

General Terms and Conditions (GTC)

-for Business Customers-
of Dr. Brill Regulatory Services GmbH · Grützühlenweg 44 22339 Hamburg · Germany

§ 1 Scope of Validity

Unless otherwise agreed in individual cases, the following General Terms and Conditions shall apply to all performance, deliveries and offers rendered to its Customers by Dr. Brill Regulatory Services GmbH, Grützühlenweg 44, 22339 Hamburg, Germany, e-mail: info@brillregulatory.com (hereinafter: Dr. Brill Regulatory). These GTC shall also apply to all future business transactions insofar as they are of a similar nature. Any terms and conditions of the Customer which are in conflict with or which deviate from or supplement these General Terms and Conditions are explicitly ruled out. Accordingly, any supplementary or deviating general terms and conditions of the Customer shall apply only if they have been explicitly agreed with Dr. Brill Regulatory. Employees of Dr. Brill Regulatory are not authorised to enter into any agreement which amends these General Terms and Conditions. Such an agreement can only be concluded with Dr. Brill Regulatory itself. Any supplementary or deviating general terms and conditions of the Customer and any subsidiary agreements, amendments and/or addenda to the agreement between Dr. Brill Regulatory and the Customer must therefore be recorded in writing in order to be valid. The foregoing shall also apply to any waiver of this written form requirement.

§ 2 Conclusion of Contract

The services offered by Dr. Brill Regulatory are intended for commercial customers only. All offers submitted by Dr. Brill Regulatory are without obligation and subject to change. Orders submitted by the Customer (for example by sending in test samples/test items or by handing over test samples/test items to Dr. Brill Regulatory) shall be deemed accepted only on issue of confirmation of order by Dr. Brill Regulatory, unless Dr. Brill Regulatory indicates that the order has been accepted by rendering performance or in any other unambiguous manner. The content and scope of the order to be performed by Dr. Brill Regulatory shall be as stated in the confirmation of order. In this respect, Dr. Brill Regulatory reserves the right to subcontract other laboratories/institutes/consultants (in the future: third parties) in agreement with the contracting party in order to fulfil its contractual obligations towards the contracting party. If Dr. Brill Regulatory uses third parties in the execution of the order, it shall be obliged to select these persons carefully. No contractual relationship shall arise between the contracting party and the third party. The results of third parties shall be identified accordingly in the interim/final reports.

§ 3 Performance

Dr. Brill Regulatory shall provide consultancy and support services ('consultancy services') within the scope of the order in accordance with the instructions of and in consultation with the contracting party. The consultancy services are derived from the order of the contracting party. The consulting services are essentially aimed at advising and supporting the contracting party in the regulatory and scientific field. Unless otherwise expressly agreed in writing, Dr. Brill Regulatory shall not be responsible for the performance of any work in this respect. The other party is aware that Dr. Brill Regulatory does not owe any success. Unless otherwise agreed in writing, Dr. Brill Regulatory shall not be bound by instructions in the execution of the order. This applies both to the manner of performance and to working hours and place of work. If the personal presence of a Dr. Brill Regulatory consultant is required, the consultant is obliged to provide the service there. The dates for this will be agreed between Dr. Brill Regulatory and the contractual partner. Dr. Brill Regulatory will carry out the order with scientific diligence to the best of its ability, based on the latest scientific and technical knowledge and the relevant legal and official regulations, in close contact with the contractual partner. Dr. Brill Regulatory reserves the right to change the scope of services for technical or scientific reasons (e.g. due to new scientific findings) as well as due to changes in legal or official regulations. In this case, the contractual partner shall be informed of the change in the scope of services. Dr. Brill Regulatory shall be entitled to charge separately for any additional expenses incurred as a result of the change in the scope of services (see § 8 of the GTC). Agreed dates and delivery periods shall only be binding if they have been expressly agreed in writing as binding between Dr. Brill Regulatory and the contractual partner and shall be understood as dates by which the provision of services shall be

completed at the latest. Otherwise, Dr. Brill Regulatory shall provide the agreed services within the time limits customary in the market. Dr. Brill Regulatory shall not be obliged to refer to or report on values or facts that are outside the specific instructions of the contractual partner or outside the generally accepted customary methods or the relevant legal and official regulations. Fixed time limits shall not begin to run until the contractual partner has fulfilled its obligations to cooperate in each individual case (see § 4 of these GTC). If the contractual partner does not make a written complaint to Dr. Brill Regulatory within one week of receipt of an interim or final report, the service provided by Dr. Brill Regulatory shall be deemed to have been accepted, provided that it is essentially free of defects. If non-compliance with a delivery date is due to force majeure, labour disputes or other events beyond the control of Dr. Brill Regulatory, the delivery date shall be postponed accordingly. This shall also apply if these hindrances occur during the delay.

§ 4 Obligations of the Customer

The contracting party shall support the advisory services of Dr. Brill Regulatory by providing appropriate cooperation. The contracting party shall provide the necessary cooperation immediately upon first request.

The contracting party is obliged to provide Dr. Brill Regulatory with all documents/information available/known to it (including, but not limited to: findings/investigation results, results of previous projects, contacts/reactions to or from public bodies, legal assessments, etc.) which are necessary for the execution of the order in good time, at the latest when the order is placed, and to inform Dr. Brill Regulatory of the measures/activities already initiated, unless this is prevented by data protection laws or other statutory/official regulations. The contractual partner also undertakes to inform Dr. Brill Regulatory of any data protection or other legal/regulatory obstacles to the disclosure of information.

If the contractual partner has a works council, general works council or group works council (hereinafter referred to as "works council"), the contractual partner undertakes vis-à-vis Dr. Brill Regulatory to involve the works council in the order in good time in accordance with the relevant participation rights of the works council. Any delays in the execution of the order due to insufficient involvement of the works council shall be borne by the contractual partner.

§ 5 Liability for Defects and General Liability

The liability of Dr. Brill Regulatory, its legal representatives and vicarious agents for breach of duty and tort shall be limited to intent and gross negligence. Dr. Brill Regulatory, its legal representatives and vicarious agents shall also be liable for slight negligence in the event of a breach of material contractual obligations (i.e. obligations whose fulfilment characterises the contract and on whose fulfilment the contractual partner may rely), but the amount of liability shall be limited to the damage foreseeable at the time of conclusion of the contract and typical for the contract. Dr. Brill Regulatory is covered by liability insurance for damage amounting to a maximum of EUR 3,000,000.00. Dr. Brill Regulatory shall not be liable for delayed, partial or non-existent performance of services if this is caused directly or indirectly by events beyond the control of Dr. Brill Regulatory (e.g. breach of the obligations of the contractual partner as defined in § 4 of these GTC). These exclusions and limitations of liability shall not apply to the extent that Dr. Brill Regulatory has assumed a guarantee, nor to damages to life, body or health, nor to mandatory statutory liability claims.

The contractual partner shall indemnify Dr. Brill Regulatory and its vicarious agents against claims for damages by third parties which arise in causal connection with the order and which exceed the liability of Dr. Brill Regulatory or its vicarious agents in accordance with the above provision. Dr. Brill Regulatory undertakes to assign to the contractual partner any claims for damages against third parties arising from the order. The contractual partner must notify Dr. Brill Regulatory in writing within 30 days of discovery of the circumstances giving rise to the claim. Claims for compensation based on infringement of obligations shall become statute barred within 12 months, beginning from the commencement of the statutory limitation period.

If Dr. Brill Regulatory fails to perform its obligations, fails to perform them on time or fails to perform them properly, the contractual partner shall only be entitled to claim damages in

lieu of performance if it has unsuccessfully set Dr. Brill Regulatory a reasonable deadline for performance, stating that it will refuse to accept the service after expiry of the deadline.

§ 6 Remuneration

Unless the parties have signed a separate agreement to the contrary, Dr. Brill Regulatory's remuneration shall be based on the prices/price lists agreed between Dr. Brill Regulatory and the Customer in each individual case. The agreed remuneration shall cover all performance to be rendered by Dr. Brill Regulatory under the contract, inclusive of all necessary preparatory and ancillary work. The remuneration shall not include any costs and expenses assumed by Dr. Brill Regulatory or any other costs specified in these General Terms and Conditions which are to be reimbursed by the Customer (additional expenditure, return shipment).

If any modifications or supplementary work is carried out at the request of the Customer after placement of the order, the additional expenditure shall be charged separately. Unless otherwise agreed, Dr. Brill Regulatory will invoice its services on a monthly basis. This does not apply to services provided by third parties. Services provided by third parties may be invoiced immediately after they have been incurred.

The agreed remuneration also does not include travel costs, expenses and cash outlays, which shall be invoiced separately. Unless otherwise agreed, Dr. Brill Regulatory's travel costs and expenses shall be charged on a time and material basis. For business travel using the client's own vehicle, travel expenses of EUR 0.50 per kilometre driven will be charged. Flights within Europe are economy class. For intercontinental flights, business class may be substituted for economy class at the discretion of Dr. Brill Regulatory.

Unless a different date is specified on the invoice, all invoices shall be due and payable in full within 14 days of the date of the invoice, without deduction of any discount or rebate, by bank transfer to the bank account of Dr. Brill Regulatory specified on the invoice. The contractual partner shall automatically be in default of payment, without the need for a reminder or any other further requirement, if he fails to pay at the time specified on the invoice or, if no such time is specified, within 14 days of the invoice date. The contractual partner shall only be entitled to rights of retention and set-off if his counterclaims have been legally established or are undisputed by Dr. Brill Regulatory. Furthermore, the assertion of a right of retention by the contractual partner is only permissible if it is based on the same contractual relationship.

§ 7 Cancellation

Termination of a current contract may only be effected by mutual agreement between the parties or for good cause. In the event of termination for good cause attributable to Dr. Brill Regulatory, Dr. Brill Regulatory shall only be entitled to payment for services rendered up to the date of termination. In all other cases, Dr. Brill Regulatory reserves the right to be indemnified against any claims by third parties and to claim the contractually agreed fee, less any expenses saved.

§ 8 Contractual Results, Rights of Use and Copyright

All content provided is made available to the contractual partner solely for the purposes of the contractually agreed services.

Dr. Brill Regulatory or third parties commissioned by Dr. Brill Regulatory expressly reserve the copyrights to expert opinions, test reports, analyses, concepts, reports, trademarks or registered designs and similar delivery items and service results to which such rights may arise. The contractual partner shall be granted a non-exclusive, free and unlimited right of use for the purpose of the application on which its order is based to the delivery items and service results created during the execution of the order and to any industrial property rights registered by Dr. Brill Regulatory and granted to it.

The granting of an exclusive, unlimited or limited right of use to the delivery items and service results created during the execution of the order requires a separate agreement and is always subject to payment.

This provision shall not apply to expert opinions and test reports prepared in the course of the execution of the order which are directly related to products or services of the other party. For these expert opinions and test reports, which are directly related to products or services of the contractual partner, the contractual partner shall receive an exclusive, free and unlimited right of use for the purpose on which the order

is based. If a joint scientific publication is to be published as part of the collaboration (e.g. in specialist journals, as part of training courses or presentations at congresses), the contracting parties shall only be entitled to publish the results of the order with the prior consent and corresponding written confirmation of the other contracting party. In the event of publication without the required consent, the other party shall be entitled to assert corresponding claims for injunctive relief/damages against the other party (if necessary in court, in summary proceedings).

§ 9 Confidentiality

For the duration of the contract and for a period of five years after termination of the contract, the parties shall not make available to third parties any information of a technical or commercial nature which has been disclosed to each other and declared confidential. This does not apply to information which was known or generally accessible to the other party or the public prior to the disclosure, or which became known or generally accessible to the public after the disclosure without the involvement or fault of the other party, or which was disclosed or made accessible to the other party by an authorised third party, or which was independently developed by an employee of the other party who had no knowledge of the disclosed information. Third parties within the meaning of this confidentiality agreement are not subcontractors of Dr. Brill Regulatory who are entrusted by Dr. Brill Regulatory with partial services within the scope of the order and who are obliged to maintain confidentiality.

§ 10 Legal Venue and Applicable Law

If the Customer is a business customer within the meaning of the German Commercial Code, a special fund under public law or a legal entity, Hamburg (Federal Land of Hamburg) shall be sole legal venue for all disputes in connection with this contractual relationship. The same legal venue shall apply if the Customer has no general jurisdiction in the Federal Republic of Germany at the time of institution of legal proceedings. These General Terms and Conditions and the entire business relationship between Dr. Brill Regulatory and the Customer shall be governed by the laws of the Federal Republic of Germany, excluding the UN Convention on Contracts for the International Sale of Goods (CISG).

The parties shall conduct a mediation procedure (qualified arbitration) to settle all disputes arising from or in connection with this contract. The mediation procedure shall commence upon receipt of a written request from one contracting party to the other contracting party to jointly conduct such a procedure ('mediation request'). If the contracting parties are unable to agree on a mediator (conciliator) within two weeks of receipt of the request for mediation, the Hamburg Mediation Centre for Commercial Disputes will appoint a mediator at the request of one of the parties. Legal action may only be taken if a party or the mediator has declared in writing that the mediation has failed. The declaration is only admissible if an initial joint negotiation with the mediator has taken place or if two months have elapsed since the request for mediation without a first mediation session having taken place. The declaration must be made in writing to the other party. Statutes of limitation and contractual limitation periods are suspended from receipt of the request for mediation. The suspension lasts until the last calendar day of the month in which the failure of the mediation is declared. Summary proceedings in court or the filing of an action to interrupt a statutory limitation period shall remain admissible at any time.

§ 11 Amendments to the General Terms and Conditions

Dr. Brill Regulatory reserves the right to amend these General Terms and Conditions at any time without stating reasons provided this does not lead to any change in the contract structure as a whole. The amended terms and conditions shall be submitted to the correspondence address stated by the Customer no later than two weeks prior to their entry into force. If the Customer does not submit a written objection to the entry into force of the new General Terms and Conditions within a period of two weeks of receipt of the new General Terms and Conditions, the amended General Terms and Conditions shall be deemed accepted. In the letter containing the amended terms and conditions, Dr. Brill Regulatory shall advise the Customer of the amended terms and conditions, the Customer's rights to object, the time limit for objections and the meaning of the amendments.

§ 12 Severability Clause

Should one or more provisions of these General Terms and Conditions be invalid or unenforceable, this shall not affect the validity of the remaining provisions. The invalid or unenforceable provision shall be replaced by a valid or enforceable provision which comes as close as possible to the economic intent of the invalid or unenforceable provision in a legally admissible way. The foregoing shall also apply if the General Terms and Conditions prove to contain gaps.

Dr. Brill Regulatory Services GmbH

Hamburg, 01 April 2024