

MEDIMMUNE LIMITED
STANDARD CONDITIONS
CONFIDENTIAL

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| <p>1 Definitions and Interpretations</p> <p>1.1 In these Conditions unless the context otherwise requires:</p> <p>1.1.1 “MedImmune Group” means the Customer and each subsidiary and holding company of the Customer, or subsidiary of such subsidiary or holding company (and “subsidiary” and “holding company” shall have the meanings given to them by Sections 736 and 736A of the Companies Act 1985);</p> <p>1.1.2 “Conditions” means these terms and conditions and any special terms and conditions agreed in writing between the Customer and the Supplier;</p> <p>1.1.3 “Agreement” means any agreement between the Customer and the Supplier for the purchase of Goods and/or Services;</p> <p>1.1.4 “Customer” means MedImmune Limited, a company incorporated in England whose registered office is Milstein Building, Granta Park, Cambridge, CB21 6GH, UK;</p> <p>1.1.5 “Goods” means the goods (including any part or parts of them) which the Supplier is to provide to the Customer pursuant to the Order in accordance with these Conditions;</p> <p>1.1.6 “Goods Legislation” means any applicable statute, statutory rule, order, directive, regulation or other instrument having force of law (including any directive or order promulgated by any competent supra-national body), all British and European standards, UKAS (United Kingdom Accreditation Service) and all other legislation for the time being in force relating without limitation to the manufacture (including raw materials or chemicals used in the production process), packaging, delivery, carriage, storage, installation and use of the Goods;</p> <p>1.1.7 “Intellectual Property” means any patent, registered design, copyright (including rights in software), design right, database right, moral right, trade mark, service mark, domain name, rights in confidential information and all similar property rights anywhere in the world in each case whether registered or not and including any application for registration of the foregoing;</p> <p>1.1.8 “Order” means any order from the Customer to the Supplier for the supply of Goods or Services as appended to these Conditions;</p> <p>1.1.9 “Services” means the services which the Supplier is to provide to the Customer pursuant to the Order in accordance with these Conditions;</p> <p>1.1.10 “Specification” means the Customer’s specifications or stipulations for the Goods and/or Services notified in writing to the Supplier;</p> <p>1.1.11 “Supplier” means the person, firm or company to whom the Order is addressed.</p> <p>1.2 The headings to clauses are inserted for convenience only and shall not affect the interpretation or construction of these Conditions.</p> <p>1.3 Words importing the singular shall include the plural and vice versa. Words importing a gender include every gender and references to persons include an individual, company, corporation, firm or partnership.</p> <p>1.4 The words and phrases “other”, “including” and “in particular” shall not limit the generality of any preceding words or be construed as being limited to the same class</p> | <p>2 Basis of Agreement</p> <p>2.1 The Agreement will be subject to these Conditions to the exclusion of all other terms and conditions (including any terms or conditions which the Supplier purports to apply under any quotation, Order acknowledgement or any other document issued by the Supplier).</p> <p>2.2 The Order is an offer made by the Customer to the Supplier and the Agreement shall come into effect upon acceptance of the Order by the Supplier. Unless previously withdrawn by the Customer, Orders shall be deemed accepted if not rejected by the Supplier by notice in writing within seven (7) days of their date. The Order number must be quoted on all correspondence and all invoices relating to such Order.</p> <p>2.3 No Order shall be capable of acceptance by the Supplier unless it is in writing and is signed by an authorised representative on behalf of the Customer.</p> <p>3 Delivery</p> <p>3.1 Delivery of the Goods shall take place strictly in accordance with the Customer’s delivery instructions whether given in the Order or separately. Each delivery must be clearly marked in accordance with the Specification and/or the Order.</p> <p>3.2 Time of delivery is of the essence of the Agreement. The Customer shall be under no obligation to accept delivery of the Goods before the specified delivery time, but reserves the right to do so.</p> <p>3.3 The Customer shall have the right to change its delivery instructions at any time on giving fourteen (14) days notice.</p> <p>3.4 A detailed advice note quoting the Order number shall accompany the Goods together with a certificate of the Supplier in such form as the Customer shall require confirming the conformance of the Goods with the Specification.</p> <p>3.5 The Customer shall not be obliged to accept quantities of the Goods which vary from those specified in the Specification or the Order.</p> <p>3.6 The Goods will be properly packed and secured in such a manner as to reach their destination undamaged and in good condition. The Customer shall not be obliged to return to the Supplier any packaging materials for the Goods.</p> <p>4 Acceptance</p> <p>4.1 The Customer shall not be deemed to have accepted any Goods until it has had a reasonable time to inspect them following delivery or after any latent defect has become apparent. For the avoidance of doubt no inspection or testing by the Customer whether before or after delivery of the Goods nor the signing of any delivery note or other document acknowledging physical receipt of any Goods shall be deemed to constitute or evidence acceptance or approval of the Goods for the purposes of the Sale of Goods Act 1979 (as amended) nor be deemed a waiver of the Customer’s rights either to cancel or return all or any part thereof where the Goods are found to be defective or not in accordance with the Agreement, Order and Specification.</p> |
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- 4.2 The Supplier shall promptly keep the Customer informed of any matter of which it is or reasonably should, as supplier of the Goods, be aware relating to the storage, transportation, handling, assembly or use of the Goods by the Customer (including legislation or advice from responsible or professional or legal bodies in respect of raw materials used in the manufacture of the Goods) and the actions it has taken or proposes to take and those that the Customer should take in relation to such matters.
- 5 Title and Risk**
- 5.1 The Goods shall be at the risk of the Supplier until they are delivered in accordance with the Agreement when, without prejudice to any right of rejection which the Customer may have under the Agreement or by law, title to and risk in the Goods shall pass to the Customer, provided that if the Customer pays for the Goods prior to delivery, title to the Goods shall pass to the Customer when payment is made.
- 6 Provision of Services**
- 6.1 If the Agreement is for or includes Services to be performed by the Supplier then, the Supplier undertakes, represents and warrants to the Customer that:
- 6.1.1 the Supplier shall carry out the Services strictly in accordance with the Order and the Specification;
- 6.1.2 the Services shall be performed by appropriately qualified and trained personnel with all due care, skill and diligence and to such high standard of quality as it is reasonable for the Customer to expect in all the circumstances;
- 6.1.3 the time of performance of the Services is of the essence of the Agreement.
- 7 Prices and Payment**
- 7.1 The price of the Goods and/or Services shall be stated in the Order. The price shall be inclusive of all packaging, packing, labelling, insurance, delivery, installation costs and all other costs incurred by the Supplier in relation to the Goods and their delivery unless otherwise specified in the Order.
- 7.2 All sums payable under the Agreement are exclusive of VAT which shall be added if appropriate at the rate prevailing at the relevant tax point but inclusive of any other applicable tax or duty payable upon such sums.
- 7.3 The Supplier may only invoice the Customer on or after delivery of the Goods or completion of the performance of the Services and invoices submitted early shall be deemed received on the date of delivery of the Goods or date of completion of the performance of the Services. Invoices shall be in such form as the Customer specifies from time to time and shall be addressed to the Accounts Department at the address for the Customer set out in these Conditions. The Customer's Order number shall be quoted clearly on each invoice and on all invoice correspondence and advice notes.
- 7.4 Unless otherwise stated in the Order, the Customer shall pay the price of the Goods or Services within sixty (60) days after the end of the month of the later of:
- 7.4.1 receipt by the Customer of an invoice issued in accordance with Condition 7.3;
- 7.4.2 or after acceptance of the Goods or Services by the Customer.
No interest shall be payable by the Customer under this Agreement in any circumstances whatsoever.
- 7.5 The prices charged by the Supplier to the Customer shall not exceed those prices charged by the Supplier to any other customer purchasing the same or similar goods and/or services in the same or smaller quantities and the Customer shall be entitled to any discount for prompt payment, bulk purchase or volume of purchase customarily granted by the Supplier.
- 7.6 If the price is stated in the Order to be on a "time and materials" or "cost plus" basis or similar the Supplier shall give the Customer access to all documents and information in the Supplier's possession or under its control to enable the Customer to satisfy itself that the amount charged by the Supplier is properly and correctly charged in accordance with the Agreement and in default the Customer shall be entitled to withhold payment in whole or in part until such default is rectified to the satisfaction of the Customer.
- 7.7 If any sums are due to the Customer from the Supplier, then the Customer shall be entitled to exercise the right to set-off such sums against any payments due to the Supplier from the Customer under or in relation to this or any other Agreement. The Supplier shall not be entitled to apply any amount due to the Customer under the Agreement in or towards payment of any sum owing by the Customer to the Supplier in relation to any matter whatsoever.
- 7.8 Any money paid by the Customer to the Supplier in respect of any Goods rejected under these Conditions together with any additional expenditure over and above the price specified in the Order reasonably incurred by the Customer in obtaining other goods in replacement of any rejected Goods shall be paid by the Supplier to the Customer within seven (7) days of the date of the Company's notice demanding the same or, at the Company's sole option, shall be deducted from the money still to be paid by the Customer to the Supplier in relation to such Goods.
- 8 Warranties**
- 8.1 The Supplier undertakes, represents and warrants to the Customer that the Goods and their packaging and labelling shall:
- 8.1.1 be accompanied with accurate, complete and comprehensible instructions for the treatment, assembly, use and/or storage of the Goods;
- 8.1.2 conform to the Specification and with any instructions of the Customer, and shall otherwise meet the requirements of the Order and this Agreement;
- 8.1.3 be of satisfactory quality, free from defects in materials and workmanship and fit for their intended purpose (whether such purpose is implied or expressly stated in the Specification, Orders or Agreement);
- 8.1.4 be free from design and other inherent defects (save to the extent that the Goods have been supplied in accordance with designs of the Customer);
- 8.1.5 comply with all Goods Legislation;

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- 8.1.6 conform strictly as to quality, quantity and description with any samples provided by the Supplier for the purpose of supply of Goods of that type.
- 8.2 The Supplier shall use its best endeavours to transfer or assign to the Customer or otherwise obtain for the benefit of the Customer any guarantee, warranty or other confirmation of quality, title or fitness for purpose given by any manufacturer of the Goods in respect of the Goods (or part thereof) to the extent that the same is capable of such transfer or assignment to the Customer or otherwise providing such benefit for the Customer.
- 8.3 Where there is any breach of the Supplier's warranty in Condition 6.1 or Condition 8.1 above or if any obligation, warranty or requirement imposed by, given or stated in the Agreement in respect of the Goods or Services is not complied with, or the Goods or any instalment of the Goods are not delivered at the specified time or the Goods delivered are damaged the Customer shall be entitled at its sole discretion without liability to the Supplier (arising out of such action) and without prejudice to any other right or remedy the Customer may have to take one or more of the following actions to:
- 8.3.1 cancel the Agreement and treat the Agreement as having never been entered into by the Supplier; and/or
- 8.3.2 reject the relevant Goods (in whole or in part) and any Goods already delivered which cannot be effectively and commercially used by reason of the non delivery of any undelivered Goods; and/or
- 8.3.3 refuse to accept any subsequent delivery of the Goods; and/or
- 8.3.4 recover from the Supplier any costs reasonably incurred by the Customer in obtaining substitute goods or services from another supplier; and/or
- 8.3.5 require the Supplier at its sole cost to replace, repair the Goods or carry out such work as is necessary within fourteen (14) days so that the Goods conform to the Agreement, Order and Specification; and/or
- 8.3.6 require the Supplier at its sole cost to re-execute the Services in accordance with the Agreement, Order and Specification within seven (7) days; and/or
- 8.3.7 treat this Agreement as discharged by the Supplier's breach and:
- 8.3.7.1 delay payment of the price for the Goods and Services until the requirements of this Agreement, Order and any Specification are entirely fulfilled,
- 8.3.7.2 refuse to make payment of the price of the Goods or Services; or
- 8.3.7.3 require the repayment of any part of the price of the Goods or Services which the Customer has paid whether or not the Customer has previously required the Supplier to repair the Goods, supply any replacement Goods or re-execute the Services; and/or
- 8.3.8 claim such damages as may have been incurred by the Customer as a result of the Supplier's breach of the Agreement.
- 8.4 If the Customer claims that an Order has not been fulfilled or has been incorrectly fulfilled the Supplier shall be deemed to accept the validity of the claim unless it serves written notice on the Customer disputing the said
- claim and stating the reasons for its dispute within seven (7) days of the date of the said claim.
- 8.5 If the Customer exercises any right under these Conditions the Customer may at its absolute discretion require the Supplier to collect the relevant Goods forthwith or return the Goods to the Supplier at the Supplier's cost.
- 8.6 The Customer's rights under these Conditions are in addition to any statutory remedies available to the Customer.
- 8.7 Supplier will provide Goods and/or Services under this Agreement in compliance with all applicable laws and regulations and with the MedImmune/AstraZeneca Code of Conduct which can be found at <http://www.astrazeneca.com/Responsibility/Working-with-suppliers>. Supplier will require its suppliers and subcontractors to comply with all applicable laws and regulations and with the MedImmune/AstraZeneca Code of Conduct. Customer may terminate this Agreement if Supplier fails to comply with this Clause 8.7.
- 9 Product Recall**
- 9.1 The Supplier shall immediately notify the Customer in writing providing all relevant details if it discovers that there is:
- 9.1.1 any defect in the Goods which have been delivered to the Customer at any time; or
- 9.1.2 any error or omission in the instructions for the use, maintenance, assembly and/or storage of the Goods; (whether or not any such defect, error or omission represents a breach of the warranty in Condition 8.1 or any other Condition) which causes or may cause any risk of death, injury or damage to property.
- 9.2 The Customer may at its discretion and at the Supplier's own cost:
- 9.2.1 recall any Goods or any other products into which the Goods have been incorporated already sold by the Customer to its customers (whether for a refund, credit or replacement which shall in each case be undertaken by the Supplier at the Customer's option); and/or
- 9.2.2 issue any notification whether in writing or otherwise to its customers about the manner of use or operation of any Goods or any other products into which the Goods have been incorporated already sold by the Customer to its customers; in each case on the basis of the identification whether by the Customer, its customers or any third party of any defect in the relevant Goods or any error or omission in the instructions for their use or assembly (whether or not that defect, error or omission represents a breach of the warranty in Condition 8.1 above or any other Condition) which the Customer reasonably concludes affects or may affect any of the Goods supplied which causes or may cause any risk of death, injury or damage to property.
- 10 Indemnity**
- 10.1 The Supplier acknowledges that the Customer places particular reliance upon the Agreement and in addition to any other remedy available to the Customer, the Supplier irrevocably and unconditionally agrees to indemnify the Customer its employees, sub-contractors and agents (who shall have no duty to mitigate their

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	loss) in full and on demand and keep them so indemnified against all claims, demands, actions, proceedings and all direct and indirect damages, losses, costs and expenses (including without limitation legal on an indemnity costs basis and other professional advisers' fees, economic loss, loss of profit, future revenue, reputation, goodwill, anticipated savings) and any consequential loss made against or incurred or suffered by any of them and whether wholly or in part resulting directly or indirectly from the matters listed below whether or not such losses or the consequences of the matters listed below were foreseeable at the date of the Agreement:			with the prior written consent of the Customer.
		12.2		The obligations of confidentiality in this Condition 12 shall not extend to any information which the Supplier can show is in, or has become part of, the public domain other than as a result of a breach of the obligations of confidentiality under these Conditions; was in its written records prior to entering into the Agreement and not subject to any confidentiality obligations; was independently disclosed to it by a third party entitled to disclose the same or is required to be disclosed under any applicable law, or by order of a court or governmental body or authority of competent jurisdiction.
10.1.1	any claims that the Goods or Services infringe the Intellectual Property of any third party by reason of the use, purchase or sale by the Customer of the Goods including any royalties being payable to any third party (save to the extent that the Goods or Services have been supplied in accordance with the Specification or designs of the Customer);	12.3		The Supplier shall not make any announcement or otherwise publicise the existence of or disclose to any person the provisions of the Agreement without the prior written consent of the Customer.
			13	Intellectual Property
10.1.2	any breach of the Agreement by the Supplier, its employees, agents or sub-contractors or any act or omission by any of them including any delays and any costs or liabilities incurred by the Customer in having to cancel any Order as a result of any such breach, act or omission or any other warranty or condition concerning the Goods or Services whether express or implied by statute or otherwise;	13.1		All materials including any Specifications supplied by the Customer, and any copies made by or for the Supplier shall be the property of the Customer, shall only be used for the purposes of this Agreement, shall be treated by the Supplier as strictly confidential and shall be returned by the Supplier as strictly confidential and shall be returned by the Supplier immediately on request to the Customer at the Supplier's sole risk and cost.
10.1.3	any liability being incurred under the Consumer Protection Act 1987 in respect of the Goods or as a result of any recall of any Goods already sold by the Customer to its customers under Condition 9 above;	13.2		Any and all Intellectual Property created or acquired in the course of or as a result of any work carried out by the Supplier under or in pursuance of the Agreement, shall, from the date of their creation or acquisition by the Supplier and otherwise promptly upon request by the Customer, belong exclusively, throughout the world, to the Customer.
10.1.4	any termination of the Agreement pursuant to Condition 14.	13.3		The Supplier shall grant or procure the grant of an adequate licence or sub-licence to the Customer at no extra cost, in respect of any Intellectual Property, or procure the grant of such a licence or sub-licence in respect of any Intellectual Property which the Supplier does not own, incorporated or utilised in the Goods or any work done by the Supplier for the Customer in pursuance of the Agreement sufficient to enable the Customer to make full use of the Goods and such work and to repair, update or maintain the Goods and such work in which such rights are incorporated.
10.2	The Supplier shall provide all facilities, assistance and advice required by the Customer or its insurers for the purpose of contesting or dealing with any action, claim or matter arising out of the Supplier's performance, or purported performance of, or failure to perform, the Agreement.	13.4		The Supplier hereby agrees and undertakes promptly at the request of the Customer, but at its own cost, to do all such acts or deeds and execute all such documents as may be required by the Customer to give effect to the provisions and intentions of this Condition 13.
11	Insurance		14	Termination
11.1	The Supplier shall at its own cost effect and keep in place with reputable insurers such insurance policies as are appropriate and adequate having regard to its obligations and liabilities under the Agreement. The Supplier shall on the written request of the Customer from time to time provide the Customer with reasonable details of the insurance maintained in force in accordance with this Condition, and, on the renewal of each policy, the Supplier shall send a copy of the premium receipt to the Customer when requested to do so in writing by the Customer. The Supplier shall do nothing to invalidate any of the policies maintained in force in accordance with this Condition.	14.1		The Customer may immediately terminate the Agreement without payment of compensation or other damages caused to the Supplier solely by such termination by giving notice in writing to the Supplier if any one or more of the following events happens:
12	Confidentiality		14.1.1	the Supplier commits a material breach of any of its obligations under these Conditions which is incapable of remedy;
12.1	The Supplier shall keep and procure to be kept secret and confidential all information disclosed or obtained as a result of the relationship of the parties under the Agreement and shall not use nor disclose the same save for the purposes of the proper performance of the Agreement or			

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- 14.1.2 the Supplier fails to remedy, where it is capable of remedy, or persists in any breach of any of its obligations under these Conditions after having been required in writing to remedy or desist from such breach within a period of thirty (30) days;
- 14.1.3 the Supplier proposes a voluntary arrangement within the meaning of Section 1 or Section 253 of the Insolvency Act 1986, or an interim order is made in relation to the Supplier under Section 252 of the Insolvency Act 1986, or any other steps are taken or negotiations commenced by the Supplier or any of its creditors with a view to proposing any kind of composition, compromise or arrangement involving the other party and any of its creditors; or
- 14.1.4 any of the following occur:
- 14.1.4.1 the Supplier is deemed to be unable to pay its debts within the meaning of Section 123 of the Insolvency Act 1986; or
- 14.1.4.2 the Supplier calls a meeting for the purpose of passing a resolution to wind it up, or such a resolution is passed; or
- 14.1.4.3 the Supplier presents, or has presented, a petition for a winding up order; or
- 14.1.4.4 an application to appoint an administrator is made in respect of the Supplier or a notice of intention to appoint an administrator is filed in respect of the Supplier; or
- 14.1.4.5 any other steps are taken by the Supplier or any other person to appoint an administrator over the Supplier; or
- 14.1.4.6 the Supplier has an administrator, administrative receiver, or receiver appointed over all or any part of its business, undertaking, property or assets; or
- 14.1.4.7 the Supplier takes any steps in connection with proposing a company voluntary arrangement or a company voluntary arrangement is passed in relation to it.
- 14.2 The termination of the Agreement shall be without prejudice to the rights and remedies of either party which may have accrued up to the date of termination.
- 14.3 Upon termination of the Agreement for any reason whatsoever:
- 14.3.1 (subject to Condition 14.2 above) the relationship of the parties shall cease save as (and to the extent) expressly provided for in this Condition 14.3;
- 14.3.2 any provision which expressly or by implication is intended to come into or remain in force on or after termination shall continue in full force and effect; and
- 14.3.3 the Supplier shall immediately return to the Customer (or if the Customer so requests by notice in writing, destroy) all of the Customer's property in its possession at the date of termination including all confidential information, together with all copies of such confidential information and shall certify that it has done so, and shall make no further use of such confidential information.
- 15 Assignment, Sub-Contracting and Third Party Rights**
- 15.1 The Customer reserves the right to perform any of its obligations or exercise any of its rights under the Agreement through any other member of the MedImmune Group provided that any act or omission of any such other company shall be deemed to be the act or omission of the Customer.
- 15.2 The Agreement is personal to the Supplier. The Supplier shall not assign, delegate, sub-
- contract, transfer, charge or otherwise dispose of all or any of its rights and responsibilities under the Agreement without the prior written consent of the Customer.
- 15.3 The Customer may assign, delegate, sub-contract, transfer, charge or otherwise dispose of all or any of its rights and responsibilities under the Agreement at any time without the prior written consent of the Supplier.
- 15.4 Each member of the MedImmune Group has the benefit of, and may enforce any of these Conditions or any provision of the Agreement.
- 15.5 Save for any company within the MedImmune Group no person who is not a party to the Agreement, (including any employee, officer, agent, representative or subcontractor of either party) shall have the right (whether under the Contracts (Rights of Third Parties) Act 1999 or otherwise) to enforce any term of the Agreement which expressly or by implication confers a benefit on that person without the express prior agreement in writing of the parties which agreement must refer to this Condition 15.5.
- 15.6 Where a person who is not a party to the Agreement who has a right to enforce any provision of the Agreement the parties may vary or cancel the Agreement by agreement between them without requiring the consent of such third party.
- 16 General**
- 16.1 The Supplier shall not exercise any right of lien, general or otherwise and howsoever arising, over any Goods or any other property of the Customer in the Supplier's possession, in respect of any sums owed by the Customer to the Supplier under the Agreement or otherwise.
- 16.2 Nothing in these Conditions shall create, or be deemed to create, a partnership or joint venture or relationship of employer and employee or principal and agent between the parties and no employee of the Supplier shall be deemed to be or have become an employee of the Customer.
- 16.3 No purported alteration or variation of these Conditions shall be effective unless it is in writing, refers specifically to the Agreement and is signed by a duly authorised representative of each of the parties to the Agreement.
- 16.4 The waiver by either party of any breach of these Conditions shall not prevent the subsequent enforcement of that provision and shall not be deemed to be a waiver of any subsequent breach of that or any other provision. Any waiver of any breach of these Conditions shall be in writing.
- 16.5 If at any time any part of these Conditions is held to be or becomes void or otherwise unenforceable for any reason under any applicable law, the same shall be deemed omitted from these Conditions and the validity and/or enforceability of the remaining provisions of these Conditions shall not in any way be affected or impaired as a result of that omission.
- 16.6 Any notice given under the Agreement or these Conditions shall be by fax or delivered by hand to the address of the party specified in the Agreement, or such other address as is notified to the other party from time to time provided that in the case of notices sent by

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- fax a confirmation copy of the transmission is delivered by hand to the recipient as set out in this Condition.
- 17 Law and Jurisdiction**
- 17.1 These Conditions and any dispute or claim arising out of or in connection with it shall be governed by, and construed in accordance with, the laws of England. All disputes or claims arising out of or relating to these Conditions shall be subject to the exclusive jurisdiction of the English Courts to which the parties irrevocably submit.
- 18 Adverse Event Reporting**
- 18.1 In performing the Services, Supplier shall be required to report adverse events to MedImmune in accordance with MedImmune policies and procedures. Such policies and procedures include maintenance of records and training for Supplier employees and/or agents (including authorized subcontractors) that may be exposed to Adverse Events and Product Complaints or may be engaged in feedback or communication of Adverse Events or Product Complaints.
- 18.2 Applicable Supplier employees and agents will complete an Adverse Event Reporting Training Program developed and provided by MedImmune prior to beginning designated projects on behalf of MedImmune, which shall include training with regard to MedImmune policies and procedures on reporting Adverse Events. Successful completion and documentation of this training is required annually for those Supplier employees and/or agents supporting designated projects. Additional training may be required at MedImmune's discretion. Supplier shall maintain records of successful adverse event training completion for all employees supporting MedImmune projects.
- 18.3 Supplier shall forward to MedImmune any information that Supplier obtains from a customer regarding an Adverse Event as defined below. The Supplier employee is responsible for reporting the Adverse Event to a MedImmune representative by calling the toll free Hot Line at 1-877-633-4411, unless another entity to which the report is to be sent is specified in the Agreement and agreed procedures set forth in the Agreement. Supplier shall forward the patient initials, patient number identification, physician phone number, drug product name and a brief description of the Adverse Event via the toll free Hot Line. The notification and reporting of all Adverse Events to MedImmune should be within one business day of receipt/ awareness of the Adverse Event.
- 18.4 Adverse Event Definition. An Adverse Event ("AE") is any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and that does not necessarily have a causal relationship with this treatment. This includes the following:
- a) an adverse event occurring in the course of the use of a product in professional practice;
 - b) an adverse event occurring from abuse/misuse of the product;
 - c) an adverse event occurring from the withdrawal of the product;
 - d) any significant failure of expected pharmacological action;
 - e) any accidental exposure (with or without an AE);
 - f) any medication error, with or without an AE (i.e., administration of expired product);
 - g) any overdose with the use of the product;
 - h) any pregnancy with the use of the product;
 - i) any exposure during breastfeeding;
 - j) any suspected transmission of infectious agents;
 - k) an unexpected therapeutic or clinical benefit from use of the product.
- 18.5 Supplier shall, on an ongoing basis, review its compliance with MedImmune's Adverse Event training requirements and reporting processes and shall notify MedImmune of any deviation from such training requirements or reporting processes.