

1 INTERPRETATION

- 1.1 **Butterworth:** Butterworth Laboratories Limited (Company no. 1185121), 54/56 Waldegrave Road, Teddington, Middlesex, TW11 8NY
- 1.2 **Client:** the person or firm who purchases Services from Butterworth;
- 1.3 **Conditions:** these terms and conditions as amended from time to time;
- 1.4 **Contract:** the contract between Butterworth and Client for the supply of Services in accordance with these Conditions;
- 1.5 **Intellectual Property Rights:** all patents, rights to inventions, utility models, copyright and related rights, trade marks, service marks, trade, business and domain names, rights in trade dress or get-up, rights in goodwill or to sue for passing off, unfair competition rights, rights in designs, rights in computer software, database rights, topography rights, moral rights, rights in confidential information (including know-how and trade secrets) and any other intellectual property rights, in each case whether registered or unregistered and including all applications for and renewals or extensions of such rights, and all similar or equivalent rights or forms of protection in any part of the world;
- 1.6 **Order:** the Client's order for Services as set out in the Client's written acceptance of a Quotation, or the Client's purchase order form, as the case may be;
- 1.7 **Quotation:** the cost for the Services and scope of the Services, as confirmed in writing by Butterworth together with the cost of obtaining any specific extra items such as certified reference materials, chromatography columns etc;
- 1.8 **Report:** has the meaning given in clause 3.10;
- 1.9 **Samples:** goods or materials provided by the Client to obtain the Services;
- 1.10 **Service(s):** any analytical service(s) provided by Butterworth.

2 BASIS OF CONTRACT

- 2.1 The Quotation constitutes an offer by Butterworth to provide the Services in accordance with these Conditions.
- 2.2 The Quotation shall only be deemed to be accepted when either the Client provides the Order and it is received by Butterworth or Butterworth receives the Samples, which ever shall be the first to occur, at which point and on which date the Contract shall come into existence.
- 2.3 The Contract constitutes the entire agreement between the parties. The Client acknowledges that it has not relied on any statement, promise or representation made or given by or on behalf of Butterworth which is not set out in the Contract.
- 2.4 Any descriptive matter or advertising issued by Butterworth, are issued for the sole purpose of giving an approximate idea of the Services described in them. They shall not form part of the Contract or have any contractual force.
- 2.5 These Conditions apply to the Contract to the exclusion of any other terms that the Client seeks to impose or incorporate, or which are implied by trade, custom, practice or course of dealing.
- 2.6 Where the Client and Butterworth have entered into a contract in writing signed by the Client and Butterworth and that contract governs the supply of Services as part of an ongoing arrangement for the provisions of services by Butterworth and has not terminated or expired, then the terms of that contract shall apply to the exclusion of these Conditions.
- 2.7 Any Quotation given by Butterworth is only valid for a period of thirty days from its date of issue unless otherwise stated.

3 THE ANALYTICAL SERVICES

- 3.1 Contracts to perform Services are accepted by Butterworth on the basis that full disclosure is made by the Client of all information and documentation which may affect such work and that Butterworth will not be liable to the Client unless such full disclosure has been made. All such information shall be retained by Butterworth in strict confidence. Upon completion of the Services Butterworth shall if requested in writing, return to the Client any documents that it has received from the Client in connection with the Services.
- 3.2 If the results of the Services are to be used for litigation or possible litigation this must be made known to Butterworth when requesting a Quotation.
- 3.3 The Client agrees to indemnify Butterworth against any claims for any loss or injury arising out of any use of Samples, where full

- 3.4 disclosure of all information and documentation referred to in clause 3.1 has not been made which may affect such use.
- 3.4 If the Client requires Butterworth to perform the Services in a shorter time than that specified in the Quotation, it is the responsibility of the Client to negotiate whether this is possible with the Butterworth's Head of Analytical Operations. If Butterworth agree a shorter time Butterworth will issue a revised Quotation to incorporate the additional charges.
- 3.5 Butterworth will include (in the Quotation), where appropriate, an additional charge for handling materials deemed by Butterworth to be hazardous and/or which require additional handling techniques. If Samples are found to be of a hazardous nature subsequent to issuing the Quotation, Butterworth reserve the right to apply an additional charge to the subsequent invoice.
- 3.6 Clients must inform Butterworth of hazards, or licensing requirements, of any kind relating to Samples when requesting a Quotation. Samples submitted must be labelled with the appropriate hazard labels, in accordance with the CHIP regulations, and a Material Safety Data Sheet (MSDS) provided. Failure to do so is a breach of health & safety regulations and may result in an additional handling charge.
- 3.7 Butterworth reserve the right to quarantine Samples until the information referred to in clause 3.6 is provided and to charge for any administration and/or specific handling involved.
- 3.8 The Client will indemnify Butterworth against any claim for any loss or injury/illness that results from handling Samples that are not clearly labelled as being of a hazardous nature.
- 3.9 All Samples will be analysed and reported on an 'as received' basis, unless otherwise instructed in writing, or documented in the agreed methodology.
- 3.10 Unless otherwise agreed in writing Butterworth will carry out the work set out in the Quotation and shall be entitled to test any Samples to destruction. All Samples remaining following analysis will be disposed of by Butterworth no earlier than one month following the date of issue of the report or certificate of analysis ("Report") containing the analytical results.
- 3.11 If requested in writing, all Samples remaining after analysis will be returned by courier and charged to the Client 'at cost' plus an administration charge.
- 3.12 Any Report issued by Butterworth will relate only to the Samples in respect of which the Services have been performed and not to the bulk from which the Samples analysed may have been selected.
- 3.13 In all matters relating to the Services, Butterworth will limit its activities to fields in which it has direct experience and knowledge. It will adhere strictly to the Client's instructions, which must be agreed and fully documented prior to any work being undertaken. All results produced will be presented as a factual Report. Butterworth employees do not act as expert witnesses, nor enter into discussions nor offer opinions on the application or consequence of the reported results.
- 3.14 Should additional copies of a Report be requested, these will be supplied at an additional charge.
- 3.15 Whilst reasonable effort is made to answer Client's questions on the facts contained within a Report, Butterworth reserve the right to charge to provide such answers.
- 3.16 All Intellectual Property Rights in the Report, written statements and other information provided in connection with the Services shall be owned by Butterworth.
- 3.17 Butterworth hereby licenses the copyright subsisting in the Report to the Client free of charge and on a non-exclusive, worldwide basis to such extent as is necessary to enable the Client to:
 - 3.17.1 comply with any obligations imposed on it by any regulator which the Client is subject to;
 - 3.17.2 provide a copy of the Report to its principal (if the Client is an agent) or any supplier to the Client, provided always that the Report is replicated in full, unamended and with any copyright notices remaining visible.
- 3.18 The Client agrees to treat the Report as confidential and not to make it public nor disclose it to any third party without Butterworth's consent, save to the extent that: (a) it is already in the public domain (through no default of the Client); (b) disclosure is required by law; or (c) disclosure is made to those third parties referred to in clause 3.17 (provided that the Client requests that those third parties treat the Report as confidential).
- 3.19 The Report must not be edited or amended in whole or in part without the prior written consent of Butterworth.

- 3.20 Butterworth shall make all reasonable efforts to supply the Services by the date agreed (if any) but Butterworth do not guarantee such a date, which is given by way of estimate only. Time shall not be of the essence in relation to the performance of the Services.
- 3.21 If Samples are submitted for analysis and the Services are cancelled before completion for any reason, Butterworth reserve the right to make an appropriate charge including administration costs, based on the number of Samples submitted and the stage at which cancellation occurred.
- 3.22 Butterworth is not responsible for any Samples until actually received by it. The delivery of the Samples to Butterworth is at the Client's risk.
- 3.23 Butterworth reserves the right to withdraw provision of the Services to any Client after acceptance of a Quotation by the Client but prior to commencement of the Services, in which case Butterworth will at its own cost return any Samples to the Client and neither party will have a claim against the other.
- 4 QUALITY ASSURANCE, METHODOLOGY AND ARCHIVING**
- 4.1 Butterworth shall maintain the level of standards required by the relevant laws and regulations which are or may become applicable to Butterworth in connection with the Services to be provided hereunder including:
- 4.1.1 UKAS Accreditation to ISO17025;
- 4.1.2 MHRA approval to Good Manufacturing Practice (GMP) as laid down in Directives 2003/94/EC and 91/412/EEC as they relate to Quality Control Laboratories and to the Principles of Good Laboratory Practice (GLP) as laid down in Directive 2004/9/EC; and
- 4.1.3 FDA approval to GMP as laid down in 21 CFR Parts 210 and 211 that apply to laboratories.
- 4.2 Butterworth shall perform the Services in compliance with its Quality System, which has been written to encompass the requirements of GMP, UKAS and GLP. As a minimum, all analysis undertaken by Butterworth will meet the requirements of GMP. It is the responsibility of the Client to inform Butterworth if the analysis required is to meet either UKAS or GLP requirements, so as to ensure that the correct documentation is prepared in performing the Services.
- 4.3 Unless specifically indicated in the deliverables section of the Quotation, the UKAS accreditation schedule does not cover the methods quoted.
- 4.4 Where the Client has requested that the Services are to be performed in compliance with GLP, this will be identified in the deliverables section of the Quotation.
- 4.5 Where Butterworth's Quality Department is required to undertake an audit or investigation resulting in a formal written response, such as in the case of a GMP 'Out of Specification' result, then Butterworth reserve the right to make an additional charge.
- 4.6 Where necessary, the Client will (wholly at its own cost) provide the services of a Qualified Person (QP), as defined in Article 48 of Directive 2001/83/EC, who has the responsibility to check that the Samples have been tested by Butterworth in compliance with GMP and meet the requirements of the Client's manufacturing or marketing authorisations, and where necessary Butterworth will provide the QP with any information in Butterworth's possession to enable him to carry out this check.
- 4.7 Unless otherwise instructed in writing, the test specific raw data, or in the case of electronically generated records, certified hard copies, will be sent with the Report. Butterworth will produce electronic copies of raw data which will be stored in its own archives.
- 4.8 Butterworth will retain in its archives (which may be in electronic form) for at least twenty five (25) years after the date of performance of the Services, the following:
- 4.8.1 all original (or, in the case of electronic archive, accurate copies of) controlled documentation including any relating to the testing methodology analytical instrument specific records and data, method validation records and all quality assurance, quality control and analytical instrument/equipment maintenance records and any other records not directly relating to the specific Services performed for the Client; and
- 4.8.2 all training records of relevant personnel.
- 4.9 Butterworth will retain in its archives (which may be in electronic form) for at least six (6) years after the date of performance of the Services the following:
- 4.9.1 authorised copies, in electronic form, of all raw data relating to the Services performed which have been supplied to the Client along with the Report; and
- 4.9.2 any original (or, in the case of electronic archive, accurate copies of) documentation supplied by the Client on submission of Samples.
- 4.10 GLP Studies will be archived in accordance with the individual study plan.
- 4.11 The Client consents to the retention of the information referred to above and on the terms referred to above.
- 4.12 Compendial Methods are not revalidated by Butterworth Laboratories Ltd. It is assumed that parameters such as system suitability or positive/negative controls inherent in the test provide sufficient evidence of Butterworth's capability to perform the test. Where the Client requires Butterworth to provide validation, verification or proof of competence for Compendial Methods, it is the responsibility of the Client to request this additional work which will be costed and set out in a separate quotation.
- 4.13 If deviations to the documented method(s) are required, these will be agreed in writing in advance of the analysis being performed and detailed on the resulting Certificate of Analysis or Report. Where pharmacopoeial or standard published methods are employed for the testing of samples, variations or adjustments documented as permissible within the method or publication may be applied. These variations or adjustments will not be detailed on the resulting Certificate of Analysis or Report and are not considered to be deviations.
- 4.14 When a Certified Reference Material (CRM) is required for an identification test Butterworth reserve the right to use a previously opened container provided it is from the current/valid batch, unless otherwise instructed in writing by the client.
- 5 PRICE AND PAYMENT**
- 5.1 Butterworth agrees to provide the Services on the basis that:
- 5.1.1 Butterworth operate a minimum submission invoice charge, which, where applicable, will be detailed on the Quotation;
- 5.1.2 any setup charges detailed assume that all samples will be received at the same time so that they can be analysed together. Further sample submissions will be subject to additional setup charges as appropriate unless otherwise indicated or agreed in writing prior to the issue of this Quotation.
- 5.1.3 If the return of materials and samples after the completion of the work is required but is not detailed in this quotation, this will be subject to the issue of a separate quotation and the minimum submission invoice charge.
- 5.1.4 Should a purchase order number or equivalent reference be required for payment of the invoice, it is the responsibility of the Client to ensure that this is provided no later than the time of the submission of Samples. Failure to provide these details in time may result in a delay to the production of a Report and may also give rise to an additional charge.
- 5.2 If the Client requests any change to the Services as specified in the Quotation, Butterworth will issue a revised Quotation to the Client.
- 5.3 Should unexpected or unforeseen problems arise, during the course of performing the Services, which affect the method(s)/technique(s) employed or the time scale, Butterworth reserve the right to reasonably vary the price and/or the time scale. Failure by the Client to agree such variations will be treated as termination of the Services, when all work done will be reported and invoiced.
- 5.4 Payment is due and payable into such bank account as may be designated by Butterworth without set-off or counterclaim in the currency used in the Quotation in immediately available funds by the end of the month following that in which the invoice is dated, unless otherwise expressly agreed in a signed document. Payment by cheque or other negotiable instrument is ineffective until it is honoured and the Butterworth bank account is credited with the amount due. Butterworth reserves the right to defer or cancel without liability the provision of any further Services if this condition is not complied with unless the Client has in good faith given Butterworth written notice that the sum is in dispute setting out the basis of the dispute.

5.5 If the Client fails to make payment in accordance with clause 5.4 above without notification to Butterworth of an acceptable reason, Butterworth shall be entitled to charge interest and collection charges as set out in the Late Payment of Commercial Debts (Interest) Act 1998 (as amended and any subordinate legislation made under it) on any sums overdue.

5.6 In instances where it is agreed that Services may take longer than one month to complete, Butterworth reserve the right to render interim invoices. This will occur either after the completion of a distinct phase of the work or at the end of each month.

5.7 For new clients Butterworth will normally issue an invoice before commencing the Services which the Client must pay before Butterworth releases the Report. Before opening a credit account for a new Client Butterworth will require satisfactory credit references.

5.8 Butterworth reserve the right to withhold Reports and discussions, and to discontinue the provision of the Services to a Client at any time if there are overdue amounts owed by that Client. Butterworth will accept no responsibility for the consequences of withholding Reports or discontinuing work in such circumstances.

6 LIABILITIES OF BUTTERWORTH

6.1 Butterworth shall carry out the Services with reasonable care and skill.

6.2 Nothing in these Conditions excludes or limits the liability of Butterworth for death or personal injury caused by Butterworth's negligent acts or fraudulent misrepresentation.

6.3 Butterworth shall not be liable whether in contract, tort (including negligence), breach of statutory duty, or otherwise, for any loss of profit, or for any indirect or consequential loss suffered by the Client howsoever caused which arise out of or in connection with the provision of the Services.

6.4 Butterworth shall not be liable for loss suffered by any third party arising out of the Services.

6.5 Butterworth's total liability to the Client in respect of all other losses arising under or in connection with the Services, whether in contract, tort (including negligence), breach of statutory duty, or otherwise, shall be limited to the lower of the loss or £250,000.

6.6 The price for carrying out the Services is determined on the basis of the exclusions from and limitations of liability contained in these Conditions. The Client expressly agrees that these exclusions and liabilities are reasonable because (amongst other matters) the likelihood that the amount of damages which could be awarded to the Client for a breach by Butterworth of these Conditions may otherwise be disproportionately greater than the price for carrying out all work in connection with the Services.

6.7 Except as set out in these Conditions, all warranties, conditions and other terms implied by statute or common law are to the fullest extent permitted by law, excluded from the Contract.

6.8 This clause shall survive termination of the Services.

7 DEFECTS AND TIME LIMITS

7.1 Butterworth retain Samples for no longer than one month after completion of the Services. The Client must give Butterworth notice of any defects in the Services in writing and by facsimile:

7.1.1 as soon as is reasonably practicable after it becomes aware of any such defects (and within one month of the same); or

7.1.2 within 6 months of the completion of the Services whichever is the earlier.

7.2 The Client may make no claim unless it has given notice strictly in accordance with clause 7.1 above.

8 FORCE MAJEURE

8.1 In the event that performance of the Services is rendered uneconomic, prevented, hindered or delayed as a result of war, hostilities, terrorist activities, acts of God, industrial unrest, civil disturbance, the act of any local or national government or authority (whether in the United Kingdom or abroad), shortage or unavailability of raw materials, equipment, labour or fuel or any other cause beyond the reasonable control of Butterworth, Butterworth may, by written notice to the Client, either cancel the Services or suspend or postpone performance of the Services with no liability on either side.

9 ASSIGNMENT

9.1 The Client shall not assign, mortgage, charge, sub-let or otherwise dispose of any agreement or any rights thereunder in whole or in

part without Butterworth's prior written consent. Any such action by the Client without such consent shall be void.

10 TERMINATION

10.1 Should the Client make default in any payment due to or at the direction of Butterworth or otherwise be in breach of its obligations under these Conditions or under any other contract with Butterworth or compound with or execute an assignment for the benefit of its creditors or commit any act of bankruptcy or being a company enter into voluntary or compulsory liquidation or suffer a receiver, administrative receiver or administrator to be appointed over all or any part of its assets or take or suffer any similar action in consequence of debt or become insolvent or should Butterworth have reasonable cause to believe that any of these events is likely to occur, Butterworth may, by notice in writing to the Client and without prejudice to any other rights forthwith suspend or cancel any uncompleted work or require payment in advance or satisfactory security for further delivery of the Services.

10.2 On termination of the Contract:

10.2.1 the Client shall immediately pay to Butterworth all of its outstanding unpaid invoices and interest and, in respect of Services supplied but for which no invoice has been submitted, Butterworth shall submit an invoice, which shall be payable by the Client immediately on receipt;

10.2.2 the accrued rights, remedies, obligations and liabilities of the parties as at expiry or termination shall not be affected, including the right to claim damages in respect of any breach of the Contract which existed at or before the date of termination or expiry; and

10.2.3 clauses which expressly or by implication have effect after termination shall continue in full force and effect.

11 DATA PROTECTION

11.1 In the course of its dealings with clients, Butterworth receives and processes information about Clients including:

11.1.1 contact details of the company;

11.1.2 credit references;

11.1.3 name and contact details of the person requesting the Services;

11.1.4 details of the Client's requirements for the Services.

11.2 All such information will be retained in confidence and will only be used for the following purposes:

11.2.1 for the proper performance of the Services;

11.2.2 to assess whether and how the Services be provided and at what cost;

11.2.3 to report to the Client on the Services;

11.2.4 to forward to the Client information regarding services provided by Butterworth and general marketing material;

11.2.5 to share the information with associated companies and professional advisers for administrative purposes; and

11.2.6 to comply with any lawful direction or regulatory requirement.

11.3 In consenting to these terms the Client consents to this use of such information.

11.4 In all other respects the information will not be shared without the Client's prior consent or as provided for in the Data Protection Act.

12 MISCELLANEOUS

12.1 Under no circumstances will any terms introduced by the Client (whether in the Order or otherwise) take priority over these Conditions unless Butterworth agrees in writing.

12.2 The failure by Butterworth to enforce at any time any one or more of these Conditions shall not amount to a waiver by Butterworth of its right subsequently to enforce such Conditions.

12.3 If any provision of these Conditions is declared by any judicial or other competent authority to be voidable, illegal or otherwise unenforceable this shall not affect the remaining Conditions, which shall continue in full force and effect. Any such provisions as shall be declared to be voidable, illegal or otherwise unenforceable shall be amended so that the amended provision achieves the intention of the parties.

13 LAW AND JURISDICTION

13.1 The application of the Uniform Laws on International Sale shall be excluded. The construction, validity and performance of these Conditions shall be governed by English law and any claim or dispute arising from them shall without prejudice to Butterworth's other rights be subject to the exclusive jurisdiction of and be determined by the English courts.