

# inter regulatory

## TERMS OF BUSINESS

*(Version 1 Reviewed: March 26, 2026)*

**1. DEFINITIONS**

**"Agreement"** means these Terms of Business and the attached Proposal thereof;

**"Background Intellectual Property Rights"** means any Intellectual Property Rights, other than Foreground Intellectual Property Rights, that are used in the course of or in connection with the provision of the Services;

**"Client"** means the name and/or registered number defined in the Proposal as the client's contracting entity;

**"Confidential Information"** means information marked in writing as confidential supplied to Inter Regulatory Limited by Client;

**"Deliverables"** means the tangible final output of the project that is defined as a Deliverable in the Proposal;

**"Intellectual Property"** (or "IP") means patents, registered and unregistered design rights, copyright, registered and unregistered trademarks and database rights;

**"Inter Regulatory"** means Inter Regulatory Limited, a wholly owned subsidiary of Scientific Holdings Limited, the contracting entity defined in the proposal.

**"Proposal"** means the proposal for services attached to these Terms of Business, as amended from time to time by agreement between the parties;

**"Staff"** means member, employee, agent or consultant of Inter Regulatory

**2. Contractual Parties**

2.1 This Agreement sets out the terms on which Inter Regulatory will provide its services to the Client. Inter Regulatory shall be entitled to subcontract the performance of all or any part of its obligations under this Agreement to Scientific Holdings or any of its subsidiaries. If any part of Inter Regulatory is transferred, then its obligations under this Agreement shall transfer to the purchaser.

2.2 Where reference is made in this Agreement or in any other correspondence connected to this Agreement to a "partner" of Inter Regulatory, the term "partner" indicates a 3rd party to which Inter Regulatory has a commercial agreement.

2.3 The terms of this Agreement are effective from the outset of Inter Regulatory relationship with Client in connection with the work contemplated in the Proposal. Pending receipt by Inter Regulatory of Client's countersigned copy of the Agreement, Client's continued instructions will amount to Client's acceptance of the terms of the Agreement.

2.4 Any advice given to Client or other work undertaken for Client by Staff will be given or undertaken by that person on behalf of Inter Regulatory and not in his or her individual capacity. Inter Regulatory Staff do not owe a personal duty of care nor assume any personal responsibility for the advice or other work.

2.5 Client agrees to indemnify and not to bring any claim in respect of loss or damage suffered by it out of or in connection with Inter Regulatory services against any of Inter Regulatory Staff, Directors, agents or connected parties. This restriction will not operate to limit or exclude the liability of Inter Regulatory Limited for the acts or omissions of any such Staff. It is agreed that any such Staff will have the right to enforce this Clause pursuant to the Contracts (Rights of Third Parties) Act 1999.

2.6 Nothing in the Agreement, however, excludes or limits any claim the Client may have against Staff or Agents for fraud.

**3. Commencement and Duration**

3.1 This Agreement shall commence on the date of approval and shall continue until Inter Regulatory has fulfilled its obligations with respect to deliverables detailed in the proposal

Or;

Unless terminated earlier by either party giving at least one month's notice to terminate.

**4. Provision and Scope of Services**

4.1 Inter Regulatory shall provide the Services to the client for the Term subject to and in accordance with the terms of this Agreement.

4.2 The scope of services to be provided under this agreement are expressly stated in section 4.3 of this document and constitute the totality of services. Pre-agreement representations, communications or otherwise and implied services shall not be included in this agreement beyond what is expressly stated in this agreement.

4.3 Services offered may include upon agreement;

A. Client has a need for certain services related to Medical Devices under the Medical Device Regulation 2017/745 intended for the E.U markets. Services may include, but may not be limited to; analytical regulatory affairs and Technical File Management of Medical Devices products, subject to and on the terms and conditions of the proposal, and therefore, this agreement.

B. Client has a need for certain services related to Medical Devices under the Medical Device Regulation 2002 intended for the U.K markets. Services may include, but may not be limited to; regulatory affairs and Technical File Management of Medical Devices products, subject to and on the terms and conditions of the proposal, and therefore, this agreement.

C. Client has a need for certain services related to products subject to the General Product Safety Regulation (EU) 2023/988 intended for the E.U. market. Services may include, but may not be limited to, regulatory affairs support, product compliance assessment, safety documentation review, and technical documentation management, subject to and in accordance with the terms and conditions of the proposal and, therefore, this agreement.

- D. Client has a need for certain services related to products intended for the U.K. market under the applicable product safety and consumer protection legislation. Services may include, but may not be limited to, regulatory affairs support, product compliance assessment, safety documentation review, and technical documentation management, subject to and in accordance with the terms and conditions of the proposal and, therefore, this agreement.
- E. Client has a need for certain services related to medicinal products for human use under the applicable European Union pharmaceutical legislation intended for the E.U. markets. Services may include, but may not be limited to, regulatory affairs support, dossier preparation and lifecycle management, and marketing authorisation maintenance, subject to and in accordance with the terms and conditions of the proposal and, therefore, this agreement.
- F. Client has a need for certain services related to medicinal products for human use under the applicable United Kingdom pharmaceutical legislation intended for the U.K. market. Services may include, but may not be limited to, regulatory affairs support, dossier preparation and lifecycle management and marketing authorisation maintenance, subject to and in accordance with the terms and conditions of the proposal and, therefore, this agreement.
- G. Client has a need for certain services related to Novel Foods under Regulation (EU) 2015/2283 intended for the E.U. markets. Services may include, but may not be limited to; regulatory affairs and dossier management of Novel Foods products, subject to and on the terms and conditions of the proposal, and therefore, this agreement.
- H. Client has a need for certain services related to Tobacco and Related Products under the Tobacco Products Directive (TPD) intended for the E.U. market. Services may include, but may not be limited to; regulatory affairs, authorised representative and dossier management of nicotine and nicotine-free vape products, subject to and on the terms and conditions of the proposal, and therefore, this agreement.
- I. Client has a need for certain services related to Tobacco and Related Products under the Tobacco and Related Products Regulations (TRPR) intended for the U.K. market. Services may include, but may not be limited to; regulatory affairs, importer services and dossier management of nicotine and nicotine-free vape products, subject to and on the terms and conditions of the proposal, and therefore, this agreement.
- J. Client has a need for certain services related to Cosmetics Products under Regulation 2009/1223 intended for the U.K. and E.U. markets. Services may include, but may not be limited to; regulatory affairs and dossier management of cosmetics products, subject to and on the terms and conditions of the proposal, and therefore, this agreement.

- 4.4 If for any reason any employee ceases to be employed by Inter Regulatory or is unable to provide the Services on behalf of Inter Regulatory, Inter Regulatory shall propose an alternative employee or contractor to fill the Key Employee's role without prior express consent. The client shall have the option, by written notice to Inter Regulatory, either to accept the person offered or terminate the relevant project element should services fall below a reasonable standard as a result of the change in personnel.

## 5. Inter Regulatory Obligations

5.1 Inter Regulatory shall perform, and shall procure that the employees and agents perform the services with due diligence, skill and care in accordance with;

- A. all generally accepted standards and practices applicable to the Services or services similar to the Services;
- B. and in compliance with all applicable laws, enactments, orders, regulations, standards and other similar instruments; and
- C. all applicable provisions of this Agreement

5.2 Inter Regulatory will obtain and maintain in force all licences, permissions, authorisations, consents and permits needed to perform the Services in accordance with the terms of this Agreement.

5.3 Inter Regulatory shall comply with all reasonable specified security requirements of the Client and shall cause its employees, agents and subcontractors to comply with such requirements.

## 6. Client Obligations

- 6.1 Client shall cooperate with Inter Regulatory and provide it with such information and assistance as Inter Regulatory shall reasonably require to enable it to provide the Services.
- 6.2 Client shall allow Inter Regulatory and its employees, agents and sub-contractors reasonable access to its facilities as necessary for the performance of the Services.
- 6.3 Client shall not prevent or mislead Inter Regulatory from disclosing information related to health, safety or performance to regulatory or other competent authorities as is lawfully required by state, national or Federal law.
- 6.4 Client shall not seek to mislead, misrepresent, take any action which could result in the effect thereof with respect to data, samples or other information where such an act could foreseeably result in false or misleading information being generated by Inter Regulatory.

## 7. Changes to the Services

- 7.1 If a party wishes to make a change to the nature, volume or execution of any of the Services or the conditions for supply, it shall submit details of the requested change in writing to the other party. Following the submission or receipt of a change request, Inter Regulatory shall, within a reasonable time, provide a written estimate to Client of:
  - A. the time required to implement the change;

- B. any proposed variations to the Charges arising from the requested change;
- C. any other impact of the requested change on the terms of this Agreement.

7.2 The parties will consider the request in good faith but Inter Regulatory will be under no obligation to accept any requested change. Each party will give its formal response to the other within a reasonable time.

7.3 Inter Regulatory may, from time to time and without prior notice, change the Services in order to comply with any applicable regulatory or statutory requirements. Where practicable, it will give Client not less than three months' notice of any change, but in any event it will give Client notice of any such change within one month of it taking effect.

## **8. Confidentiality**

8.1 Each party undertakes that it shall not at any time disclose to any person any confidential information concerning the business, affairs, customers, clients or suppliers of the other party, except as permitted by clause 8.2

8.2 Each party may disclose the other party's confidential information:

- A. to its employees, officers, representatives, contractors, subcontractors or advisers who need to know such information for the purposes of carrying out the party's obligations under this Agreement. Each party shall ensure that its employees, officers, representatives, subcontractors or advisers to whom it discloses the other party's confidential information comply with this Clause (8); and
- B. as may be required by law, a court of competent jurisdiction or any governmental or regulatory authority.

8.3 No party shall use any other party's confidential information for any purpose other than to exercise its rights and perform its obligations under this Agreement.

## **9. Charges and Payment**

9.1 In consideration of Inter Regulatory providing the Services, Client shall pay the Charges to Inter Regulatory. The breakdown of the Charges between the different elements and the basis for their calculation are set out in this agreement.

9.2 Client shall in addition reimburse all reasonable travel and accommodation expenses incurred by the employees and agents of Inter Regulatory in providing the Services to Client, to the extent that they are consistent with Clients travel and expenses policy, within 14 days of receipt of Inter Regulatory invoice and all relevant receipts

9.3 Client shall pay the Charges monthly in arrears. Inter Regulatory shall invoice Client each month for the Charges incurred in the previous month.

9.4 Client shall pay invoices in full within 14 days of receipt in cleared funds to the bank account nominated in writing by Inter Regulatory.

9.5 If a party fails to make any payment due to the other party under this Agreement by the due date for payment, then, without limiting the other party's remedies, the defaulting party shall pay interest on the overdue sum from the due date until payment of the overdue sum, whether before or after judgment.

9.6 Interest under Clause 9.5 will accrue each day at 2% a year above the Bank of England's base rate from time to time, but at 2% a year for any period when that base rate is below 0%.

9.7 If Client disputes any invoice or other request for payment, Client shall immediately notify Inter Regulatory in writing. The parties shall negotiate in good faith to attempt to resolve the dispute promptly. Inter Regulatory shall provide all such evidence as may be reasonably necessary to verify the disputed invoice or request for payment. Where only part of an invoice is disputed, the undisputed amount shall be paid on the due date as set out in Clause 9.4. Inter Regulatory's obligations to provide the Services shall not be affected by any payment dispute, including its obligations to provide the Services to which the payment dispute relates for the first 30 days of dispute. Inter Regulatory reserves the right to withdraw services where agreement cannot be reached within 30 days of a dispute being raised.

9.8 In relation to payments disputed in good faith, interest under this Clause is payable only after the dispute is resolved, on sums found or agreed to be due, from the due date until payment.

9.9 The Charges are exclusive of amounts in respect of VAT and local/national taxes where applicable. Clients shall, on receipt of a valid VAT invoice from Inter Regulatory, pay to Inter Regulatory such additional amounts in respect of VAT as are chargeable on a supply of the Services.

9.10 Professional fees are related to the time spent by Staff engaged on the Project. Expenses directly associated with the Project, including travel and subsistence (in accordance with Inter Regulatory Limited's expenses policy), materials, software and equipment costs will be charged separately with a handling charge of 15%. At the end of the Project, any unspent expenses budget may be added to the fees budget. Air travel more than four hours shall be business class.

9.11 The Client shall be responsible for any importation fees, duties or other such costs associated with the receipt of samples and shall make payment within fourteen (14) days of invoicing.

9.12 A 5% pass through charge will apply to all subcontracted work expressly requested by the client.

9.13 If the cost of providing the Services changes to a material extent, Inter Regulatory shall notify Client of the change in writing, giving the following details:

- A. the reasons for the change in the cost of providing the relevant Services;
- B. the amount of the change in the cost of providing the relevant Services; and
- C. the proposed change to the Charges

9.14 Proposed changes to the Charges shall be subject to Clients' approval (which shall not be unreasonably withheld). Client shall give its response to Inter Regulatory in writing within two weeks of receipt of notice from Inter Regulatory of the proposed change. If the proposed change is accepted, the revised Charges shall apply from the first day of the next month.

**10. Intellectual Property**

- 10.1 All Background Intellectual Property Rights are and shall remain the exclusive property of the party owning them (or, where applicable, the third party from whom its right to use the Background Intellectual Property has derived).
- 10.2 Each party shall grant or procure the grant of all such licences to the other party to use Background Intellectual Property Rights as are necessary to allow the other party to exercise its rights and perform its obligations under this Agreement.
- 10.3 Under this Agreement, with regard to Foreground Intellectual Property Rights:
- A. Inter Regulatory assigns and shall procure the assignment of any Foreground Intellectual Property Rights that arise in any Work Product to Client, with full title guarantee and free from third party rights. The Client permits licenses to Inter Regulatory to use those Foreground Intellectual Property Rights, free of charge and on a non-exclusive, worldwide basis to such extent as is necessary to enable Inter Regulatory to supply the Services. If this Agreement is terminated, this licence will automatically terminate; and
  - B. Inter Regulatory shall own all other Foreground Intellectual Property Rights that arise or are obtained or developed in connection with the provision of the Services. Inter Regulatory licenses Client to use those Foreground Intellectual Property Rights, free of charge and on a non-exclusive, perpetual, worldwide basis to such extent as is necessary to enable Client to use the Work Product and the Services.
- 10.4 To the extent that Inter Regulatory subcontracts performance of the Services, it shall procure that all Foreground Intellectual Property Rights that arise from the work of its subcontractor shall be assigned to Inter Regulatory absolutely. The provisions of Clause 1-3(a) shall apply to any Foreground Intellectual Property Rights in the Work Product assigned to Inter Regulatory pursuant to this Clause 10.4.
- 10.5 Inter Regulatory shall obtain irrevocable written waivers of all moral rights in any works which are the subject of the Foreground Intellectual Property Rights to which any individual is now or may be at any future time entitled under Chapter IV of Part I of the Copyright Designs and Patents Act 1988 or any similar provisions of law in any jurisdiction
- 10.6 Each party shall, at its own cost, promptly do or procure the doing of all such acts and things and execute or procure the execution of all such documents as may from time to time be required to give effect to this Clause.
- 10.7 Except as expressly provided in this Agreement, no rights or obligations in respect of a party's Intellectual Property Rights are granted to the other party or to be implied from this Agreement.
- 10.8 Inter Regulatory retains all right, title and interest in methods, knowhow, and ideas in the Deliverables, and in IP outside the Deliverables. In the event that Inter Regulatory owns or controls any IP necessary for Client to exploit the results of the Project then Inter Regulatory undertakes to grant Client a perpetual, irrevocable, worldwide, non-exclusive, license to the IP, with the right to grant sublicenses, on terms to be agreed.
- 10.9 Notwithstanding delivery, Client;
- A. has no right to use any part of the Deliverables or results of the Project, until payment of all outstanding sums is made in full, and;
  - B. will not receive title to goods and IP, until payment of all outstanding sums is made in full.

**11. Termination**

- 11.1 Without affecting any other right or remedy available to it, either party to this Agreement may terminate it with immediate effect by giving written notice to the other party if:
- A. the other party fails to pay any amount due under this Agreement on the due date for payment and remains in default not less than thirty days after being notified in writing to make such payment;
  - B. the other party commits a material breach of any term of this Agreement and (if such breach is remediable) fails to remedy that breach within a period of thirty days after being notified in writing to do so;
  - C. the other party takes any step or action in connection with it entering administration, provisional liquidation or any composition or arrangement with its creditors (other than in relation to a solvent restructuring), applying to court for, or, obtaining a moratorium under Part A1 of the Insolvency Act 1986, being wound up (whether voluntarily or by order of the court, unless for the purpose of a solvent restructuring), having a receiver appointed to any of its assets or ceasing to carry on business or if the step or action is taken in another jurisdiction, in connection with any analogous procedure in the relevant jurisdiction;
  - D. 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;
- or
- E. the other party's financial position deteriorates to such an extent that in the terminating party's opinion the other party's capability to adequately fulfil its obligations under this Agreement has been placed in jeopardy.
- 11.2 Without affecting any other right or remedy available to it, Client may terminate this Agreement or one or more of the Service Lines at any time on giving not less than 30 days' prior written notice to Inter Regulatory.
- 11.3 The Client will be liable for all reasonable professional fees and expenses incurred by Inter Regulatory during the notice period and in bringing the project to an orderly close.

**12. Limitations of Liability**

12.1 References to liability in this clause 12 apply to every liability arising under or in connection with this Agreement including but not limited to liability in contract, tort (including negligence), misrepresentation, restitution or otherwise.

12.2 Nothing in this clause 12 shall limit the Clients' payment obligations under this Agreement.

12.3 Nothing in this Agreement limits any liability which cannot legally be limited, including liability for:

1. death or personal injury caused by negligence;
2. fraud or fraudulent misrepresentation.

12.4 Subject to clause 12.2 and clause 12.3, clause 12.4(B) identifies the kinds of loss that are not excluded. Subject to that, clause 12.4(A) excludes specific types of loss;

A. In no event shall Inter Regulatory be liable for any Direct, Indirect or Consequential Damages or Losses relating to:

- A. loss of profits;
- B. loss of sales or business;
- C. loss of agreements or contracts;
- D. loss of anticipated savings;
- E. Wasted Expenditure
- F. loss of use or corruption of software, data or information;
- G. loss of or damage to goodwill;
- H. fines for noncompliance by the Client;
- I. third party claims made against the Client;
- J. product liability claims;
- K. loss to reputational damage/intangible loss
- L. indirect or consequential loss.

B. Types of loss and specific losses not excluded:

- A. sums paid by Client to Inter Regulatory pursuant to the Agreement, in respect of any Services not provided in accordance with the Agreement;
- B. additional costs of procuring and implementing replacements for, or alternatives to Services not provided in accordance with the Agreement. These include consultancy costs, additional costs of management time and other personnel costs, and costs of equipment and materials; and
- C. losses incurred by Client arising out of or in connection with any third party claim against Client which has been caused by the act or omission of Inter Regulatory. For these purposes, third party claims shall include demands, fines, penalties, actions, investigations or proceedings, including those made or commenced by subcontractors, Inter Regulatory 's personnel, regulators and customers of Client.

12.5 Client agrees to indemnify and hold Inter Regulatory harmless from and against all claims and demands resulting from;

- A. any costs related to unsuccessful regulatory approval.
- B. any third-party claim relating to misuse of the third party's confidential information or IP which has been supplied by Client to Inter Regulatory
- C. any product liability claim for products related to the Project;
- D. damage or loss resulting from the use or operation of the products, methods, equipment or other results of the Project;
- E. all direct and indirect damages losses, liabilities, costs and expenses arising from the above, including legal costs;

**13. Staff**

13.1 Client shall not, without prior written consent from Inter Regulatory, offer employment, partnership, membership, or consultancy contract to any Staff, agent or contractor or 3rd party engaged by Inter Regulatory in the course of delivering this scope of this agreement either during the Project or within twelve months of its completion.

**14. General**

14.1 This Agreement constitutes the entire agreement between the parties and supersedes and extinguishes all previous agreements, promises, assurances, warranties, representation and understandings between them, whether written or oral, relating to its subject matter.

- 14.2 All amendments of this Agreement shall be agreed in writing. Receipt of a purchase order, signature of a delivery note, or other similar reference to alternative terms shall not constitute a variation of this Agreement.
- 14.3 Each party irrevocably agrees that the courts of England and Wales will have exclusive jurisdiction to settle any dispute or claim (including non-contractual disputes or claims) arising out of or in connection with this Agreement or its subject matter or formation.
- 14.4 Neither party shall be in breach of this Agreement nor liable for delay in performing, or failure to perform, any of its obligations under this Agreement if such delay or failure result from events, circumstances or causes beyond its reasonable control.
- 14.5 Neither party shall assign, transfer, mortgage, charge, subcontract, delegate, declare a trust over or deal in any other manner with any or all of its rights and obligations under this Agreement without the prior written consent of the other party (such consent not to be unreasonably withheld or delayed).
- 14.6 No variation of this Agreement shall be effective unless it is in writing and signed by the parties (or their authorised representatives).
- 14.7 No failure or delay by a party to exercise any right or remedy provided under this Agreement or by law shall constitute a waiver of that or any other right or remedy, nor shall it prevent or restrict the further exercise of that or any other right or remedy. No single or partial exercise of such right or remedy shall prevent or restrict the further exercise of that or any other right or remedy.
- 14.8 If any provision or part-provision of this Agreement is or becomes invalid, illegal or unenforceable, it shall be deemed deleted, but that shall not affect the validity and enforceability of the rest of this Agreement. If any provision or part-provision of this Agreement is deemed deleted the parties shall negotiate in good faith to agree a replacement provision that, to the greatest extent possible, achieves the intended commercial result of the original provision.
- 14.9 This Agreement does not give rise to any rights under the Contracts (Rights of Third Parties) Act 1999 to enforce any term of this Agreement.
- 14.10 Any notice given to a party under or in connection with this Agreement will be in writing and will be delivered by hand or by pre-paid first-class post or other next working day delivery service at its registered office (if a company) or its principal place of business (in any other case) or sent by email to the signatories of this agreement for the client and to; [David.Lawson@inter-regulatory.com](mailto:David.Lawson@inter-regulatory.com) on behalf of Inter Regulatory.

This Agreement has been entered into on the date of 'Authorisation of proposal'.