PCI Pharma Services ("PCI") Terms and Conditions (x3xxII)

- 1 INTERPRETATION. Any reference to a statute or statutory provision is a reference to it as amended or re-enacted. A reference to a statute or statutory provision includes all subordinate legislation made under that statute or statutory provision. A reference to writing or written includes email.
- **2 DEFINED TERMS.** Where referred to herein, it shall be understood that the following terminology applies:
- 2.1 Affiliates: shall mean with respect to PCI, any corporation, firm, partnership, or other entity that is controlled by or under common control with PCI; with respect to Client, any corporation, firm, partnership, or other entity that controls, is controlled by or is under common control with Client. For purposes of this definition, "control" shall mean the ownership of at least fifty percent (50%) of the voting share capital of such entity or any other comparable equity or ownership interest.
- 2.2 <u>Applicable Law</u>: shall mean all applicable laws, statutes, rules, ordinances, regulations, directives, standards or requirements of any regulatory body, including without limitation GMP, applicable to (i) PCI's performance of its Services within those jurisdictions of Service performance, and (ii) Client's Materials, Products and other Intellectual Property Rights, and their development or commercialization anywhere in the world.
- **2.3** API: active pharmaceutical ingredient.
- **2.4** <u>API Inventions</u>: any Invention that relates exclusively to the Client IP or Client's patented API.
- **2.5** <u>Client</u>: the entity identified in the Proposal that is acquiring the goods, Products or Services described in the Proposal.
- **2.6** <u>Client IP</u>: all Intellectual Property Rights and embodiments hereof owned by or licensed to Client as of the date hereof or developed by Client other than in connection with the Proposal.
- **2.7** <u>Client Materials:</u> any API (in the case of Product manufacturing Services), investigational drug product, comparators and other materials and information supplied by or on behalf of Client to PCI for the purpose of performing the Services.
- **2.8** Contract: the contract between PCI and Client for the supply of Products and Services in accordance with the Proposal and these Terms and Conditions.

- 2.9 Data Protection Laws: all data protection and privacy laws and regulations applicable to the processing of personal data, personal information, or personally identifiable information, as such terms are defined under applicable data protection and privacy laws and regulations, including without limitation (i) with respect to the United States, the California Consumer Privacy Act of 2018, any applicable notification laws and regulations relating to personal data breach or breach of a security system, the rules of the U.S. Federal Trade Commission, and any other state or federal laws or regulations in the United States regarding data protection and privacy; (ii) with respect to the European Economic Area (the "EEA," which includes the 27 European Union Member States, Iceland, Lichtenstein and Norway), Switzerland and the United Kingdom ("UK") (collectively, the "EU"), the EU General Data Protection Regulation ((EU) 2016/679) and the Data Protection Act of 2018 in the UK, as well as any compliance obligations set forth in any Standard Contractual Clause agreements as designated by EU, UK or Swiss authorities and used by the parties to achieve such compliance; and (iii) in each case the equivalent of any of the foregoing in any relevant jurisdiction together with any statutory modification, consolidation, revision or re-enactment of the foregoing from time to time, and as applicable to each of PCI and Client within those jurisdictions.
- **2.10** Excluded Items: for purposes of this Contract, include APIs, comparator drug products and/or ancillary clinical trial items purchased by PCI on behalf of Client, third-party depot fees, freight charges, surcharges, taxes, customs, duties and levies.
- **2.11** FDA: means the United States Food and Drug Administration.
- **2.12** FD&C Act: means the United States Federal Food, Drug and Cosmetic Act, as amended, or supplemented from time to time.
- **2.13** Force Majeure Event: an act of God, or a national emergency, pandemic, fire, flood, explosion, accident, extreme weather, inability to obtain materials, trade union action or difficulty of practice beyond a party's reasonable control preventing or delaying it from performing its obligations under this Contract save that an inability to pay is not a Force Majeure Event.
- 2.14 GMP: means, as applicable, the FDA's current Good Manufacturing Practices, as set forth in the Title 21 of the United States Code of Federal Regulations, and any equivalent non-US laws and regulations that are applicable to the activities hereunder, including the MHRA's Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2017 (The Orange Guide), the European Union's current Good Manufacturing Practices pursuant to the European Commission in Directive 91/356/EEC as amended by 2003/94/EC, and/or, if

Manufacturing Services will be provided within Australia, the TGA's Code of Good Manufacturing Practices for medical products, in each case as such regulations and guidelines may be revised from time to time. "GMP" and "cGMP" are often used interchangeably and shall have the same meaning.

- 2.15 Intellectual Property Rights: patents, rights to inventions, copyright and neighboring and related rights, moral rights, trademarks and service marks, business names and domain names, rights in get-up and trade dress, goodwill and the right to sue for passing off or unfair competition, rights in designs, rights in computer software, database rights, rights to use, and protect the confidentiality of, confidential information (including know-how and trade secrets), and all other intellectual property rights, in each case whether registered or unregistered and including all applications and rights to apply for and be granted, renewals or extensions of, and rights to claim priority from, such rights and all similar or equivalent rights or forms of protection which subsist or will subsist now or in the future in any part of the world.
- **2.16** Invention: means any Intellectual Property Rights developed by either party in connection with the Proposal.
- **2.17** <u>PCI</u>: the specific PCI Pharma Services Affiliate as identified in the Proposal, trading as PCI Pharma Services.
- **2.18** PCI IP: means all Intellectual Property Rights and embodiments thereof owned by or licensed to PCI as of the date hereof or developed by PCI other than in connection with the Proposal.
- **2.19** <u>Process Inventions</u>: means any Invention, other than an API Invention, that relates to the PCI IP or relates to developing, formulating, manufacturing, filling, processing, packaging, labelling, analyzing or testing pharmaceutical products generally.
- **2.20** Products: the finished bulk products or finished packaging containing Client Materials (and, if applicable, any comparators or other materials) to be produced by PCI in accordance with the Proposal.
- **2.21** Proposal: the proposal to which these Terms and Conditions are attached or incorporated by reference, and any amendment or change order relating thereto subsequently agreed to in writing by PCI and Client.
- **2.22** Services: the services in respect of the Product or services, supplied by PCI to Client on the terms of the Contract.
- **2.23** <u>Terms and Conditions</u>: these terms and conditions as amended from time to time.

- 3 **CONTRACT FORMATION.** The Proposal constitutes PCI's offer to provide the Services solely in accordance with the Proposal and these Terms and Conditions, and supersedes all previous written and oral quotations, representations and/or agreements. Acceptance can be made by Client by any commercially reasonable means, including Client's acceptance of the Proposal, Client's issuance of a purchase order. Client's acceptance of Products or Services provided hereunder, or Client's acknowledgment or return of PCI's acknowledgment form or by electronic transmission. Acceptance hereof by Client is expressly limited to the exact terms hereof and shall evidence Client's unconditional agreement to these Terms and Conditions. If Client shall use its own purchase order or other form to order from PCI, such form shall be used for convenience only. These Terms and Conditions take precedence over and supersede any conflicting, different, inconsistent, or additional terms contained in any of Client's documentation or electronic transmissions, and any such conflicting, different, inconsistent or additional terms are hereby objected to and rejected by PCI. All stenographic and clerical errors are subject to correction, where this Contract is found to be an acknowledgment, if such acknowledgment constitutes an acceptance of an offer, such acceptance is expressly made conditional upon Client's assent to the terms of such acknowledgment, and acceptance of any part of Products or Services delivered by PCI shall be deemed to constitute such assent by Client.
- 4 TERMS AND CONDITIONS OF SALE. These Terms and Conditions apply to the Contract to the exclusion of any other terms that Client seeks to impose or incorporate, whether oral or written, and whether contained in any of Client's documentation or electronic transmissions, or which are implied by trade, custom, practice or course of dealing. No variation to these Terms and Conditions shall be effective unless in writing and signed by an authorized signatory of PCI and Client.
- PRICES. The price for the Services quoted by PCI in the Proposal may be increased from time to time to the extent that PCI's costs of providing the Services increase as a result of (i) changes in specifications for the Services; (ii) manufacturer pricing changes for API, comparator drug products and/or ancillary clinical trial items at any time; (iii) subsequent increases in the cost of labor and/or materials or services provided by third parties: (iv) changes to the purchase volume and size/frequency of production runs; and (v) any agreements, codes, or legislative enactments made/enacted in pursuance of any Applicable Law. Charges for carrier/courier services quoted by PCI in the Proposal are estimates only; actual charges are based on size, weight, destination, etc., and will be calculated at the time of shipment. Prices quoted by PCI are based upon the assumption of continuous production without interruptions caused by Client, unless otherwise agreed. If any material or component supplied by Client to PCI for the purpose of the Services is insufficient in quantity to allow PCI to complete the specified volume in

- full, Client shall be billed for any unused materials, components or products purchased by PCI in respect of the Proposal.
- **6 TAXES.** Prices do not include sales, revenue, excise, occupation, use, value added or other taxes or customs duties which are applicable now or which may hereafter be levied, imposed, or assessed, which, if applicable, shall be the sole responsibility of and shall be paid by Client or reimbursed by Client if paid by PCI.
- **DELIVERY.** Delivery of Products and Client Materials by PCI is made EXW PCI's facility (Incoterms® 2020) and is completed when the Products or Client Materials are presented by PCI for loading on the carrier's or courier's vehicle at PCI's facility. Client agrees to provide PCI with proof of export of the Products upon request. Notwithstanding such EXW terms noted above, and pursuant to clauses 8.1, 8.4, and 9 below, the parties agree that risk of loss for the Products and Client Materials remains with Client at all times and that Client is responsible for insuring Products and Client Materials. To the extent there is any conflict between any provisions of the Incoterms® 2020 referenced herein and the terms of this Contract, the terms of this Contract will prevail. PCI shall arrange for collection of the Products and Client Materials by the carrier/courier against the account nominated by Client. If Client does not nominate a specific carrier/courier account, PCI may use any reputable carrier/courier on Client's behalf. All carrier/courier costs are charged back to Client by PCI. All carriage and shipment of Products are subject to the carrier's/courier's conditions of carriage and liability limitations. Client remains liable to PCI for any unpaid balance of the fees irrespective of any loss or damage during or after such delivery. Any dates quoted for delivery of Products or Services are approximate only and the time of delivery is not of the essence. PCI shall not be liable for any failure or delay in delivery of the Products or Services that is caused by a Force Majeure Event, by the carrier/courier or Client's failure to provide PCI with adequate delivery instructions or any other instructions or Client Materials that are relevant to the supply of the Products or performance of the Services.

8 CLIENT MATERIALS.

- **8.1** Title and risk of loss to Client Materials shall remain with Client while such items are in the possession of PCI and for the duration of the Services. Title and risk of loss to PCI-supplied materials incorporated into the Products shall transfer to Client upon PCI's issuance of the batch records relating to such Products for submission to Client for approval. PCI shall have no obligation to insure Client Materials or the Products against any loss or damage.
- **8.2** Client warrants that (i) no Client Materials delivered by or on behalf of Client to PCI will be, at the time of shipment or delivery, adulterated, misbranded or otherwise prohibited within the meaning of

- the FD&C Act or similar law of any other jurisdiction, nor an article which may not, under the provisions of Section 505 of the FD&C Act, be introduced into interstate commerce; (ii) no Client Materials or the use thereof infringe, or are alleged to infringe, the Intellectual Property Rights of any third party: (iii) all Client Materials will be suitable for the purposes of providing the Services and will have the same physical characteristics and properties as the sample(s) or specifications previously submitted to PCI and upon which PCI issued Proposals for Services: (iv) prior to importation of Client Materials by or on behalf of Client to a PCI facility from another country, if applicable, and prior to PCI's release of the packaged Product to another PCI facility, distribution depots and/or investigational site. Client shall have obtained a valid and effective investigational new drug application, clinical trial authorization or similar foreign approval required for distributing, handling, storing or using the Client Materials and the packaged Product in each jurisdiction where such facility, distribution depot and/or investigational site is located; (v) for commercial Products, it holds a valid marketing authorization; and (vi) it is responsible for providing PCI with and / or approving the labelling and packaging requirements applicable to the Client Materials and the packaged Product in each jurisdiction of clinical or commercial distribution.
- **8.3** Client shall deliver all Client Materials to PCI in appropriate packaging and shall provide safety data sheets on Client Materials in sufficient time for review and training by PCI prior to delivery.
- 8.4 **EXCEPT FOR LOSS OR DAMAGE CAUSED TO CLIENT MATERIALS** OR THE PRODUCTS AS A DIRECT RESULT OF PCI'S GROSS NEGLIGENCE OR WILFUL MISCONDUCT IN HANDLING OR STORAGE, CLIENT SHALL BE SOLELY RESPONSIBLE FOR ANY LOSS OR DAMAGE TO CLIENT MATERIALS OR THE PRODUCTS. PCI'S AGGREGATE LIABILITY FOR LOSS OR DAMAGE TO CLIENT MATERIALS OR THE PRODUCTS SHALL NOT BE GREATER THAN THE LESSER OF (A) THE VALUE DECLARED BY CLIENT ON THE CUSTOMS INVOICE FOR SHIPMENT OF THE LOST OR DAMAGED CLIENT MATERIALS. (B) THE ACTUAL INVOICE PURCHASE PRICE PAID BY CLIENT TO A THIRD PARTY FOR THE LOST OR DAMAGED CLIENT MATERIALS. (C) THE MANUFACTURING COSTS OF THE LOST OR DAMAGED CLIENT MATERIALS IF PRODUCED BY CLIENT OR CLIENT'S AFFILIATE, (D) 50% OF THE FEES INVOICED OR TO BE INVOICED TO CLIENT FOR THAT PART OF THE SERVICES RELATED TO THE LOST OR DAMAGED CLIENT MATERIALS/PRODUCTS, OR (E) US\$50,000.
- **8.5** Client shall remove expired or obsolete Client Materials from PCI's facility within thirty (30) days of PCI's request. Client will be billed shipping costs plus an administration fee to ship such Client Materials, as set out in the Proposal. If after sixty days Client has not taken possession or provided instructions regarding such Client Materials, they will be

considered abandoned and may be discarded according to PCI's established procedures. If needed, Client will be billed for any fees associated with disposition of these Client Materials, components, or equipment at cost, plus an administration fee as set out in the Proposal.

- 9 INSURANCE. Client shall maintain liability insurance, including clinical trials insurance, product and general liability insurance, for Client Materials and Products pursuant to one or more insurance policies with a reputable insurer, with limits of not less than the equivalent of US\$10,000,000 per occurrence and annual aggregate. Additionally, Client shall either self-insure or carry property insurance with a reputable insurer against the perils of physical loss, including those generally associated with "all risk" property insurance, flood, earth movement and theft, to protect all Client Materials and Products at PCI's facility, any distribution depot or while in transit.
- **CREDIT APPROVAL.** In order to provide PCI with adequate assurance of performance by Client, shipments, deliveries and performance of the Services shall at all times be subject to the approval of and the requirements of the Credit Department of PCI, including the requirements that Client pay part or all of the purchase price in advance if requested to do so under the Proposal.
- TERMS OF PAYMENT. Except as otherwise provided in the Proposal, PCI will invoice Client for the Services as follows: nonrefundable capacity reservation fees are invoiced upon execution of a Proposal; if applicable, project management and storage and distribution Services will be invoiced for Services rendered during the previous month on a monthly basis or upon PCI's receipt of the applicable depot charges; manufacturing and packaging Services will be invoiced upon PCI's issuance of the relevant batch record(s) for submission to Client for approval: and analytical testing Services will be invoiced upon delivery of the testing report(s). Payment of all non-disputed charges shall be made in the currency specified in the invoice within thirty (30) days of the date of invoice. The currency exchange rate, if applicable, will be calculated at the time the invoice is prepared and will be based on the monthly average exchange rate published by The Wall Street Journal as determined by PCI's corporate finance division. PCI may require the pre-payment of costs or fees as identified in the Proposal. Charges unpaid after thirty (30) days shall bear interest at the rate of two percent (2.0%) a month, not to exceed the maximum rate permitted by Applicable Law. PCI reserves the right to increase the rate of interest on any overdue accounts, including those accounts already overdue, upon giving Client thirty (30) days' prior written notice.
- **TOOLING AND / OR EQUIPMENT.** With Client's consent, PCI will purchase any tooling and / or equipment required specifically to perform the Services as identified in the Proposal, and PCI will invoice

Client for such purchase. Except as otherwise provided in a Proposal, title and risk of loss to the tooling/equipment shall reside and remain with Client. If Client does not request transfer of Client owned tooling/equipment within three (3) months following completion of the relevant Services, all rights, title, and interests in and to the tooling/equipment shall be automatically assigned to PCI, free of any liens, without any further action required of Client. Client shall be responsible for all non-minor repairs and replacements of such tooling and equipment.

13 CANCELLATION/POSTPONEMENT.

- 13.1 Contracted Services can only be cancelled or postponed with the consent of PCI. Upon such cancellation or postponement, PCI agrees to cease work as promptly as reasonably possible and hold all completed and partially completed Products and any work in progress for Client. Client shall pay PCI for all capacity reservation fees, work and materials which have been committed and/or identified in the Proposal, and costs of all non-refundable deposit or other fees paid in advance or nonrefundable or non-cancellable materials purchased or ordered in reliance on such Proposal, plus (other than for Product manufacturing services per clause 0) a reasonable cancellation or postponement charge, which, unless otherwise agreed in writing, shall be computed on the basis of PCI's full cost plus appropriate mark-up, said cost to include without limitation all engineering work in connection with tooling; all work in progress; all raw materials; all supplies; and all commitments made by PCI in connection with the Proposal, less such reasonable allowances as PCI may make for standard components and for the balance of any material as scrap.
- 13.2 If production has stopped or been put on hold by Client, PCI shall invoice Client for all materials and components or products which have been committed and/or identified in the Proposal, which amounts shall be immediately due and payable.
- 13.3 In the case of Client's cancellation or postponement of Product manufacturing Services, a cancellation or postponement charge shall be calculated according to the number of business days' written notice of cancellation or postponement provided by Client prior to the planned commencement of production or other related Services, as set out in the Proposal.

14 IMPORT/EXPORT.

14.1 Unless otherwise agreed by Client and PCI in a separate written Importer of Record agreement, Client shall act as the importer of record and the principal party in interest for Client Materials and / or Products as the case may be. Except in the case where PCI and Client have

executed an Importer of Record agreement, delivery of Products and Client Materials by Client or Client's designate to PCI is made DDP PCI's Facility (Incoterms® 2020) and is completed on the unloading of the Products or Client Materials at PCI's facility. Notwithstanding such DDP terms noted above, and pursuant to clauses 8.1, 8.4, and 9 above, the parties agree that risk of loss for the Products and Client Materials remains with Client at all times and that Client is responsible for insuring Products and Client Materials.

- Client is solely responsible for the proper release and clearance of Client Materials and Products from customs, and Client acknowledges that it is the owner of Client Materials and Products for customs purposes. Client shall provide PCI with all information necessary for PCI to receive or deliver the Client Materials and/or Products, including import/export documentation/information and temperature and storage conditions. Client shall be solely responsible for the proper classification, origin determination and marking, and valuation of Client Materials and/or Products for customs purposes (including without limitation the assignment of the proper commodity codes).
- 14.3 If Client Materials or Products are to be exported out of the U.S., Client shall obtain all required export or import licenses. Client shall be responsible for all costs, charges, expenses and import and export taxes and duties for delivery and transportation of Client Materials and Products to and from PCI's facility and, if applicable, any other designated depot, site, or other destination.
- 15 INTELLECTUAL PROPERTY RIGHTS. All Client IP and API Inventions shall be owned solely by Client and no right therein or license is granted to PCI under this Proposal except for use in performing the Services. All PCI IP, improvements thereto and Process Inventions shall be owned solely by PCI and no right therein or license is granted to Client under this Proposal unless expressly set out herein.
- CONFIDENTIALITY AND PUBLICITY. Each party undertakes that it shall not at any time during the Contract, and for a period of seven (7) years after termination of the Contract, disclose to any third parties any confidential or proprietary information concerning the business, affairs, customers, clients, or suppliers of the other party, whether in writing or other tangible form, orally or otherwise. For the purpose of the Contract, confidential or proprietary information shall not include information that was in the public domain prior to any disclosure hereunder or which becomes part of the public domain through no fault of the recipient, information in the possession of either party prior to disclosure hereunder and not having been disclosed to the other by either party, information independently developed by either party and not the result of information disclosed hereunder, or information disclosed to

either party by a third party having a lawful right to do so. Neither party will make any press release or other public disclosure regarding this Proposal or the transactions contemplated hereby without the other party's express prior written consent, except as required by applicable law, by any governmental agency or by the rules of any stock exchange on which the securities of the disclosing party are listed, in which case the party required to make the press release or public disclosure shall use commercially reasonable efforts to obtain the approval of the other party as to the form, nature and extent of the press release or public disclosure prior to issuing the press release or public disclosure.

NON-SOLICITATION. It is agreed that during the period of Service performance and for a period of one (1) year following the completion or termination of all Services hereunder, neither Client nor its Affiliates shall, directly or indirectly, recruit, solicit or hire any employee of PCI or its Affiliates with whom Client or its Affiliate has had access to under this Contract; save that these restrictions shall not apply where, (i) an employee of PCI or its Affiliate responds unprompted to a generally advertised job opening, or (ii) a former PCI employee has since leaving PCIs employment held alternative employment with a third party for a period of at least one (1) year.

18 REPRESENTATIONS & WARRANTIES.

- 18.1 PCI warrants that any Product shall conform substantially with any approved production samples and agreed specifications, except that PCI makes no representations or warranties in relation to unvalidated manufacturing processes, analytical testing methods, engineering runs or Product or materials resulting therefrom. Any claim for defects must be made within ten (10) days after delivery of the Products, and no Product may be returned without PCI's prior written approval. If any defects are notified to PCI in accordance with this clause 18.1, PCI may re-inspect any such Product. If PCI agrees that Product is non-conforming due to PCI fault, PCI shall at its option, remanufacture (in the case of Product manufacturing services) with any Client Materials to be provided by Client, at Client's cost, and/or repackage Product (including any conforming Client Materials recovered from the non-conforming Product, or otherwise provided by Client, at Client's cost), otherwise Client shall receive a pro rata credit.
- **18.2** PCI hereby represents and warrants to Client that: (i) PCI will perform the Services in compliance with Applicable Law and in accordance with the terms of this Contract; (ii) PCI will perform the Services in a professional and workmanlike manner consistent with recognized industry standards; and (iii) neither PCI nor its representatives or employees involved with Service performance have been debarred pursuant to the FD&C Act.

- 18.3 Client hereby represents and warrants to PCI that, (i) Client will perform its obligations under this Contract in compliance with Applicable Law, and (ii) all information provided to PCI in connection with the Services, including without limitation, all customs information and packaging specifications, is true, accurate and complete and in compliance with Applicable Law.
- 18.4 EXCEPT AS SET OUT IN THIS CLAUSE 18 PCI GIVES NO WARRANTY AND MAKES NO REPRESENTATION IN RESPECT OF THE PRODUCT AND SERVICES AND ALL OTHER WARRANTIES AND CONDITIONS, WHETHER EXPRESSED OR IMPLIED BY STATUTE OR COMMON LAW ARE EXCLUDED TO THE EXTENT LEGALLY PERMITTED.

19 LIMITED LIABILITY AND INDEMNITY.

19.1 Nothing in these Terms and Conditions shall limit or exclude a party's liability for fraud or fraudulent misrepresentation or any other losses that cannot be excluded or limited by law.

19.2 SUBJECT TO CLAUSE 19.1:

- 19.2.1 PCI SHALL UNDER NO CIRCUMSTANCES WHATSOEVER BE LIABLE TO CLIENT, WHETHER IN CONTRACT, TORT (INCLUDING NEGLIGENCE), BREACH OF STATUTORY DUTY, OR OTHERWISE, AND WHETHER DIRECTLY OR INDIRECTLY ARISING, FOR ANY PENALTIES OR INDIRECT, SPECIAL OR CONSEQUENTIAL LOSS, INCLUDING WITHOUT LIMITATION ANY LOSS OF PROFIT, LOSS OF DATA, LOSS OF USE, LOSS OF REVENUE, LOSS OF PRODUCTION OR FOR ANY LOSS OF OPPORTUNITY.
- 19.2.2 SUBJECT TO CLAUSES 19.1 AND 19.2.1, PCI'S TOTAL LIABILITY TO CLIENT IN RESPECT OF ALL OTHER LOSSES ARISING UNDER OR IN CONNECTION WITH THE CONTRACT, WHETHER IN CONTRACT, TORT (INCLUDING NEGLIGENCE), BREACH OF STATUTORY DUTY, OR OTHERWISE, SHALL IN NO CIRCUMSTANCES EXCEED THE AGGREGATE AMOUNT INVOICED BY PCI FOR THE PARTICULAR SERVICES THAT ARE THE SUBJECT OF SUCH CLAIM, LESS EXCLUDED ITEMS.
- 19.3 Client shall indemnify and hold PCI and its Affiliates harmless from any and against any losses, all claims, damages, liability, for loss or damage, and from all court costs (including legal and other professional fees), attorney's fees and other expenses paid or incurred by or imposed upon PCI as a result of or in connection with the defense of any action brought or asserted by third parties arising from (i) the violation of any governmental regulation occasioned by the use of any package, label, or material provided or approved by Client in the performance of the Services; (ii) Client's breach of its obligations hereunder, including Client's breach of any representation or warranty hereunder; (iii) personal injury, death or property damage caused by Client's negligent acts or omissions

or willful misconduct; and (iv) PCI's performance of the Services in compliance with the Contract, including without limitation the storage, distribution, handling, use, non-use, demonstration, consumption, ingestion, digestion, manufacture, production and assembly of Client Materials and Products and transportation thereof, except to the extent such claim, liability legal action arises from PCI's negligent acts or omissions or willful misconduct.

20 GOVERNMENT REGULATIONS.

- 20.1 In the event the Services relate to the manufacturing and / or packaging of items regulated by the FDA or, where applicable, the United Kingdom Medicines and Healthcare Products Regulatory Agency (MHRA), or, where applicable, Health Canada, the Therapeutic Goods Administration (TGA) of Australia, or any European Union competent authority (including, without limitation the Health Products Regulatory Authority (HPRA) of Ireland or The Health Department of the Landesamt für Arbeitsschutz, Verbraucherschutz und Gesundheit (LAVG) of Germany) or any other government agency, counterpart agency or authority, Client shall be responsible for establishing all regulatory controls and compliance with such regulations covering Client's activities, including but not limited to the following: inspection of PCI's facilities for pre- and post-manufacturing and / or packaging quality control; testing; manufacturing; labelling; packaging; and establishing stability testing. Client may conduct such inspection of PCI's facilities not more frequently than once per annum (unless such inspection is for cause). Additional audits will be invoiced separately at the current rates for such services. PCI will promptly notify Client of any regulatory inspections directly related to the Products or Services. Client accepts reasonable and documented costs charged by a regulatory authority for such inspections.
- **20.2** PCI may conduct Out-of-specification (OOS) investigations, without prior approval from the Client. If an OOS investigation indicates that PCI is responsible for the OOS result, PCI will not charge Client for the investigation costs. If an OOS investigation does not indicate that PCI is responsible for the assignable cause of an OOS result, the cost of the investigation plus additional testing costs will be invoiced to Client as set out in a Proposal.
- **20.3** Prior to performance of the Services, and upon mutual agreement, Client and PCI will enter into a supplementary agreement as to technical/quality matters relating to such Services.

21 TERMINATION AND DEFAULT.

21.1 Without affecting any other right or remedy available to it, either party may terminate the Contract with immediate effect by giving written notice to the other party if: (i) the other party commits a material

breach of any term (including failure to pay outstanding amounts) and (if such a breach is remediable) fails to remedy that breach within thirty (30) days of that party being notified in writing to do so, or (ii) the other party takes any step or action in connection with its filing a petition in bankruptcy or entering administration, provisional liquidation or any composition or arrangement with its creditors (other than in relation to a solvent restructuring), being wound up or adjudicated bankrupt or insolvent (whether voluntarily or by order of the court, unless for the purpose of a solvent restructuring), having a receiver or trustee appointed to any of its assets or ceasing to carry on business or, if the action is taken in another jurisdiction, in connection with any analogous procedure in the relevant jurisdiction, or (iii) the other party suspends, or threatens to suspend, or ceases or threatens to cease to carry on all or a substantial part of its business.

- 21.2 Without affecting any other right or remedy available to it, in the case of default or breach by Client in the performance of its obligations arising out of this Contract, PCI may terminate this Contract and/or suspend the performance of any of the Services. On suspension or termination, Client shall immediately pay to PCI all of PCI's outstanding invoices and PCI shall submit an invoice in respect of all Services that have been performed but for which no invoice has been submitted and, in the case of Product manufacturing Services, for PCI's reasonable fees and costs in relation to the cessation of Services. Client shall, in addition, be liable for PCI's expenses incurred in exercising any remedies available to it including reasonable legal fees and expenses. All unpaid obligations shall bear interest at the contract rate provided under terms of payment above. Any remedies of PCI under the Contract shall be cumulative and not exclusive and are in addition to any other remedies PCI may have.
- **22 DATA PROTECTION.** Each party agrees that, in the performance of its respective obligations under this Contract it will comply with and ensure that its employees and/or sub-processors (as applicable) comply with all applicable Data Protection Laws, and it shall not by any act or omission cause the other party to be in breach of any requirements of such Data Protection Laws.
- claim arising out of or relating to this Contract that the parties cannot resolve within a period of sixty (60) days, either party, upon notice to the other, may resort to litigation or some other dispute resolution procedure. This Contract and all matters and disputes relating to this Contract, including without limitation all claims whether sounding in contract, tort, breach of statutory duty or otherwise, shall be governed, construed, and interpreted in accordance with the substantive laws of the State of New York, without giving effect to the principles of conflicts of law thereof or any other jurisdiction. The parties exclude application of

the United Nations Convention on Contracts for the International Sale of Goods. Each of Client and PCI irrevocably submits to the non-exclusive jurisdiction of any state or federal court sitting within New York, New York, and any such proceeding shall be conducted in the English language.