proposal. All payments shall be made to AMRI at the address specified on the front of the invoice. All amounts past due 30 days or more shall incur interest at the rate of 1.5% per month or the highest rate permitted by law (whichever is greater). The Customer assumes responsibility for all legal fees and other collection costs made necessary by default in payment.

12. **EXPEDITING, RESCHEDULING & CANCELLATION:** **Expediting Fees:** Sixty (60) days prior notice is required to schedule all manufacturing or engineering runs (i.e. formulation and/or fill operations). Scheduling requiring <60 days will be charged a twenty percent (20%) expediting fee. Scheduling requiring manufacturing services to be performed during non-business hours will be charged an additional thirty percent (30%). **Rescheduling & Cancellation Fees:** All notices of rescheduling, delay, holds or cancellation of tasks must be submitted by Customer in writing. Tasks rescheduled, delayed, put on hold, or cancelled without notice in writing will be considered to be rescheduled or cancelled with zero days' notice. 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 will be deemed to have been cancelled and cancellation fees will apply.

Cancellation, delay, hold or rescheduling of Tasks will incur the following fees:

Number of days before scheduled run or commencement of Task	Rescheduling Fee	Cancellation Fee
>30 days	No Charge	50% of Task Price
16 – 30 days	25% of Task Price	100% of Task Price
8 – 15 days	50% of Task Price	100% of Task Price
0 – 7 days	75% of Task Price	100% of Task Price

In addition to the Cancellation Fees stated above, when canceling an entire project the Customer is responsible for project costs incurred up to the date of receipt of the cancellation notice as well as any associated costs to close down the project.

As stated in section I, Customer's failure to provide payments, information, materials, supplies, or equipment according to the timeframes stated in this document shall result in expediting, rescheduling, or cancellation fees.

LYOPHILIZATION: Notwithstanding the above, Customer agrees to pay one hundred percent (100%) of the agreed price upfront and is noncancellable.

13. EQUIPMENT, SUPPLIES, OUTSIDE SERVICES & WASTE DISPOSAL: Unless otherwise specified in the Proposal, the Customer will be invoiced at AMRI's cost plus fifteen percent (15%) for all materials, supplies, outside services and equipment necessary to complete the project. Notwithstanding this, Customer agrees to pay AMRI's costs in advance for special purchase items which either individually or in the aggregate exceed \$10,000.00. Customer is responsible for waste disposal costs directly associated with Customer's Deliverable which will be billed to Customer at AMRI's cost plus fifteen percent (15%).

14. CHANGES: Any change or expansion in scope of Services or the Specifications, the obligations of either party with respect to such change, and any increase in fees, shall only be effective upon the mutual execution of a written Change Order or similar document incorporating the terms of such change. A change may require additional unanticipated services and/or additional supplies and equipment not included in the scope of the original project quotation. AMRI will invoice Customer for additional laboratory and fill suite usage at rates up to \$55,000 / day, hourly services at a rate of \$250/hour and additional supplies, outside services and equipment at AMRI's cost plus fifteen percent (15%).

15. CONFIDENTIAL INFORMATION: The exchange of Confidential Information shall be governed by the Confidentiality Agreement (the "CDA") in place between the parties. If there is no CDA in place, then the following applies: The Parties anticipate that they will exchange proprietary and confidential information during the term of this Agreement. The Parties shall treat all information (whether written or oral) exchanged hereunder as confidential, and each Party shall use the same degree of care used to protect and maintain its own confidential or proprietary information from unauthorized use or disclosure. Neither Party shall use the other Party's proprietary or confidential information for any purpose other than in performance of this Agreement. Neither Party shall disclose the other Party's confidential or proprietary information to any third party without prior written permission from the disclosing Party. The receiving Party may disclose the other Party's confidential or proprietary information to its employees and officers requiring access thereto solely as necessary to perform the Services, provided that each such employee and officer is bound by a written agreement to maintain the confidential or proprietary information in strict confidence and to use such information solely to perform the Services.

16. **INDEMNIFICATION:** Customer shall indemnify and hold AMRI, its Affiliates and their directors, officers, employees and agents (“AMRI Indemnitee”) harmless from and against any and all third party claims, damages, liabilities, losses, costs and expenses, including but not limited to attorneys’ fees (collectively, “Claims”) arising from or related to: (i) Customer’s or a third party’s use or sale of the Deliverables or results of the Services, or Customer’s or a third party’s manufacture, use or sale of any product or service incorporating the Deliverables, including without limitation any Claims attributable to any product incorporating Deliverables or other Customer product (whether based on strict liability, inherent design defect, negligence, failure to warn, breach of contracts or any other theory of liability); (ii) any Claims that any Deliverable or Customer materials infringe a third Party’s patent or other intellectual property rights; (iii) any negligence or misconduct of Customer or any of its directors, officers, employees, or agents (“Customer Indemnitee”); and (iv) Customer’s failure to comply with all applicable laws, statutes, rules, regulations and orders of governmental, public and quasi-public authorities; except to the extent that such Claim is caused by the gross negligence or willful misconduct of AMRI Indemnitees.

17. **LIMITATION OF LIABILITY:** AMRI shall under no circumstances be liable for lost profits, loss of use, loss of business, business interruption, loss of data, cost of cover, or any direct, indirect, special, consequential or incidental damages of any nature whatsoever, however caused and under any theory of liability whether based in contract, warranty, tort (including, without limitation, negligence), force majeure, strict liability, statutory or otherwise, arising out of or in connection with this Project(s) or Agreement(s), even if Customer has been advised of such damages. Notwithstanding anything to the contrary herein, any limitations on liability will not be applicable to liabilities to the extent arising from the violations of law, recklessness, or willful misconduct by AMRI. At no time shall AMRI be responsible for API or excipient costs. AMRI’s responsibilities and liability with respect to the Deliverable become null and void thirty (30) days after Customer is notified that quality control samples are available or that the executed batch record is complete, whichever occurs first. Customer assumes sole responsibility and liability for products made with raw materials, excipients, supplies, or equipment from suppliers not validated by AMRI. Customer assumes sole responsibility and liability for all shipping and product labeling. Customer assumes sole responsibility and liability if it requests that AMRI to ship Deliverables to Customer or Customer’s agent under quarantine or without labeling or labels that do not comply with FDA/cGMP requirements. AMRI’s total aggregate liability under the terms of this Agreement shall never exceed the fees paid by Customer to AMRI for the Services at issue.

18. **WARRANTIES:** Except as set forth herein, AMRI makes no warranties of any kind, express or implied, including any warranty of merchantability or fitness for a specific purpose with respect to any materials, information, or products it provides. CUSTOMER WARRANTS THAT ANY PRODUCT, MATERIALS, PROCESSES, AND THE LIKE FURNISHED TO AMRI UNDER THE AGREEMENT FOR THE PERFORMANCE OF SERVICES WILL NOT INFRINGE ON ANY EXISTING PATENT, TRADEMARK OR COPYRIGHT. UNLESS OTHERWISE STATED HEREIN, AMRI DOES NOT MAKE ANY WARRANTY, EXPRESS OR IMPLIED BY STATUTE OR IN WRITING, REGARDING THE SERVICES OR THE DELIVERABLES, INCLUDING WITHOUT LIMITATION ANY WARRANTY REGARDING THEIR FITNESS FOR PURPOSE, THEIR QUALITY, THEIR MERCHANTABILITY OR THEIR NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS. ANY OTHER REPRESENTATIONS OR WARRANTIES MADE BY ANY PERSON OR ENTITY, INCLUDING EMPLOYEES OR REPRESENTATIVES OF A PARTY HERETO, THAT ARE INCONSISTENT HERewith, SHALL BE DISREGARDED AND SHALL NOT BE BINDING ON SUCH PARTY.

19. **ANTI-BRIBERY AND ANTI-CORRUPTION PRACTICES:** AMRI is committed to complying with all applicable anti-corruption laws, regulations and policies worldwide. AMRI expects its customers, suppliers and business partners to comply with all such laws that prohibit the making, offering or promise of any payment or anything of value, directly or indirectly, to a government official or a government agency (“Officials”), when the payment is intended to influence an act or decision or the retention of business. Accordingly, Customer represents, agrees and warrants that it shall comply with all applicable anti-corruption laws, rules and regulations, including but not limited to the United States Foreign Corrupt Practices Act and the UK Bribery Act, and that it shall not make

any payment of money, gifts, services or anything of value either directly or indirectly, to an Official, when the payment is intended to influence an act or decision or the retention of business.

20. **LEGAL EXPENSES:** If any legal action is initiated by or against AMRI with respect to this Agreement or any underlying Services or Deliverable, Customer will reimburse and/or indemnify, as applicable, AMRI for any and all legal expenses, including attorney's fees, incurred in said legal action.

21. **ASSIGNMENT:** Customer may not transfer or assign, by operation of law or otherwise, its rights or obligations under this Agreement or any Proposal, in whole or in part, without AMRI's written consent. AMRI's consent shall not be unreasonably withheld.

22. **WAIVER:** No delay or omission in exercising any right or remedy shall operate as a waiver thereof or of any other right or remedy, and no single or partial exercise thereof shall preclude any other or further exercise thereof or the exercise of any other right or remedy. The rights, powers, elections and remedies of the Parties hereunder are cumulative and in addition to those which the Parties have at law or in equity. AMRI's failure to object to any provision contained in any communication from Customer shall not be deemed an acceptance of such provision or a waiver of any provision of this Agreement.

23. **COMPLIANCE WITH LAWS:** Customer shall, in the performance of the Agreement, comply with all applicable laws, statutes, rules, regulations and orders of governmental, public and quasi-public authorities.

24. **FORCE MAJEURE:** AMRI shall not be liable for, or in connection with, any failure or delay in performance due wholly or partly to any strike, lock out or industrial disturbance at or affecting AMRI's premises, or to any event whatsoever beyond its control (e.g., flood, fire, etc.) which prevents or hinders AMRI from performing the services as provided for under the Agreement.

25. **GOVERNING LAW: ARBITRATION:** The terms of this Agreement shall be governed by the laws of the Commonwealth of Massachusetts without regard to the conflicts of law provisions thereof. Each party agrees to exclusive jurisdiction and venue in the courts of the Commonwealth of Massachusetts. All disputes arising from or related to this Agreement may be submitted to arbitration in Boston, Massachusetts (or at a location agreed to by AMRI) under the rules then prevailing of the American Arbitration Association and judgment may be entered on any award in a court of competent jurisdiction. The parties acknowledge and agree that the United Nations Convention on Contracts for the International Sale of Goods is specifically excluded from application to this Agreement.