STATEMENT OF TERMS AND CONDITIONS
PRODUCTION SERVICES

Any order to conduct GMP Production Services by BioReliance shall be upon the terms and conditions of the Contract as defined below.

1.1 Definitions

In these Terms and Conditions the following expressions shall have the following meanings, namely:

"Affiliate" means any company which directly or indirectly controls, is controlled by or is under common control with the relevant party in the Contract ("control" shall mean the ownership of at least 50% of the voting rights in such company or otherwise having the right and power to control the management of such company);

"BioReliance Confidential Information" means all information and data, whether written or oral, pertaining to BioReliance that is not commonly known by or available to the public including, without limitation, technical and non-technical data, formulae, procedures, methods, assays, techniques, know-how, specifications, drawings, designs and processes including, without prejudice to the foregoing generality, BioReliance Methodology;

"BioReliance Methodology" means, where applicable to the Services, the BioReliance working documents constituting standard operating procedures ("SOPs"), and Production Protocols excluding any Client Confidential Information contained therein;

"Contract" means the formal agreement governing the provision of the Production Services by BioReliance to the Client, which incorporates (1) these Terms and Conditions and the Quotation, each of which shall become binding on the Client upon the Client's execution and delivery of the Quotation to BioReliance and (2) the Specifications;

"Client" means the party with whom BioReliance enters into a Contract;

"Client Confidential Information" means all information and data, whether written or oral, pertaining to the Client or the Material that is not commonly known by or available to the public including, without limitation, technical and non-technical data, formulae, procedures, methods, techniques, know-how, specifications, drawings, designs and processes;

"Client Information" means the Client Confidential Information and the Data;

"Data" means all documentation, records, raw data, specimens or other work product generated during the performance of the Production Services;

"Facility" means the premises of BioReliance at which the Production Services are undertaken and may incorporate more than one physical building;

"Final Report" means a report containing a summary of all production test data and other work carried out by BioReliance in the provision by it of the Production Services;

"GMP" means all current laws and regulations related to Good Manufacturing Practices as specified in Directive 2003/94/EEC and including all current UK governmental requirements (including The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004 No 1031) where applicable), and all other applicable laws, guidelines and/or regulations pertaining thereto and which may be applicable or come into force from time to time;

"Material" means the material supplied by the Client and to be used by BioReliance in providing the Production Services, more fully described in the Technical Specification;

"Price" means the price to be charged for the Production Services, as detailed in the Quotation;

"Process" means those production processes and operations employed by BioReliance and which are to be carried out by BioReliance to produce the Product as more particularly described in the Technical Specification;

"Product" means the product to be produced by BioReliance in providing the Production Services in accordance with the Contract and as detailed in the Technical Specification;

"Production Protocols" means the BioReliance working documents incorporating all the procedural steps required to perform the Process in accordance with, and as set out in the Technical Specification;

"Production Services" means the production services more fully described in the Contract and may include, but are not limited to, cell and virus banking, clinical bulk manufacture and final filling clinical bulk material;

"Quality Assurance Audit" means the audit and review of all records pertaining to the manufacture of the Product, which comprise environmental monitoring records, equipment records, raw material records, quality control records, batch records and any final products compliance testing reports to ensure that the Product complies with the Specifications;

"Quotation" means the document describing the Production Services generally and detailing the Price and the payment terms;

"Regulations" means GMP and all other relevant laws and regulations applicable to the Production Services;

"Results" means all data and information generated as a result of, or otherwise arising out of, the provision by BioReliance of the Production Services and which form the basis of the Final Report;

"Specifications" means the Production Protocols, SOPs and Technical Specification utilised in providing the Production Services;

"Technical Specification" means the document which shall describe in detail the Production Services, incorporating the detailed technical specifications of all steps to be taken in the provision of the Production Services and providing a description of the respective responsibilities of BioReliance and Client, the terms of which shall require to be agreed by BioReliance and Client prior to commencement of the Production Services;

"**Terms and Conditions**" means the terms and conditions contained in this document.

2. STANDARD OF PERFORMANCE.

2.1 BioReliance will perform the Production Services using due care in accordance with (a) the Specifications, (b) generally prevailing industry standards, and (c) the Regulations.

2.2 BioReliance will make commercially reasonable efforts to start and complete the Production Services in a timely fashion and will notify the Client if BioReliance determines that there are likely to be substantial changes in the proposed start or completion dates of the Production Services. Where any time-scales have been provided by BioReliance for the completion of the Production Services such estimates have been provided in good faith and are based on information reasonably available to BioReliance at the time BioReliance provided such estimates.

3. FEES AND PAYMENT.

3.1 Client shall make payment to BioReliance of the Price in accordance with the Quotation issued to Client for the Production Services. Unless otherwise agreed in writing by BioReliance, payment terms shall be net thirty (30) days from date of invoice. If BioReliance does not receive payment by the due date, an interest charge may be added at the rate of 1% per month or part thereof (12% per year) or the maximum legal rate, whichever is less, to unpaid invoices from the due date thereof until settlement in full without prejudice to the rights of BioReliance to take such action as it considers appropriate to secure payment of all such sums outstanding.

3.2 In addition to entitlement to interest as aforesaid should any invoice remain unpaid beyond the due date BioReliance reserves the right to suspend work on the Production Services and/or withhold delivery of any Product or Final Report not yet delivered (in which case any estimated timescale for completion of the Production Services shall be deemed to be extended by the period of suspension or withholding).

3.3 Any discounts for performance of Production Services must be expressly offered to Client by BioReliance in writing. Under no circumstances will BioReliance honour any discounts automatically taken by Client for any reason, even if Client has informed BioReliance in writing of the possibility of such discount. BioReliance may charge the interest rates set forth above for any unpaid amounts owed to BioReliance as a result of such unauthorized discount.

4. MATERIAL.

4.1 Client will provide BioReliance with sufficient amounts of the Material with which to perform the Production Services, as well as all sufficient and comprehensive data and information, including but not limited to material safety and data sheets, concerning the stability of the Material, handling, storage and safety requirements. In the event Client becomes aware of any additions, deletions, or modifications to any such requirements during the course of the Production Services or any retention of any samples of Material, it shall immediately notify BioReliance thereof. Unless otherwise required by the Regulations, upon completion of the Production Services, any remaining Material will be destroyed by BioReliance within 4 months of issue of the last relevant Final Report unless agreed otherwise with the Client or unless required in respect of any investigation under Section 8 hereof.

4.2 Where regulatory approval is required for BioReliance to work with the Material, BioReliance's obligation to begin performance of the Production Services shall be subject to the receipt of all such approvals. The Client (or, to the extent otherwise agreed in writing between BioReliance and the Client, BioReliance) shall use all commercially reasonable endeavors to ensure that BioReliance receives all such approvals in a timely manner, consistent with any time estimates provided by BioReliance, by diligently applying for, and pursuing receipt of such approvals. Each of BioReliance and the Client will endeavour to provide its reasonable assistance to the other party in such other party's foregoing efforts; provided that the Client shall reimburse BioReliance for all reasonable out-of-pocket costs and expenses incurred by BioReliance in providing such assistance. If there is any delay in the obtaining of any such approvals, then any estimates provided by BioReliance shall be deemed extended by a period equal to the duration of such delay. If such approvals are not, or cannot be, obtained, then the terms of Section 21.1 will apply.

4.3 If BioReliance has agreed to undertake the procurement of any custom or non-standard materials from a third party in connection with the performance of the Production Services, then BioReliance's obligation to procure such materials shall be subject to BioReliance's reaching agreement with such third party on terms and conditions of such procurement which are satisfactory to BioReliance in BioReliance's sole discretion. BioReliance shall not have any obligation to procure any such custom or non-standard materials if such an agreement cannot be reached with such third party.

4.4 Risk of loss or damage to the Material shall remain with the Client. In the event of any loss of, or damage to, the Material required for the Production Services, or if additional Material is required to enable BioReliance to repeat all or any part of the Production Services, then BioReliance shall carry out the work necessary to perform the Production Services or to repeat the Production Services or the relevant part thereof if applicable as soon as reasonably practicable after receipt from the Client of sufficient quantities of the replacement or additional Material to enable BioReliance to do so (and that at BioReliance's sole cost where the requirement to repeat is the fault of BioReliance and at the cost of the Client where otherwise). If the loss of, or damage to, the relevant Material, or the need for additional Material to enable BioReliance to repeat all or any part of the Production Services, is the result of BioReliance's breach of any warranty or obligations of BioReliance under the Contract, then BioReliance shall reimburse the Client for the reasonable cost of shipping such replacement or additional Material to BioReliance but, for the avoidance of doubt, not the cost of producing any such replacement or additional Material.

5. PRODUCT

5.1 Where estimates of quantities of the Product are provided by BioReliance in the Contract or Specifications the Client acknowledges that these are estimates only and any failure by BioReliance to produce the estimated quantity of the Product shall not be deemed to be a breach of the Contract and BioReliance shall not be liable for any loss, damage, costs or expenses of any nature, whether direct or consequential, resulting from a failure to produce any specific quantity of the Product save where such a failure is due to BioReliance's non-compliance with the terms of the Contract.

5.2 BioReliance is not responsible for, and makes no warranty with regard to, genetic alterations, including the formation of replication competent viruses (such as replication competent adenovirus or replication competent retrovirus) which occurs during the production of the Product. Such genetic alterations shall not be the basis for a claim by the Client.

5.3 BioReliance provides no warranties relating to the description or quality of the Product or its fitness for a particular purpose or use under any conditions whether or not known to BioReliance except as may be specified in the Contract, and the Client shall fully indemnify, and keep indemnified and hold harmless, BioReliance against any and all claims, actions, costs, expenses or other liabilities whatsoever in respect of:-

5.3.1 any liability under the Consumer Protection Act 1987, unless such liability is caused by the negligent act or omission of BioReliance;

5.3.2 any negligent or willful act or omission of the Client or any third party in relation to the use, processing, transport or storage of the Product.

6. QUALIFIED PERSON

6.1 Where required under the Regulations BioReliance shall provide the services of a Qualified Person (as defined in the Regulations) who shall have responsibility for releasing the Product to the Client and certifying that the Product has been manufactured in accordance with the terms of the Specifications and in compliance with the principles of the Regulations. Such certification shall, for the avoidance of doubt, relate solely to the Production Services being provided by BioReliance to the Client and with respect to the release of the Product by BioReliance to the Client, and it is acknowledged and accepted by the Client that neither BioReliance nor their Qualified Person shall have any responsibilities for the final release of the Product for the purposes of clinical trials nor for ensuring compliance with any authorisation that may be required by Client or any third party for use of the Product in clinical trials, and the Client shall free and relieve BioReliance and the Qualified Person of all liability in respect of such matters except to the extent that any such liability arises as a result of the negligence or willful misconduct of BioReliance or the Qualified Person in implementing their respective obligations as provided for in these Terms and Conditions.

6.2 For the purposes of enabling the Qualified Person to perform his/her responsibilities as defined in this Section 6 it is an essential condition that the Client shall provide to BioReliance to the extent reasonably required by BioReliance to comply with the Regulations (i) all relevant information from any applicable marketing or other authorisations relating to the Product and (ii) information on the Material and on the Client's process and other relevant information.

6.3 It shall be the responsibility of the Client to satisfy itself that all relevant requirements of such marketing or other authorisations, insofar as same relate to the Production Services, have been incorporated within the Specifications. Neither BioReliance nor the Qualified Person shall have any responsibility for checking the terms of any such marketing or other authorisations or other related documentation.

6.4 It shall be the responsibility of the Client, either directly or through any person appointed by the Client with overall responsibility for certification of the finished product batch for release for the purposes of use in clinical trials, to satisfy itself that the Qualified Person appointed by BioReliance for the Production Services, and the role of the Qualified Person as described in this Section 6 is sufficient for its purposes.

6.5 In undertaking such responsibilities the Qualified Person shall ensure that the following requirements have been met:

6.5.1 The Product and its manufacture comply with the terms of the Specifications;
6.5.2 Manufacture and testing has been carried out in accordance with the Regulations;
6.5.3 The principal manufacturing equipment and testing processes comprised within the Production Services have been validated;
6.5.4 Any deviations or planned changes in production or quality control have been authorised by the persons responsible in accordance with the procedures defined in the Specifications and any other relevant documentation;
6.5.5 All appropriate checks and tests have been performed, including any additional sampling, inspection, tests or checks initiated as a result of deviations or planned changes;
6.5.6 All necessary production and quality control documentation has been completed and endorsed by the members of staff authorised to do so in accordance with BioReliance's internal procedures; and
6.5.7 All audits have been carried out as required by BioReliance's quality assurance system.

6.6 BioReliance shall be responsible for the actings or omissions of the Qualified Person under these Terms and Conditions and, for the avoidance of doubt, it is acknowledged and accepted by the Client that the Qualified Person shall have no personal liability to the Client or any third party in respect of such matters.

7. DELIVERY OF MATERIAL AND PRODUCT

7.1 The Client shall make delivery of Material to the Facility and shall be entirely responsible for any and all costs associated with such delivery.

7.2 BioReliance shall make delivery of the Product to the Client ex-works at the Facility (Incoterms 2000) at which time all right and title in the Product shall pass to the Client and the Client shall at that time be responsible for the whole risk of loss or damage to the Product from the point of delivery.

7.3 BioReliance shall have no responsibility for the packaging of the Product unless agreed otherwise in writing by BioReliance and the Client, and if such a responsibility exists, it shall be subject always to the terms of Section 7.2.

7.4 The Client shall be responsible for all charges associated with the packaging and carriage of the Material and/or Product.

8. APPROVAL OF PRODUCT

8.1 The Client shall have a period of three months from receipt of the latest of the Product or the Final Report in which to notify BioReliance in writing of any failure of the Product to meet the agreed specification as detailed in the Specifications.

8.2 In the event that no written notification is received within the said three month period, the Client shall be deemed to have accepted the Product as meeting specification.

8.3 In the event of BioReliance's receipt of a notice pursuant to Section 8.1 and BioReliance acknowledges following upon such internal investigations as BioReliance shall deem reasonably necessary that the Product fails to meet the specification and that such failure has arisen as a result of BioReliance having failed to comply with its obligations under Section 2.1 hereof and that such failure is not due to any act or omission of the Client, or those acting on behalf of or on the instructions of the Client, BioReliance shall, at its own cost and as soon as reasonably practicable replace such part of the Product as has failed to meet specification provided that the Client shall supply BioReliance with appropriate quantities of any replacement Material reasonably required by BioReliance to enable it to repeat the Production Services or the appropriate part thereof.

8.4 In the event that BioReliance, acting reasonably, is unable to replace the failed Product or to repeat the Production Services it shall refund to the Client that part of the Price that relates to that part of the Production Services relating to the production of the failed Product.

8.5 In the event of BioReliance receiving notice from the Client pursuant to Section 8.1, the Client shall make available to BioReliance the failed Product for inspection at the Facility and neither BioReliance nor the Client shall take any steps to manipulate or otherwise interfere with the Product until a final resolution is agreed in terms of this Section 8, other than for the purposes of carrying out bona fide testing of a sample of the failed Product.

8.6 In the event of a dispute arising as to whether the Product has failed to meet the agreed specification or as to whether any failure to meet the agreed specification is as a result of any act or omission of the Client or any party acting on behalf of the Client or with the authority of the Client or any third party following upon delivery of the Product to the Client, the dispute shall be referred to an independent expert.

8.7 The independent expert (acting as an expert and not an arbiter) shall be appointed by agreement between BioReliance and the Client or in the absence of agreement within a period of 14 days of the request for referral having been notified by either BioReliance or the Client to the other party, by the President for the time being of the Association of the British Pharmaceutical Industry.

8.8 The decision of the expert on the matter under referral, including the award of expenses, shall be final and binding on the parties in the absence of manifest error.

8.9 Should it be a condition of the Contract, or should the Client request and BioReliance consent to the Product being released to the Client prior to the completion of the Quality Assurance Audit or prior to the completion of any tests (including mycoplasma and sterility) forming part of the Production Services or services relating thereto and release of the results thereof, the Client warrants that the Product shall not be used by it, prior to such completion and release of results, for the purposes of clinical trials and the Client further acknowledges that any use of the Product prior to acceptance by it pursuant to Section 8.1 shall be at the Client's risk, and in respect of any such use of the Product prior to such acceptance the Client undertakes to indemnify BioReliance against any and all loss suffered, or any and all claims made against BioReliance, by the Client, or any third party as a result of such use of the Product by the Client, or any third party

8.10 The remedy under Section 8 shall be the only remedy available to the Client in respect of a failure of the Product to meet specification.

9. CHANGES.

9.1 Client shall have the right to request reasonable changes in or modifications ("Changes") to the Specifications for Production Services which BioReliance has agreed to conduct and which have not been completed. All such Changes shall be in writing and shall be signed by authorized representatives of BioReliance and Client. If such Changes result in an increase in the cost of the Production Services, the Price shall be adjusted commensurate with such increase. If such Changes affect the projected completion date of the Production Services, the completion and report due dates shall be adjusted commensurate with such affect.

9.2 In the event that BioReliance should deem it advisable or necessary to make variations to, or deviate from, the Specifications, BioReliance shall obtain the Client's approval if BioReliance considers that any such variation or deviation will affect the Product, the Results or the Price.

10. DATA.

Client shall be the exclusive owner of and shall have title to all Data. Client shall not own or have title to any BioReliance Methodology. Unless otherwise agreed to, upon completion of the Production Services, BioReliance shall store and maintain all Data together with, where applicable, archive samples of Product and process intermediates in accordance with the Regulations. After three (3) years (or such other period as may be specified in the Regulations), BioReliance shall be entitled to contact Client for instructions regarding the return, continued storage, or disposal of all Data. Should Client wish to have the Data returned, BioReliance will inventory, box and ship Data to the address specified. Client shall bear all shipping costs. The cost to inventory and box the Data will be borne by BioReliance. Should Client wish BioReliance to continue to store the Data BioReliance shall be entitled to charge a reasonable fee for such storage. Should Client wish the Data to be disposed of the disposal costs will be borne by BioReliance. In the event no response is received from Client within thirty (30) days of the date of the contact letter, BioReliance shall at its discretion be entitled either to charge a fee to Client for continued storage of the Data or return the Data to the Client (the Client bearing the shipping costs).

11. STORAGE OF PRODUCT.

In the event that the Production Services include storage by BioReliance of the Product on behalf of the Client, the following conditions shall apply to such storage :-

11.1 BioReliance shall not undertake to store all the Product on behalf of the Client and the Client undertakes to store such quantities of the Product at a separate location as shall reasonably be required to protect their interests.

11.2 In respect of any damage to or destruction of the Product while at the Facility and under BioReliance's control, the limit of BioReliance's liability to the Client shall be Ten Pounds (£10) Sterling per vial. It shall be the responsibility of the Client to arrange its own insurance cover against damage to or destruction of the Product in respect of any value in excess of said figure of Ten Pounds (£10) Sterling per vial.

12. CONFIDENTIALITY.

12.1 During performance of the Production Services and for ten (10) years thereafter, BioReliance will treat all Client Information as confidential and will not knowingly disclose the same to any person other than Client or its designated representatives or to BioReliance's Affiliates where reasonably required.

12.2 The foregoing provisions of Section 12.1 shall not apply to that part of Client Information which BioReliance can prove: -

a) is already lawfully known to BioReliance; or
b) is or becomes publicly known by any means whatsoever, through no wrongful act of BioReliance; or
c) is received from a third party without breach of any obligation of confidentiality owed by that third party to the Client; or
d) is independently developed by or for BioReliance without use of or reference to the Client Information.

12.3 During performance of the Production Services and for ten (10) years thereafter and subject to the provisions of Section 12.2, Client will treat all BioReliance Confidential Information as confidential and will not knowingly disclose same to any third party other than Affiliates where reasonably required.

12.4 Notwithstanding the provisions of Sections 12.1 and 12.3, BioReliance and its Affiliates may disclose or use the Client Information, and the Client and its Affiliates may disclose or use the BioReliance Confidential Information (a) to the extent necessary to make any required governmental or regulatory filing or submission or (b) to the extent required under applicable law in connection with any court action or any proceeding, audit, investigation, or inquiry by or before any Government, local or foreign governmental agency, commission, bureau, authority, court or arbitration tribunal; provided that the party required to make any of the foregoing disclosures provides written notice to the other party as soon as is reasonably practicable after becoming aware of such requirement and co-operates with such other party, at such other party's expense, to obtain a protective order or other similar determination with respect to the information required to be disclosed.

12.5

13. REPORTS.

BioReliance shall deliver a Final Report on completion of the Production Services unless the Client requests otherwise. If the Client requests a draft Report, the Client shall have thirty (30) days from receipt of the draft Report to review the draft Report and provide comments to BioReliance. Within thirty (30) days of receipt of any Client comments, BioReliance will provide Client with the Final Report. If no comments are received from Client within thirty (30) days following delivery of the draft Report to the Client, the draft Report shall be issued to Client as a Final Report.

14. FACILITY VISITS AND CLIENT AUDITS.

Upon reasonable advance notice, BioReliance will permit a maximum of two (2) Client representatives to visit BioReliance's Facilities annually for a maximum of two (2) working days and during normal working hours, to observe progress of the Production Services, discuss the Production Services with appropriate officials of BioReliance, and inspect and copy batch manufacturing records and Data relevant to the Production Services. Additionally Client may request "for cause" audits to address product quality issues. With the exception of "for cause" audits, BioReliance reserves the right to make a reasonable charge for additional auditing time and/or additional Client representatives. Facility visits shall also be permitted during the Data retention period described in Section 10 above. During Facility visits, Client may inspect, but shall not be permitted to copy or remove, in whole or in part, any of the BioReliance Methodology. While on BioReliance's premises, Client shall adhere to any and all safety, security, and confidentiality measures required by BioReliance.

15. USE OF NAMES.

Client shall not use BioReliance's name or the names of BioReliance's employees in any advertising or sales promotional material or in any publication without prior written consent of BioReliance. BioReliance will not use Client's name or the names of Client's employees in any advertising or sales promotional material or in any publication without prior written consent of Client. Notwithstanding the above, Client shall be permitted to use BioReliance's name in any regulatory submission associated with the Client's project for which the Production Services are being performed without prior written consent of BioReliance, and BioReliance shall be permitted to use Client's name to the extent necessary to comply with regulatory requirements without prior written consent of Client.

16. INVENTIONS AND PATENTS.

16.1 Client shall become the exclusive owner of and BioReliance hereby assigns to Client all concepts, inventions, improvements, designs, programmes, formulae, know-how, methods, processes and writings, whether or not copyrightable or patentable, relating exclusively to the Material or Product and discovered exclusively as a result of performing the Production Services (collectively, the "Inventions"). If requested by Client, BioReliance shall, at Client's expense, do all things reasonably necessary to assist Client to obtain patents or copyright on any Inventions to the extent the same may be patented or copyrighted.

16.2 Notwithstanding the foregoing, "Inventions" shall not include, and BioReliance is and shall continue to be the sole owner of, all concepts, inventions, improvements, designs, programmes, formulae, know-how, methods, processes, and writings utilized or developed in conducting the Production Services to the extent relating solely and generally to the business, processes, practices, or services performed by BioReliance for its Clients, including such as relate to the BioReliance Methodology.

17. CLIENT'S WARRANTY.

Client represents and warrants that it will comply with all applicable laws and regulations governing use of the Product, and agrees to use the Product solely for the purposes set forth in, and in accordance with, any approved uses therefor. Client represents and warrants that it owns or possesses, has access to, or is licensed under all patents, patent applications, inventions, improvements, trademarks, trade names, copyrights, licenses, information, proprietary rights, processes and know-how necessary to permit BioReliance's use of the Material and the Client Confidential Information in performance of the Production Services, and that the performance of the Production Services utilising the Material and Client Confidential Information will not result in any infringement, misappropriation or violation of any agreement, or conversion of or conflict with the rights of third parties. Client has not received, nor has Client any knowledge of, any conflict with the asserted rights of other individuals or entities with respect to any intellectual property rights used or to be used in connection with the Material and the Client Confidential Information. Client represents and warrants that it is sufficiently self-insured or possesses sufficient insurance coverage against any liability arising under the Contract.

18. LIMITED WARRANTY; REMEDY; DAMAGES.

18.1 The undertaking of BioReliance to perform the Production Services is a contract for services only. The sole warranty with respect to its services is that it will perform the Production Services with due care in accordance with the Specifications, generally prevailing industry standards, and the Regulations. Subject to the terms of Section 8 any claim by the Client for a breach of such warranty shall be made in writing to BioReliance on or before the first anniversary of the later of the date that the relevant Final Report is delivered to the Client or the Product released to the Client. Subject to the terms of Section 8, the sole remedy of the Client for breach of such warranty shall be to require BioReliance to re-perform the Production Services (or such portions thereof as may reasonably be required to be re-performed), and, in such event BioReliance shall diligently pursue the re-performance of the Production Services or portions thereof until completion.

18.2 THE WARRANTY SET FORTH IN SECTION 18.1 IS IN LIEU OF ANY AND ALL OTHER WARRANTIES RELATING TO THE PRODUCTION SERVICES TO BE PERFORMED, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE WHETHER ARISING BY STATUTE OR OTHERWISE IN LAW OR UNDER CONTRACT, DELICT, TORT OR OTHERWISE. UNDER NO CIRCUMSTANCES SHALL BIORELIANCE BE LIABLE TO THE CLIENT OR ANY THIRD PARTY CLAIMING BY OR THROUGH THE CLIENT FOR ANY LOST PROFITS OR REVENUE, INCIDENTAL, INDIRECT, CONSEQUENTIAL, SPECIAL, PUNITIVE OR EXEMPLARY DAMAGES OR ANY FINES OR PENALTIES WHETHER IN CONTRACT, DELICT, TORT, NEGLIGENCE OR OTHERWISE, EVEN IF BIORELIANCE IS ADVISED OF THE POSSIBILITY OF SUCH DAMAGES OR LOSSES. BIORELIANCE'S LIABILITY TO THE CLIENT FOR THE BREACH OF ANY TERMS AND CONDITIONS OF THE CONTRACT (OTHER THAN ANY BREACH OF THE WARRANTY IN SECTION 18.1, WHICH SHALL BE GOVERNED BY THE EXCLUSIVE REMEDY CONTAINED IN SECTION 18.1 AND SECTION 8 IF APPLICABLE), SHALL BE LIMITED TO DIRECT DAMAGES IN AN AMOUNT NOT TO EXCEED THE FEE PAID OR TO BE PAID BY THE CLIENT TO BIORELIANCE IN CONNECTION WITH THE AFFECTED PART OF THE PRODUCTION SERVICES.

18.3 Nothing in these Terms and Conditions shall be deemed to exclude or restrict (to the extent not permissible in law to so exclude or restrict) any liability in law which BioReliance may have for death or personal injury resulting from the negligence of BioReliance in performing the Production Services or for fraud.

19. INDEMNIFICATION.

19.1 Except where caused by the reckless or willful misconduct of BioReliance, the Client shall indemnify, defend and hold harmless BioReliance, its parents, subsidiaries, and Affiliates and their respective officers, directors, employees, and agents from and against any and all expenses (including, but not limited to, reasonable lawyer's fees), damages, judgments, and losses incurred or suffered by any such indemnified party as a result of or in connection with any claim, demand, or cause of action asserted or brought by a third party (including, but not limited to, officers, employees, and agents of the Client) for (i) physical injury to or death of persons or physical damage to property arising out of or based upon the manufacture, sale, or use of any quantity of the Product, or any derivative thereof or product related thereto, by or on behalf of the Client, whether such manufacture, sale, or use took place prior to conclusion of the Production Services or thereafter and whether or not such manufacture, sale, or use took place in reliance, in whole or in part, on the Production Services or any portion thereof, or (ii) physical injury to or death of persons or physical damage to property arising out of BioReliance's use of any quantity of the Materials in accordance with the Specifications, Regulations, and/or other written or verbal instructions issued by Client; or (iii) infringement, unlawful disclosure or misappropriation of copyright, patent, trade secret or other intellectual property by reason of the performance of the Production Services on the Materials.

19.2 The Client shall be responsible for arranging and maintaining in force appropriate insurance cover at its cost against (1) any loss of or damage to the Material whilst the Material is in BioReliance's possession for the purposes of enabling BioReliance to perform the Production Services and (2) products liability insurance cover for a minimum sum of Ten Million Pounds £10,000,000 Sterling for the Product and, if reasonably practicable, to have the Facility noted as an address on such insurance cover. At the request of BioReliance the Client shall exhibit to BioReliance evidence of such insurance cover.

20. FORCE MAJEURE.

20.1 It is mutually understood and agreed that neither BioReliance nor the Client shall be responsible for failure or delay in performance of its obligations under or in connection with the Contract due to causes beyond its reasonable control, including but not limited to, acts of God, governmental actions, fire, labour difficulties, shortages, civil disturbances, transportation problems, interruptions of power or of communications, breakdown of machinery, failure of suppliers or subcontractors, or natural disasters. This Section 20.1 shall not apply to Client's obligation to make any payment to BioReliance. Provided always that the party seeking the benefit of this Section 20.1 shall promptly notify the other party thereof in writing and shall use reasonable endeavours to remedy, remove or mitigate the cause and effects of such an event.

20.2 If performance of the Production Services by BioReliance shall be delayed by any such circumstances or conditions of the type described in Section 20.1 hereof for a period of at least three months, then, at any time thereafter (provided that such delay is then still continuing by such circumstance or condition), either BioReliance or the Client shall have the right to terminate the Contract and, subject to Section 28 hereof, thereby be discharged from further performance of and liability under the Contract; provided that the Client shall pay BioReliance that proportion of the Price for the Production Services carried out by BioReliance to the date of termination.

21. TERMINATION.

21.1 In the event that it becomes apparent that BioReliance shall be unable to complete the Production Services as a result of a difficulty arising in connection with the Material or the Client Information or from some other technical or commercial difficulty outwith the reasonable control of BioReliance, and should BioReliance and the Client be unable to resolve such difficulty following a period of consultation between the parties not exceeding 30 days, either BioReliance or the Client shall be entitled to terminate the Contract on providing written notice to the other of such decision to terminate subject always to the Client making payment to BioReliance of that proportion of the Price relating to that part of the Production Services carried out by BioReliance at the date of termination together with the reasonable costs incurred by BioReliance as a result of said termination including the loss of income from any unoccupied laboratory space, provided that BioReliance shall take such steps as are reasonable to minimise such losses.

21.2 Either party shall be entitled to terminate the Contract by written notice to the other party in the event that: -

21.2.1 the other party materially breaches any of the provisions of the Contract and such breach is not remedied within 30 days of a written notice being given by the non-defaulting party requiring any such breach to be remedied.

21.2.2 the other party ceases for any reason to carry on business or compounds with its creditors, or enters into liquidation (excepting always liquidation of a solvent company for organisational purposes), or has a receiver or manager appointed or is the subject of an application for an administration order.

21.3 Client shall be entitled to terminate any part of the Production Services in progress which shall include the period of preparation of the necessary paperwork prior to commencement of practical production work, subject always to Client making payment of that part of the Price commensurate with the percentage of work completed at time of termination together with payment of actual non-cancellable costs incurred by BioReliance in performance of the Production Services prior to cancellation and the loss of income from any unoccupied laboratory space, provided that BioReliance shall take such steps as are reasonable to minimise such losses

21.4 Client shall be entitled to cancel or postpone the Production Services in which circumstances the following cancellation charges would apply:

21.4.1 If cancelled/postponed prior to 3 months before the agreed commencernent date, a cancellation fee of 10% of the Price specified is due;

21.4.2 If cancelled/postponed 1 to 3 months before the agreed cornmencement date a cancellation fee of 30% of the Price specified is due

21.4.3 If cancelled/postponed 1 month or less before the agreed commencement date, a cancellation fee of 75% of the Price is due.

22. SUB-CONTRACTING.

With the exception of Affiliates, to whom BioReliance shall be entitled to sub-contract all or any part of the Production Services, BioReliance shall not sub-contract all or any part of the Production Services without the consent of the Client.

23. ASSIGNMENT.

Neither BioReliance nor the Client may assign its rights or delegate its responsibilities hereunder without the prior written consent of the other not to be unreasonably withheld, delayed or conditioned.

24. INDEPENDENT PARTIES.

Nothing in these Terms and Conditions shall be construed as to create any relationship between BioReliance and Client other than that of independent contracting parties. Neither party shall have any right, power or authority to assume, create or incur any expense, liability or obligation, express or implied, on behalf of the other.

25. WAIVER.

No waiver by either party of any breach of any provision hereof shall constitute a waiver of any other breach of that or any other provision hereof.

26. SEVERABILITY.

If any part, term or provision of the Contract is determined to be invalid or unenforceable, the remainder of the Contract shall not be affected, and the Contract shall otherwise remain in full force and effect.

27. NOTICES.

Any notice to be given under, or in connection with the matters contemplated by, the Contract shall be in writing and signed by or on behalf of the party giving it and shall be served by delivering it personally or sending it by facsimile or pre-paid overnight courier service or first-class mail to the registered office or principal place of business of the other party (marked for the attention of the 'Legal Dept'), (or as otherwise notified by that party hereunder). Any such notice shall be deemed to have been received:

(a) if delivered personally, at the time of delivery;
(b) in the case of pre-paid recorded delivery or registered post, 48 hours from the date of posting;
(c) in the case of registered airmail, five days from the date of posting; and
(d) in the case of fax, at the time of transmission, subject to evidence of successful transmission.

For the purpose of this Section 27 "business day" means any day which is not a Saturday, a Sunday or a public holiday in the place at or to which the notice is left or sent.

28. CONTINUING OBLIGATIONS.

On the termination of the Contract for any reason the accrued rights, obligations and remedies of the parties under the Contract shall not be affected. Any provision of the Contract which is expressed or intended to have effect on, or to continue in force after, the termination of the Contract shall have such effect, or, as the case may be, continue in force, after such termination.

29. ENTIRE AGREEMENT.

The Contract constitutes the entire agreement between the Parties with respect to the subject matter of the Contract, and supercedes any conflicting terms that may be set forth on Client's purchase order, BioReliance's invoice, or any other documentation of either party, unless agreed to in writing by authorized representatives of both parties. The Contract is not intended to confer upon any person other than BioReliance and Client any rights or remedies hereunder. There are no representations, warranties, understandings or agreements relating to the Contract which are not fully expressed herein. No amendment, modification, waiver or discharge of any provision of the Contract will be valid unless in writing and signed by an authorized representative of the party against which such amendment, modification, waiver or discharge is sought to be enforced.

30. GOVERNING LAW.

The Contract will be governed by and construed in accordance with the law of Scotland, without regard to any provisions relating to the conflict of jurisdictional legal requirements. Both parties submit to the exclusive jurisdiction of the Scottish courts as regards any claim, dispute or matter arising out of or relating to the Contract and its implementation or effect unless provided for otherwise in the Contract and expressly waive any objections or defenses based on lack of personal jurisdiction or venue.

June 2008