

ELEMENT MATERIALS TECHNOLOGY LIFE SCIENCES

TERMS AND CONDITIONS (US)

1. Formation of Contract

- 1.1 These terms and conditions ("**Terms and Conditions**") together with any quotation, proposal, estimate, or fee quote ("**Quotation**") provided by or on behalf of Element Materials Technology Boulder LLC ("**Company**") shall apply to all contracts for the supply of **Services** (as defined below) to the client identified in the Quotation ("**Client**").
- 1.2 These Terms and Conditions shall supersede and override any terms or conditions contained in or referred to in the Client's purchase order or acceptance of a quotation or specification and shall prevail over any inconsistent terms or conditions contained or referred to in the Company's confirmation of order, or implied by law (unless the law in question cannot be excluded), trade, custom, practice or course of dealing. Any phrase introduced by the terms "**including**", "**include**", "**in particular**" or any similar expression, shall be construed as illustrative and shall not limit the sense of the words preceding those terms.
- 1.3 Written and oral Quotations shall be valid for sixty (60) days from the date thereof and the Company may withdraw any such Quotation at any time. No Quotation given by the Company shall be an offer to contract with any person and no contract shall come into existence except in accordance with Section 1.4.
- 1.4 The Client's purchase order or the Client's acceptance of a Quotation constitutes an offer by the Client to purchase the Services specified in the Quotation upon these Terms and Conditions. No offer placed by the Client shall be accepted by the Company other than by a written acknowledgement issued and executed by the Company or (if earlier) by the Company starting to provide the Services, when a contract for the supply and purchase of those Services on these Terms and Conditions will be established (such contract, together with these Terms and Conditions, the "**Contract**").
- 1.5 No acceptance or acknowledgement, even if in writing and signed by the Company, of the Client's purchase order or any other document pertaining to the Services shall constitute acceptance of any provision of the Client's purchase order or any other document that conflicts with or adds to these Terms and Conditions unless the Company specifically agrees to such a variation of these Terms and Conditions pursuant to and in accordance with Section 3.1.
- 1.6 The delivery to the Company by the Client of any item for testing or calibration by the Company (a "**Sample**") or the delivery of any request by the Client to the Company for the provision of any similar services shall, upon acceptance of that Sample or request by the Company, constitute an 'offer' (as referred to in Section 1.4). If the Company begins such testing, calibration or similar services on that Sample, the offer shall be deemed to have been accepted by the Company and a Contract shall be formed. These Terms and Conditions shall apply to that Contract.

2. Definitions and Interpretation

- 2.1 In these Terms and Conditions the following terms have the following meanings:

"**Clinical Trial**" means a clinical trial, proof of concept, or similar study being conducted by or on behalf of Client;

"**Clinical Trial Materials**" means any materials Manufactured by the Company for a Clinical Trial or in connection with a proof of concept or similar study;

"**Company Property**" means intellectual property developed, acquired or otherwise obtained by Company prior to, or independently of, the Contract, or intellectual property developed by Company during the provision of Services which is of a general application and does not specifically relate to the Work Product, including without limitation,

concepts, ideas, inventions, know-how, trade secrets, designs, and testing and other *operating* plans, methods, and techniques;

"**Deliverable**" or "**Deliverables**" means the items resulting from the Services to be delivered to the Client as specified in the Quotation.

"**FDA**" means the United States Food and Drug Administration;

"**Governmental and Regulatory Rules**" means all applicable laws, rules, regulations, requirements, guidance, and guidelines of the FDA and all other governing agencies or authorities, whether United States, foreign, state or local;

"**Manufacture**" or "**Manufacturing**" means, with regards to any Clinical Trial Materials, the formulation, development, clinical manufacturing, testing, storing, handling, labelling, packaging, releasing and shipping to the Client or third parties designated by the Client as set forth in the Quotation;

"**Sample**" means (a) with respect to Testing Services not related to Manufacturing by the Company, any materials, item, product or compound supplied by Client to form the basis of such Test, and (b) with respect to any Manufacturing by the Company under this Contract, any material, item, product or compound purchased from vendors or supplied by the Client, and including any materials generated by the Company, to form the basis of a Test or to be used in Manufacturing, including without limitation, any active pharmaceutical or biological ingredient supplied by Client or a third party for Manufacturing;

"**Service**" or "**Services**" means the services specified in the Quotation;

"**Test**" or "**Testing**" means any testing, analysis, assay, inspection, sampling and sample preparation or the like specified in a Quotation;

"**Third Party Property**" means intellectual property licensed or obtained by Company from third parties; and

"**Work Product**" means any information or item prepared or created by Company in performing the Services specified in the Quotation, including results, reports, certificates, test or inspection records, drawings, recommendations, or advice.

3. Variation including Cancellation, Postponement and Amendment

- 3.1 These Terms and Conditions may not be varied or waived by either party unless the variation or waiver is in writing and is signed by an officer or duly authorized signatory of the Company. The variation or waiver must set out the Section(s) or sub-condition(s) to be varied or waived and the detail of each such variation or waiver.
- 3.2 The Client may cancel, postpone or amend any order (in whole or in part) at any time, provided that the Client shall pay to the Company the full amount of the Consideration (as defined in Section 4.1) relating to such order plus all Costs (as defined in Section 4.1) relating to such order incurred by the Company prior to the date of the cancellation, postponement or amendment plus any other losses, expenses and costs incurred by the Company as a result of the cancellation, postponement or amendment.
- 3.3 The Company reserves the right to review and amend any Quotation prices where documentation, specification or other materials relating to the Contract have materially changed since the original Quotation was given or where additional services not envisaged by the Quotation are requested, for example, producing written descriptions of detailed procedures undertaken as part of the Services. For the avoidance of doubt, approval of such additional requests shall remain at the Company's discretion.

4. Prices & Payment

- 4.1 The Client shall pay the Company the charges set out in the Quotation or any agreed amendment thereof, as applicable, or as otherwise agreed by the parties, for the provision of the Services (“**Consideration**”) and shall pay the Company on demand for any expenses incurred in the provision of the Services (“**Costs**”), unless expressly agreed otherwise in writing.
- 4.2 The Company may issue invoices in respect of Services:
- 4.2.1 upon completion of the Services; or
- 4.2.2 upon completion to the Company’s reasonable satisfaction of separate parts of the Services, in which case, the Company will invoice for that proportion of the total Consideration for the Services performed under the Contract; or
- 4.2.3 in a manner otherwise specified in the Quotation, including individual lines on the Quotation, or order confirmation.
- 4.3 The Client shall pay the Consideration and Costs stated in any invoice for Services provided pursuant to these Terms and Conditions in full, without deduction or set-off, within thirty (30) days of the date stated on that invoice. The Client shall be responsible for all sales, use and excise taxes, and any other similar taxes, duties and charges of any kind imposed by any federal, state or local governmental entity on any amounts payable by the Client. Any such taxes shall be in addition to the amount of the Consideration. In the event that the Client is required by law to make such payment of the Consideration subject to the deduction of withholding tax, the sum paid by the Client shall be increased to the extent necessary to ensure that after such deduction or withholding the Company receives an amount equal to Consideration and Costs it would have received had no such deduction or withholding been required.
- 4.4 The Client shall pay the Consideration and Costs to the Company by electronic bank transfer (or other payment method agreed upon by the parties) in cleared funds in the currency specified in the Company’s Quotation, proposal or order confirmation. All payments due to the Company shall be payable within the specified time irrespective of whether or not the Client has recovered payment from a third party and, for the avoidance of doubt, but without prejudice to the generality of the foregoing, including fees due to the Company when acting as or engaged to serve as experts or as expert witnesses in an adjudicatory proceeding.
- 4.5 When there is a default of payment within the thirty (30) days stated on the invoice, the Company may: suspend any further Services being carried out for the Client; withhold the provision of any Work Product; alter or withdraw credit terms; and amend terms, prices or Service levels. The amount outstanding from time to time shall bear interest, calculated from the due date of the invoice to the date of receipt of the amount in full at a rate equivalent to 3% per annum above the base rate from time to time of HSBC Bank in the relevant currency specified in the Company’s Quotation, proposal or order confirmation.
- 4.6 The Company may retain or set off any sums owed to it by the Client which have become due and payable against any sums due to the Client under this Contract or any other agreement between the parties or any Affiliated Company of a party. “**Affiliated Company**” means, in relation to a party, that party, any subsidiary or holding company of that party, and any subsidiary of a holding company of that party.
- 4.7 During the provision of the Services and for 6 months following completion thereof, the Client shall not
- 4.7.1 solicit or entice away (or assist anyone else in soliciting or enticing away) any member of the Company’s staff with whom the Client has had dealings in connection with the Contract and/or the provision of the Services during the 12 months immediately prior to the earlier of the date of the Client’s purchase order or the date of the Quotation; or
- 4.7.2 employ (directly or through a third party) any person as referred to in sub-condition 4.7.1 or engage a person in any way to provide services to the Client.

This Section 4.7 shall not apply to any member of the Company’s staff who without having been previously approached directly or indirectly by the Client responds to an advertisement placed by the Client or on the Client’s behalf.

In the event of a breach of this Section 4.7, which leads to the departure of any person as referred to in sub-condition 4.7.1, the Client will pay to the Company, on demand, as liquidated damages and not as a penalty (the parties acknowledging that actual damages would be impracticable or extremely difficult to calculate with reasonable certainty), a sum equivalent to 50% of the total annual remuneration package paid by the Company to the individual prior to his or her departure. The Client acknowledges that this provision is a fair and reasonable term intended to be a genuine assessment of the likely loss to the Company.

- 4.8 The Company reserves the right to renegotiate the fees and/or to decline to conduct the Services if new information regarding the logistics, (e.g., device failures that significantly increase the cost of the Services) or volunteer subject safety is discovered after the Contract is executed.

5. Services

- 5.1 Subject to all conditions set forth in this Article 5, the Company warrants that it will complete the Services in a satisfactory and workmanlike manner, consistent with industry standards. The Client expressly acknowledges and agrees that the Company gives no warranty that any result or objective can be achieved through the Services and that, where results are based on smaller scale tests and theoretical studies, results may require careful validation in order to be extrapolated to a production scale.
- 5.2 The Company will use its commercially reasonable efforts to complete Services and provide the Deliverables or Clinical Trial Material to the Client by any date reasonably requested in writing by the Client, but the Company shall not be liable to the Client for: (i) any delay in the performance of any obligation under the Contract; or (ii) damages suffered by the Client by reason of such delay.
- 5.3 The Company’s obligation to complete Services under the Contract shall be subject to any obligation it may have to comply with any law or other regulation binding on it which may be in force from time to time. Additionally, the parties shall perform their obligations under this Contract and each Quotation to the extent applicable to the Services: applicable provisions of the study protocol; agreed upon standard operating procedures; the Good Clinical Practice standards as set forth in the ICH (as defined below) Harmonized Tripartite Guidelines for Good Clinical Practice (“GCP Guidelines”); and the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (“ICH”) Guidelines.
- 5.4 No employee, agent or other person is authorized to give any warranty or make any representation on behalf of the Company in relation to the Contract, or to assume for the Company any other liability in connection with the Services, unless such warranty, representation or assumption of liability is given to the Client in accordance with Section 3.1.
- 5.5 With respect to Manufacturing of Clinical Trial Materials, the Company’s sole obligation is to Manufacture the agreed upon Clinical Trial Materials in accordance with Governmental and Regulatory Rules applicable to such Services. The Client shall be responsible for all other aspects of the Clinical Trial, including compliance with applicable Governmental and Regulatory Rules. The Company has the right to cease or suspend Manufacturing if it learns that Client has violated applicable Governmental and Regulatory Rules.
- 5.6 The Client represents and warrants to the Company the completeness and accuracy of all documents and information supplied to the Company for the purposes of the Company fulfilling the Services, both at the time of supply and subsequently.
- 5.7 The Client shall obtain and shall maintain in effect all necessary licenses, permissions, authorizations, approvals, consents and permits with respect to any Clinical Trials and the use of the Clinical Trial Materials.
- 5.8 Deliverables are prepared on the basis of information known to the Company at the time that the Services are carried out. Although the Company will use all reasonable endeavors to ensure accuracy, the Services depend, inter alia, on the effective co-operation of the Client, including its staff, and on the information submitted to the Company. All Services are performed and Deliverables are prepared on the basis that:

- 5.8.1 there is no responsibility to any person or body other than the Client;
- 5.8.2 they are not produced for any particular purpose and no statement is to be deemed, in any circumstances to be or give rise to a representation, undertaking, warranty or contractual condition unless specifically stated;
- 5.8.3 the Deliverable is determined solely by the professional analysis or work undertaken by the Company's staff in accordance with each individual Contract and any forecasts by the Company of the results is an estimate only;
- 5.8.4 the Company is entitled to be paid the Consideration upon performance of the agreed upon Services irrespective of the results or conclusions reached in the Deliverables or in the Clinical Trial;
- 5.8.5 the results of any Testing Services shall address the items and information submitted only and are not to be regarded as representative of any larger population from which the Sample was taken; and
- 5.8.6 the results are final and approved by the Company. The Company shall be under no liability where the Client has acted on preliminary, unapproved results or advice.
- 5.9 Company shall not be liable for a breach of the warranty set forth in Section 5.1 above or otherwise for a breach of its obligations under this Article 5 unless the Client gives written notice of the claimed defect in Services, reasonably described, to the Company within the time period set forth in sub-condition 9.4.1 below. Subject to the foregoing, unless the Company disputes the validity of any such claim of defect, the Company shall, in its sole discretion, either: (i) repair or re-perform such Services (or the defective part); or (ii) credit or refund the price of such Services at the pro rata Contract rate. **THE REMEDIES SET FORTH IN THIS SECTION 5.9 SHALL BE THE CLIENT'S SOLE AND EXCLUSIVE REMEDY AND THE COMPANY'S ENTIRE LIABILITY FOR ANY BREACH OF THE LIMITED WARRANTY SET FORTH IN SECTION 5.1 OR BREACH OF ANY OTHER OBLIGATION UNDER THIS ARTICLE 5.**

6. Client's Property

- 6.1 The Client shall supply as much information as possible, including a unique purchase order number, reference or authorization, about each Sample, the intended use of the Clinical Trial Materials, the project, the materials supplied by Client to be used in the Manufacturing, the Deliverables for the project and Service requirement in order to assist in achieving an efficient service. If a Client provides the Company with detailed instructions in writing as to the treatment and handling of particular items of its property, the Company will use its commercially reasonable efforts to comply with such instructions. Where information relating to the Sample, intended use of the Clinical Trial Materials, the project, the materials supplied by Client, Deliverables and/or the Service requirements is incorrect, incomplete or misleading and the Company is involved in additional work, the Company reserves the right to charge for such additional work.
- 6.2 The Client shall inform the Company in writing prior to the Company carrying out any Service on a Client site or Sample or handling any material that is of a dangerous or unstable nature, as well as notify the Company of any actual or potential health and safety hazards relating to a Sample or material and arising from the Company's performance of the Services, and shall provide instruction on the safe visiting of the site or safe handling of the Sample or such material. The Client shall accept full responsibility for appropriate safety labeling pertaining to the Sample or material and any equipment provided to the Company by the Client.
- 6.3 The Client acknowledges and expressly agrees that, subject to Section 6.4 where the Contract specifies that the Services include non-destructive testing of the Sample, the performance of the Services may damage or destroy any and all Samples and any other materials or property delivered by Client to the Company in relation to the Contract. Under no circumstances will the Company be responsible for any additional costs or damages, including consequential, special, indirect, or incidental damages and indirect costs or losses, resulting from destruction or loss of the Client's property.

When testing, analysis or other services are carried out, the Company shall not be liable in respect of any costs or losses resulting from damage to or destruction of any property belonging to the Client unless the Client notifies the Company in writing before delivery to the

Company and the property itself delivered to the Company is clearly marked "Do Not Destroy or Damage". If such notice is given and the Client's property is so marked, the Company's liability and the Client's sole and exclusive remedy for damage to or destruction of the Client's property is limited to the lesser of:

- 6.4.1 the value of Client's property; or
- 6.4.2 the cost of the Services performed on the damaged or destroyed property pursuant to the Contract.

7. Re-Delivery

- 7.1 The Company will at the Client's reasonable written request, deliver the Client's property (other than that which is destroyed as part of the Services) back to the Client after performing Services relating to that property. The Company may use any method of delivery that it reasonably decides and will do so as the agent of the Client and will not have any liability in respect of any such item so delivered. The Company may at its discretion instruct any person delivering such property to the Client to invoice that Client directly in respect of that delivery and the Client shall make any and all claims for property damaged in transit directly and solely against such delivery company or other person.
- 7.2 Unless specifically instructed to the contrary in writing by the Client, the Company reserves the right to properly dispose of Client's property after completion of the Services provided that the length of time Client's property is kept after completion of the Services before being destroyed will be at the absolute discretion of the Company. The Company reserves the right to invoice the Client for any costs of disposal. Where property of the Client is, in the sole opinion of the Company, too bulky or too unstable to allow storage time of more than one month, it will be at the absolute discretion of the Company as to the length of time such property is kept before being destroyed.

8. Title & Security

- 8.1 Unless expressly stated to the contrary in the Quotation, all Samples and Clinical Trial Materials are and shall remain at all times (including, without limitation, while at the Company's Premises as defined in Section 12 of this Contract and during transportation to and from the Company's Premises) at the entire risk of the Client who shall be responsible for effecting and maintaining its own insurance coverage in relation thereto, it being hereby acknowledged by the Client that the charges of the Company do not include insurance. The Company shall not be liable for loss or damage to Samples and Clinical Trial Materials while at the Company's Premises caused by theft, vandalism, or acts of nature, including fire, earthquake, tornado, explosion, water or other casualty. The Client warrants that all Samples and Clinical Trial Materials shall not present any hazard to the Company's facilities, vehicles, equipment or personnel.
- 8.2 Unless expressly stated to the contrary in the Contract, Samples of a stable nature shall be retained up to thirty (30) days from the date of completion of delivery of any Deliverables required by the Quotation and then either delivered to Client, stored, or destroyed at Client's expense.
- 8.3 Where Samples are, in the sole opinion of the Company, too bulky or too unstable to allow storage time of more than one (1) month, it will be at the absolute discretion of the Company as to the length of time such Samples are kept before being destroyed.
- 8.4 Samples shall be returned to the Client only if prior instructions in writing in that regard are received by the Company and the Client shall be charged for all costs associated therewith (including carriage).

9. Liability and Indemnity

- 9.1 This Article 9 sets out the entire financial liability of the Company, its employees, agents and sub-contractors to the Client in respect of any breach of the Contract, any use made of Samples or any part of them on which Services are carried out, and any representation, warranty, statement, or tortious act or omission (including negligence or breach of statutory duty) arising under or in connection with the Contract.
- 9.2 Other than as expressly set out herein and as specifically warranted in writing to the Client by an officer or duly authorized signatory of the Company in accordance with Section 3.1, all warranties, conditions and other terms implied by statute or common law (including without limitation any warranties of merchantability or fitness for a particular purpose, quality, safety, non-toxicity, efficacy, absence of errors,

accuracy, completeness of results, the prospects or likelihood of success of the Clinical Trial, or the validity, scope, or non-infringement of any Intellectual Property Rights involved in the development of a drug product, the Clinical Trial Materials or their Manufacturing) are, to the fullest extent permitted by law, expressly disclaimed and excluded from the Contract.

9.3 SUBJECT TO THE REMAINING SECTIONS IN THIS ARTICLE 9, THE COMPANY SHALL NOT BE LIABLE, WHETHER IN TORT (INCLUDING FOR NEGLIGENCE OR BREACH OF STATUTORY DUTY), CONTRACT, MISREPRESENTATION OR OTHERWISE FOR:

9.3.1 LOSS OF PROFITS; LOSS OF BUSINESS; LOSS OF REVENUE; LOSS OF MARKETS; LOSS OR DAMAGE INCURRED AS A RESULT OF A THIRD PARTY CLAIM; DEPLETION OF GOODWILL AND/OR SIMILAR LOSSES; LOSS OF ANTICIPATED SAVINGS; LOSS OF GOODS; LOSS OF CONTRACT; LOSS OF USE; LOSS OR CORRUPTION OF DATA OR INFORMATION; EX GRATIA PAYMENTS; OR

8.3.2 ANY SPECIAL, INDIRECT, INCIDENTAL, OR CONSEQUENTIAL LOSS, COSTS, DAMAGES, CHARGES, FINES, PENALTIES, OR EXPENSES; OR PURE ECONOMIC LOSS.

THIS SECTION 9.3 SHALL APPLY REGARDLESS OF WHETHER SUCH LOSSES OR DAMAGES WERE FORESEEABLE AND WHETHER OR NOT THE COMPANY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH LOSSES OR DAMAGES, AND NOTWITHSTANDING THE FAILURE OF ANY AGREED OR OTHER REMEDY OF ITS ESSENTIAL PURPOSE.

9.4 SUBJECT TO SECTIONS 9.3 AND 9.8, THE COMPANY'S TOTAL LIABILITY TO THE CLIENT IN CONTRACT, TORT (INCLUDING CLAIMS FOR NEGLIGENCE OR BREACH OF STATUTORY DUTY) MISREPRESENTATION, RESTITUTION OR OTHERWISE ARISING IN CONNECTION WITH THE PERFORMANCE OR CONTEMPLATED PERFORMANCE OF THE CONTRACT SHALL IN ALL CIRCUMSTANCES BE LIMITED TO THE GREATER OF (i) US \$5,000 OR (ii) THE CONSIDERATION FOR THE SERVICES PAYABLE EACH CALENDAR YEAR UNDER THE CONTRACT THAT ARE SUBJECT TO THE CLAIM. UNDER NO CIRCUMSTANCE SHALL COMPANY'S LIABILITY EVER EXCEED ITS PROPORTIONATE SHARE WHERE MORE THAN ONE PARTY HAS LIABILITY. Save in the case of fraud or fraudulent concealment by the Company, the Company shall be under no liability in respect of any claim under the Contract and any such claim shall be wholly barred and unenforceable unless:

9.4.1 the Client notifies the Company in detail and in writing of the alleged basis for the claim within two (2) months of the Client becoming aware thereof and within one (1) year after the completion of the Services to which the claim relates; and

9.4.2 the Company is permitted to inspect any and all property with respect to which the Services are claimed to have been defective or to which Client's claim otherwise relates.

9.5 EXCEPT FOR THE LIMITED WARRANTY SET FORTH IN SECTION 5.1 ABOVE, THE COMPANY MAKES NO WARRANTY WHATSOEVER WITH RESPECT TO THE SERVICES, INCLUDING ANY: (A) WARRANTY OF MERCHANTABILITY; OR (B) WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE; OR (C) WARRANTY OF TITLE; OR (D) WARRANTY AGAINST INFRINGEMENT OF INTELLECTUAL PROPERTY RIGHTS OF A THIRD PARTY; WHETHER EXPRESS OR IMPLIED BY LAW, COURSE OF DEALING, COURSE OF PERFORMANCE, USAGE OF TRADE OR OTHERWISE.

9.6 The Client acknowledges that the above provisions of this Article 9 are reasonable and reflected in the price which would be higher without those provisions and the Client will accept such risk and/or insure accordingly. The Client agrees to indemnify, keep indemnified and hold harmless the Company from and against all losses which the Company may suffer or incur arising out of or as a result of:

9.6.1 breach of any law by the Client in connection with the performance of the Services;

9.6.2 any claim threatened or made against the Company by any third party arising out of the Services or out of any delay in performing or failure to perform the Services (even if such claim is solely or partly attributable to the fault or negligence of the

Company) to the extent such claim is in excess of the Consideration paid for the Services under the Contract that are subject to the claim; or

9.6.3 any claims arising as a result of any misuse or unauthorized use of any Deliverables issued by the Company or any Intellectual Property Rights belonging to the Company (including trademarks) pursuant to this Contract; or

9.6.4 any claim threatened or made against the Company by any third party related to the use or effects of any Clinical Trial Materials, including without limitation, claims for injuries and/or death to humans and claims relating to any Clinical Trial.

Notwithstanding any other provision of these Terms and Conditions, the Client's liability under this indemnity shall be unlimited.

9.7 Nothing in these Terms and Conditions limits or excludes the liability of the Company for:

9.7.1 death or personal injury to the extent resulting from the Company's negligence; or

9.7.2 liability incurred by the Client to the extent resulting from fraud or fraudulent misrepresentation by the Company; or

9.7.3 any other matter which may not be limited or excluded by law to the extent arising out of the errors or omissions of Company.

9.8 This Article 9 shall survive termination of the Contract.

10. Intellectual Property Rights

10.1 In this Article 10, the following definitions apply:

Intellectual Property Rights: all patents, rights to inventions, utility models, copyright and related rights, trademarks, service marks, trade, business and domain names, rights in trade dress or get-up, rights in goodwill or to sue for passing off, unfair competition rights, rights in designs, rights in computer software, database rights, topography rights, moral rights, rights in confidential information (including know-how and trade secrets) and any other intellectual property rights (now existing or hereafter created), in each case whether registered or unregistered and including all applications for and renewals or extensions of such rights, and all similar or equivalent rights or forms of protection in any part of the world;

10.2 Upon the Client discharging all its obligations under the Contract, including payment of the Consideration, the Company shall assign to Client all of Company's (and, to the extent applicable, will cause its subcontractors and personnel to assign the entirety of their) right, title and interest in and to the Deliverable, including any Intellectual Property Rights in the Deliverable.

10.3 The Client acknowledges and agrees that certain Company Property and certain Third-Party Property may be used and/or generated by Company in the performance of Services under this Contract. The Company and/or its licensors shall retain ownership of all rights, including all Intellectual Property Rights, in all Company Property and/or Third-Party Property (as the case may be) provided, however, Client will obtain a non-exclusive, irrevocable, royalty-free right and license, with the right to sublicense, under Company's Intellectual Property Rights in any Company Property to the extent incorporated into or necessary for Client to fully utilize and capitalize the Deliverable,

(a) to reproduce, create derivative works of, distribute, publicly perform, publicly display, digitally transmit and otherwise use the Deliverable in any medium or format, whether now known or hereafter discovered; (b) to use, make, have made, sell, offer to sell, import and otherwise exploit any product or service based on, embodying, incorporating or derived from the Deliverable; and (c) to exercise any and all other present or future rights in the Deliverable.

10.4 All Intellectual Property Rights in all service mark(s), trademark(s), certification mark(s) and other names and logos owned by the Company shall remain the property of the Company and cannot be sold or licensed by the Client.

10.5 When certification is granted the Company shall award, upon Client's written request, a license to the Client to use the Company's certification mark(s) and logos for the certification validity period, subject to the applicable terms of use (as amended from time to time) which are issued with every certification and are available on request.

10.6 The Client shall indemnify the Company against all losses to which the Company may become liable as a result of a claim that (i) the Manufacturing or use of any Clinical Trial Material, or (ii) any data, equipment or other materials supplied by the Client for the performance of the Services, involves the infringement of any Intellectual Property Rights of any third party.

10.7 Except for the Client's limited rights to use the Deliverables as set forth in Article 11, this Contract does not grant and shall not be construed as granting, any rights to either party to any name or mark of the other party. Neither party is granted any right to the other party's name in connection with any publication and may not give any press release or make any other public announcement regarding this Contract, the Services or any transaction between the parties without the express prior written consent of the other party.

11. Use of Deliverables and Work Product

11.1 The Deliverables and Work Product constitute confidential information that is to be protected and shall be used solely to:

11.1.1 assist the Client in completing its internal requirements and the Company in performing Services for the Client;

11.1.2 comply with the Client's client and other third party requirements for the delivery and use of the data recited in the Deliverable and/or Work Product;

11.1.3 present or respond on a claim in a court of law against Company or Client brought by a third-party or between the parties (provided that, this sub-condition does not apply where a claim is the purpose for which Client ordered the Deliverable and/or Work Product and Company agreed to provide the Services with knowledge of the claim at the time ordered); or

11.1.4 present or respond as required by law or any regulatory body.

11.2 The Client hereby undertakes that it shall not:

11.2.1 except as set out in Section 11.1, disclose a Deliverable or Work Product (or information contained within the Deliverable or Work Product) to any third party without the prior written consent of the Company;

11.2.2 replicate or present a Deliverable or Work Product except in full as delivered by the Company without the prior written consent of the Company; or

11.2.3 use a Deliverable or Work Product, or any portion thereof, in any manner that might reflect unfavorably upon the Company or its group, or which might be, or might include statements, interpretations or comments that could be, misleading or false.

12. Premises

The Company's premises (the "**Premises**") are a designated security area and:

12.1.1 the Company reserves the right to refuse admission to the Premises; unless otherwise agreed in advance by the Company, one visitor per Client may be admitted on request to witness the Services carried out for that Client; and

12.1.2 visitors to the Premises shall conform to the Company's regulations and procedures.

12.2 Where any aspect of the Service is undertaken on premises not occupied by the Company or under its direct control, the Client must ensure that all necessary safety measures are in place to comply with all applicable health and safety regulations, and save as otherwise agreed in writing between the parties or where identification of asbestos is part of the scope of the Services to be provided by the Company to the Client, the Client must ensure all asbestos has been removed and/or is safely contained in every area to be visited by the Company's personnel during the visit to said premises.

12.3 In addition to any specific Client obligations set out in the Quotation and the provisions of Section 12.2, where Services are provided at the premises of the Client, the Client shall: (i) provide the Company with necessary access to any Client premises; (ii) ensure that any premises provided by the Client for the provision of any part of the Service is suitable for that purpose; (ii) provide all usual auxiliary and operating materials (including gas, water, electricity, lighting etc.) relevant to any

Client supplied premises; and (iv) provide the Company with any permits required for the performance of the Service.

13. Court and Other Proceedings

13.1 In the event that the Client requires the Company to present the results or findings of Services carried out by the Company in witness statements, court hearings or other legal proceedings, the Client shall pay to the Company such costs and fees for such presentations and the preparation thereof as the Company may charge to clients generally from time to time for such services and the Client shall be liable for such costs in addition to the Consideration

13.2 In the event that the Company is required by a party other than the Client to present the results or findings of Services carried out by the Company for the Client in any legal proceedings relating to the Client, the Client shall pay all costs and fees arising from any services which the Company is required to do as a result, including the preparation of any witness statement and the preparation for and appearance at any court hearing and reasonable travel and out-of-pocket expenses. The Client shall pay all such costs, whether or not the Client has paid all outstanding Consideration under the Contract and whether or not the Company has closed the Client's file in respect of the matter.

13.3 If any aspect or element of the Services (including any Sample) is, or is likely to be, the subject of or relevant to legal proceedings, such factor must be provided by Client to the Company in writing before the Services are carried out. If that fact is not disclosed to the Company at that stage, the Company may not, in its absolute discretion, be prepared to provide testimony and/or documentation, or serve as the expert witness on behalf of the Client.

13.4 This Article 13 shall survive termination of the Contract.

14. Termination

For the purposes of this Article 14, "**Sanctions Rules**" shall mean any applicable trade or economic sanctions, export control, embargo or similar laws, regulations, rules, measures, restrictions, restricted or designated party lists, licenses, orders, or requirements, in force from time to time, including without limit those of the United States, the European Union, the United Kingdom, and the United Nations.

14.1 If the Client becomes subject to any of the events listed in Section 14.2, the Company may terminate the Contract with immediate effect by giving written notice to the Client.

14.2 For the purposes of Section 14.1, the relevant events are:

14.2.1 if the Client commits a breach of any terms of the Contract or any other contract with the Company which is incapable of remedy or, if capable of remedy, has not been remedied by the Client in accordance with a written notice from the Company requiring remedy within the period specified in the said notice;

14.2.2 if the Client fails to make payment of the Consideration within the specified time;

14.2.3 the Client (a) makes any voluntary arrangement with a general assignment for the benefit of its creditors; (b) becomes insolvent, ceases or suspends payment of any of its debts, or becomes unable to pay its debts generally as they become due; (c) becomes subject, voluntarily or involuntarily, to any proceeding under any domestic or foreign bankruptcy or insolvency law; or (d) is dissolved or liquidated or takes any corporate action for such purpose;

14.2.4 an encumbrancer takes possession, or a receiver, trustee, or administrator or similar agent is appointed, over any of the property or assets of the Client;

14.2.5 the Client ceases, or threatens to cease, to carry on business;

14.2.6 the Company reasonably believes that any of the events mentioned at sub-conditions 14.2.1 to 14.2.5 above is about to occur in relation to the Client and notifies the Client accordingly; and

14.2.7 if the Company reasonably believes that providing the Services or dealing with the Client would be in breach of Sanctions Rules, the Client fails to satisfy due diligence requests made by the Company in connection with compliance with Sanctions Rules or other relevant laws or regulations or the Client does anything

which is in breach of, or would cause the Company to be in breach of, Sanctions Rules.

14.3 On termination of the Contract for any reason the Client shall immediately pay to the Company all indebtedness to the Company with applicable interest.

14.4 Termination of the Contract, however arising, shall not affect any of the parties' rights, remedies, obligations and liabilities that have accrued as at termination.

14.5 Sections and sub-conditions which expressly or by implication survive termination of the Contract shall continue in full force and effect.

15. Force Majeure

4.9 The parties shall not be liable for delay in performing, or failure to perform, any obligation under the Contract if such delay or failure to perform is caused directly or indirectly by any act of God, flood, drought, earthquake or other natural disaster, pandemic, epidemic, war, armed conflict, imposition of sanctions, embargo, or breaking off of diplomatic relations, riot, accident, terrorism, explosion, strike or labor dispute, any law, or any action taken by a government or public authority, including without limitation imposing an export or import restriction, quota or prohibition, or failing to grant a necessary license or consent, delay or default by subcontractor or supplier of materials, components or services, the existence of any circumstance making performance commercially impracticable or any other cause beyond the party's reasonable control, provided that this Article 15 shall not apply to any obligation to make any payments due to the Company under the Contract. Without limiting the foregoing, if the Company's performance of its obligations under these Terms and Conditions is prevented or delayed by any act or omission of the Client or its agents, subcontractors, consultants or employees, the Company shall not be deemed in breach of its obligations under these Terms and Conditions or otherwise liable for any costs, charges or losses sustained or incurred by the Client, in each case, to the extent arising directly or indirectly from such prevention or delay.

16. Waiver of Compliance

Waiver by either party hereto of a breach by the other party of any of the provisions of these Terms and Conditions shall not be deemed a waiver of future compliance therewith, and such provisions shall remain in full force and effect.

17. Entire Agreement

17.1 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.

17.2 Each party agrees that it shall have no remedies in respect of any statement, representation, assurance, or warranty (whether made innocently or negligently) that is not set out in the Contract. Each party agrees that it shall have no claim for innocent or negligent misrepresentation or negligent misstatement based on any statement in the Contract.

18. Severability

If any provision or remedy provided in these Terms and Conditions is found invalid or unenforceable or unlawful under any applicable law in whole or in part, it shall be either deemed to be amended in so far as it is possible to do so in order to make it enforceable while retaining its purpose, or severed from the Contract if it is not possible to do so, and the remaining provisions of these Terms and Conditions, including any remaining default remedies, shall be given effect in accordance with the intent hereof. In the Company's sole discretion, it may terminate the Contract by not less than seven (7) days' written notice to the Client in the event that it considers that such deletion will have a materially adverse effect on its rights under the Contract.

19. No Partnership or Agency

19.1 Nothing in the Contract is intended to, or shall be deemed to, establish any partnership or joint venture between any of the parties, make any party the agent of another party, or authorize any party to make or enter into any commitments for or on behalf of any other party.

19.2 Each party confirms it is acting on its own behalf and not for the benefit of any other person or entity.

20. Third Parties

A person who is not a party to the Contract shall not have any rights under the Contract to enforce any term of the Contract. The Contract is for the sole benefit of the parties hereto and their respective successors and permitted assigns, and nothing herein, express or implied, is intended to or shall confer upon any other person or entity any legal or equitable right, benefit or remedy of any nature whatsoever under or by reason of the Contract.

21. Data Protection

For the purposes of this Article 21, "Data Protection Laws" shall mean (a) up to and including 24 May 2018 the Directive 95/46/EC as transposed into domestic legislation of each Member State of the European Economic Area and in each case as amended, replaced or superseded from time to time, and (b) on and from 25 May 2018 the EU General Data Protection Regulation 2016/679 of the European Parliament and of the Council ("GDPR") and/or (c) any federal, state, local, international or other applicable laws, rules or regulations governing the use and protection of data..

21.1 Within this Article 21, "Process/Processing/Processed", "Data Controller", "Data Processor", "Data Subject", "Personal Data" and "Personal Data Breach" shall have the same meaning as in the Data Protection Laws; provided that the US Data Protection Laws shall be controlling should there be a conflict between any Data Protection Laws, and thereafter the GDPR, if applicable, shall have priority.

21.2 The Client agrees not to provide or otherwise make available Personal Data to the Company, other than business contact information (for example, business, telephone number, job title, and email address), unless otherwise required for the provision of the Services, in which case such additional Personal Data shall be specifically identified in advance by Client and acceptance of the Personal Data is agreed to in writing by the Company.

21.3 Where Personal Data is Processed by a party under or in connection with the Contract that party, as Data Processor, shall:

21.3.1 not Process, transfer, modify, amend or alter the Personal Data or disclose or permit the disclosure of the Personal Data to any third party other than as required to meet the other party's (as Data Controller) lawful, documented and reasonable instructions (which shall unless otherwise agreed be to process Personal Data as necessary to provide the Services pursuant to the terms of this Contract), unless required by a law to which the Data Processor is subject, provided that in such a case, the Data Processor shall inform the Data Controller of that legal requirement before Processing, unless that law prohibits such information on important grounds of public interest. In particular, the Data Controller instructs the Data Processor to transfer data outside the EEA subject to the Data Processor complying with the requirements of Articles 45 to 49 of the GDPR;

21.3.2 upon becoming aware of a Personal Data Breach:

- (a) notify the Data Controller without undue delay; and
- (b) provide reasonable co-operation (at the cost of the Data Controller) to the Data Controller in connection with the Personal Data Breach;

21.3.3 upon receiving any request, complaint or communication relating to the Data Controller's obligations under the Data Protection Laws:

- (a) notify the Data Controller as soon as reasonably practicable;
- (b) assist the Data Controller by implementing appropriate technical and organizational measures to enable the Data Controller to comply with any exercise of rights by a Data Subject under any Data Protection Laws in respect of Personal Data processed by the Data Processor under this Contract or comply with any assessment, enquiry, notice, or investigation under any Data Protection Laws, provided in each case that the Data Controller shall reimburse the Data Processor in full for all costs reasonably incurred by the Data Processor performing its obligations under this sub-condition 21.3.3;

- 21.3.4 ensure that at all times it has in place appropriate technical and organizational measures as required by the applicable Federal and State laws, Article 32 of the GDPR, if applicable, and any other applicable Data Protection Laws;
- 21.3.5 ensure that its employees who may have access to the Personal Data are subject to appropriate confidentiality obligations;
- 21.3.6 implement appropriate organization and technical measures to assist the Data Controller in meeting its obligations in relation to the applicable Federal and State laws, Articles 33 to 36 of the GDPR, if applicable, and any other applicable Data Protection Laws taking into account the nature of processing and the information available to the Data Processor;
- 21.3.7 not authorize any sub-contractor to process the Personal Data ("sub-processor") other than with the prior written consent of the Data Controller, it being acknowledged that the Data Controller consents to the appointment of sub-processors who may from time to time be engaged by the Data Processor who in each case are subject to terms between the Data Processor and the sub-processor which are no less protective than those set out in this Article 21, provided that the Data Processor notifies the Data Controller of the identity of such sub-processors and any change to them; and
- 21.3.8 cease Processing the Personal Data within ninety (90) days upon the termination or expiry of this Contract or, if sooner, the Service to which it relates and as soon as possible thereafter (at the Data Controller's option), either return, or securely wipe from its systems, the Personal Data and any copies of it or of the information it contains, other than to the extent that the Data Processor is required to retain the Personal Data due to a legal or regulatory requirement, or by a requirement of an accreditation body.

21.4 The Data Processor shall make available to the Data Controller such further information and (as applicable) allow for and contribute to any audit or review exercise, conducted by the Data Controller or an auditor mandated by the Data Controller to provide assurance that the Data Processor is in compliance with the obligations set out in this Article 21, provided always that this requirement shall not oblige the Data Processor to provide or permit access to information concerning: (i) the Data Processor's internal pricing information; (ii) information relating to other clients of the Data Processor; (iii) any Data Processor non-public external reports; or (iv) any internal reports prepared by the Data Processor's internal audit or compliance functions. The Data Processor must immediately inform the Data Controller if, in its opinion, an instruction provided by the Data Controller pursuant to this Contract infringes the GDPR or any other applicable Data Protection Laws.

22. Sub-contracting

- 22.1 Unless otherwise restricted by the terms of the Contract and/or obligations under any accreditation or governing approval and good manufacturing practices, the Company shall be entitled, in its absolute discretion, to sub-contract the whole of or any part of the Service and in such event, the Company shall inform Client thereof.
- 22.2 The Company may assign, delegate, license or hold in trust, all or any part of its rights or obligations under the Contract.
- 22.3 The Contract is personal to the Client which may not assign, delegate, license, hold on trust or sub-contract all or any of its rights or obligations under the Contract without the Company's prior written consent.

23. Confidentiality

For the purposes of this Article 23, "**Confidential Information**" shall mean all information which a party may have or acquire before or after the date of the Contract which relates to a party's business, products, developments, trade secrets, know-how or other matters connected with the Services and information concerning a party's relationships with actual or potential clients, customers or suppliers and all other information designated as confidential or which ought reasonably to be considered confidential.

- 23.1 Each party (the "**Recipient**") shall keep all Confidential Information of the other party (the "**Disclosing Party**") in the strictest confidence. Save for the purposes of fulfilling its obligations under the Contract, the Recipient shall not, without the prior written consent of the Disclosing Party, disclose, divulge or grant access to the Confidential Information

which it has received and shall not permit any of its employees, agents or officers to disclose, divulge or grant access to such Confidential Information.

- 23.2 Notwithstanding Section 23.1, a Recipient may disclose Confidential Information which it has received if:
 - 23.2.1 it is required to do so by any governmental, local government or regulatory authority, any accreditation body or by law (but then only to the extent it is strictly required to do so);
 - 23.2.2 it is strictly necessary for the purpose only of obtaining professional advice in relation to the Contract;
 - 23.2.3 it was already known to the Recipient prior to the time of disclosure by the Disclosing Party (where the Recipient can prove the same with documentary evidence); or
 - 23.2.4 it is information which subsequently becomes public knowledge other than by breach of the Contract by the Recipient.
 - 23.2.5 it is otherwise independently developed by the Recipient without reference to or use of the Disclosing Party's Confidential Information
- 23.3 In the event of an information request being made to a Recipient pursuant to any applicable freedom of information laws regarding any Confidential Information, then the Recipient shall notify the Disclosing Party and shall not disclose any information until an analysis has been made as to whether the information requested is capable of benefiting from an exemption from disclosure.
- 23.4 The obligations of the parties under this Article 23 shall continue to apply after termination of this Contract, without a time limitation.

24. Export Control License

For the purposes of this Article 24, "**Export Control License**" shall mean any public or governmental license, approval, permit or similar (whether temporary or permanent), issued directly or indirectly, by any United States, United Kingdom or other foreign authority with jurisdiction over the parties or the goods subject to the contract which, from time to time, it is necessary to obtain in order to be entitled to market, import, export, or re-export products and/or provision of services, and/or transfer of technology and/or Intellectual Property Rights including without limitation, the U.S. Export Administration Regulations, and the U.S. International Traffic in Arms Regulations.

- 24.1 The Company's performance of its obligations under this Contract may, wholly or partly, be subject to Export Control Licenses. If any such Export Control License requires signed end user certificates or any other United States or foreign governmental or court approvals or consents, the parties agree to assist each other in completing the relevant end user certificates or other such approvals or consents and the Client undertakes to conform to and apply the terms of such, end user certificates, Export Control Licenses or restrictions.
- 24.2 The Client represents and warrants that it shall inform the Company in writing, prior to the Company receiving any goods or information from the Client or carrying out any Service, of any applicable Export Control License requirement, import or export restrictions that may apply to the Services to be provided by the Company, including any instances where any products, information or technology may be exported/imported to or from a country, to or from a party, or involving an end use that is restricted from such transaction under the above state applicable laws.
- 24.3 The Company shall make reasonable efforts to obtain the necessary Export Control Licenses, but the parties acknowledge that the issuance of Export Control Licenses is at the sole discretion of the relevant authorities. If any necessary Export Control License is delayed, denied or revoked, the Company shall notify the Client thereof in writing as soon as reasonably practicable, and the Company shall be entitled to a corresponding extension of the time for provision of the Services, and, in case any necessary Export Control License denied or revoked, terminate the Contract, wholly or partly, without liability in relation to the Client.
- 24.4 Should the Services or any product of the Company be subject to any Export Control Licenses or any other United States or foreign governmental or court restrictions, the Client undertakes to conform to and apply the from time to time valid terms of such Export Control Licenses or restrictions.

25. Anti-Corruption

25.1 The Client undertakes to comply with all applicable laws, statutes, regulations and codes relating to anti-bribery and anti-corruption including but not limited to the Foreign Corrupt Practices Act of 1977 and the U.K. Bribery Act 2010 (“**Anti-Corruption Laws**”) and that it shall not do, nor omit to do, any act that will lead to the Company being in breach of any of the Anti-Corruption Laws. The Client shall:

- 25.1.1 comply with the Company’s anti-corruption policies as may be notified by the Company to the Client and updated from time to time (“**Relevant Policies**”);
- 25.1.2 promptly report to the Company any request or demand for any undue financial or other advantage of any kind received by the Client in connection with the performance of the Contract;
- 25.1.3 promptly notify the Company (in writing) if a foreign public official becomes an officer or employee of the Client or acquires a direct or indirect interest in the Client (and the Client warrants that it has no foreign public officials as direct or indirect owners, officers or employees at the date of this Contract);

26. Notices

All notices to be served by one party on the other must be in writing and shall be deemed duly delivered or served at the time of service if delivered personally and seventy-two hours after posting if posted by certified or registered mail (return receipt requested, postage prepaid) in each case to the registered address, if applicable, or if not applicable the last known address of the other party.

27. No Waiver

No failure or delay by the Company to exercise any right, power or remedy will operate as a waiver of it nor will any partial exercise preclude any further exercise of the same or of some other right, power or remedy.

28. Governing Law

28.1 The Contract and any dispute or claim arising out of or in connection with it or its subject matter or formation (including non-contractual disputes or claims) shall be governed by and construed under the laws of the State of Delaware, USA, without giving effect to any choice or conflict of law provision or rule.

28.2 Notwithstanding Section 28.1, the Contract shall be deemed executed and to be performed in the state where the Services are performed (“**Jurisdictional State**”). Each party irrevocably agrees that any legal suit, action or proceeding arising out of or in connection with the Contract or its subject matter or formation (including non-contractual disputes or claims) shall be instituted in the state or federal courts located in the Jurisdictional State, and each party irrevocably submits to the exclusive jurisdiction of such courts in any such suit, action or proceeding. The parties irrevocably and unconditionally waive any objection to the laying of venue of any suit, action or proceeding in such courts of the Jurisdictional State and irrevocably waive and agree not to plead or claim in any such court that any such suit, action or proceeding brought in any such court has been brought in an inconvenient forum.

28.3 If any legal proceeding is instituted to enforce or interpret the provisions of the Contract, the prevailing party(s) shall be entitled to recover its, his, her, or their costs, including reasonable attorney fees and expert witness fees, from the non-prevailing party(s) in the proceeding. For purposes of this Section 28.3, reasonable legal fees include the reasonable fees, charges, expenses of counsel, whether in house or outside counsel, whether incurred at the trial court level, appeal or in bankruptcy, administrative or probate proceedings or otherwise and court costs.