

General Terms and Conditions (GTC)

1 General Principles and Application

- 1.1 All legal transactions between the Client and Gabriele E. M. Berghammer (referred to below as Service Provider) shall be exclusively subject to these General Terms and Conditions (GTC). The applicable version shall be the one in force at the time the contract is concluded. The Client expressly acknowledges to have taken note of these GTC in a legally binding manner, so that they have become an integral part of the contract. This also applies in the event that Client refers to his own terms and conditions.
- 1.2 These GTC also apply to all future transactions between the contracting parties without the need for repeated mention of them in additional contracts.
- 1.3 Conflicting terms and conditions of the Client are not considered a part of the contract unless explicitly agreed to in writing by the Service Provider.

2 Definitions

For the purpose of these GTC, the following definitions shall apply:

“Work Order” sets out the exact type, scope, requirements, and timelines of the service to be performed. A Work Order can be placed orally or in writing.

“Deliverable” refers to any services, work, work results, data, documents or materials the Service Provider is asked to provide or prepare as part of a Work Order.

“Commissioned Text” shall mean the Deliverable of a medical writing project.

“Source Text” is the text to be translated.

“Target Text” shall mean the Deliverable of a translation project.

“Source Material” shall mean any data, documents, and other material the Client provides to the Service Provider for the preparation of the Deliverable, such as, in particular, medical and scientific raw data checked for correctness and plausibility by the Client, final statistics reports, pertinent publications, parallel text, terminology lists, style guides, pertinent templates, and any other background information and materials essential for the preparation of the Deliverable.

“Supportive Services” shall be understood to include project management, consulting services, or other value-added services, such as medical writing training, English language coaching, adapting a translation to the requirements of the target-language culture (‘localization,’ ‘transcreation’), formatting documents, developing document templates, creating style guides, performing literature searches, editing, proofreading, creating and maintaining terminology lists or databases, or using and maintaining translation management systems, including alignment.

3 Subject Matter and Scope of Services

- 3.1 These GTC shall apply to
 - medical writing
 - translation
 - and supportive services
 in German and/or English.

- 3.2 The scope of the Services to be rendered shall be defined by the Work Order placed by the Client.

4 Duties of the Contractual Parties

- 4.1 The Service Provider undertakes to carry out all commissioned tasks to the best of her knowledge, in accordance with the general rules for service providers, and in agreement with the principles of economic efficiency. However, the Service Provider does not owe any success. She shall not be liable for the Deliverable fulfilling the purpose intended by the Client. This responsibility rests solely with the Client.

- Commissioned Texts shall be prepared in accordance with generally accepted medical writing guidelines (e.g., those issued by the *International Conference on Harmonisation* [ICH], the *European Medicines Agency* [EMA], or the *International Committee of Medical Journal Editors* [ICMJE]). Both the Client and the Service Provider acknowledge that the final responsibility for the content of the Commissioned Text shall rest with the individuals acting as listed authors of the Commissioned Text.
- Target Texts shall essentially be prepared in accordance with the rules and regulations of ÖNORM EN ISO 17100.
- Unless otherwise agreed, the selection and implementation of the processes best suited for the performance of each order in question shall be at the discretion of the Service Provider.

- 4.2 The Client undertakes to inform the Service Provider before preparation of the cost estimate about the exact purpose of the Deliverable, e.g., whether it is intended for

- a particular target audience or country,
- the purpose of information only,
- for publication and/or advertising purposes,
- legal purposes or for use in marketing authorization or patent procedures, or
- any other purpose that requires specific aspects to be taken into consideration.

- 4.3 The Client shall inform the Service Provider, before preparation of the cost estimate, about the level of service to be applied to the Deliverable. Possible levels of service range from a rough initial draft without any review cycles to a thoroughly polished and quality-controlled finalized text, including all required review cycles. If review cycles are planned, the Client shall inform the Service Provider, before preparation of the cost estimate, about the number and type of experts involved in the review process.

- 4.4 Although quality-control measures are included in every step of the writing and translation process as part of the Service Provider’s professional expertise, formal and systematic quality-control measures (e.g., checking numbers against the Source Material) have to be explicitly agreed upon to become part of the contract.

- 4.5 The Client shall make sure that any information and documents required to fulfill the Work Order be placed in good time and without special request at the disposal of the Service Provider. He undertakes to be available for questions while the Deliverable is being prepared and to supply the Service Provider with any additional data, documents, and other material that the Service Provider deems necessary to complete the Work Order. The Client shall keep the Service Provider informed of all events and circumstances which may be of significance for the execution of the Work Order, even if these do not become known until work on the Deliverable is already in progress. The costs associated

with the Service Provider having to repeat work or with work being delayed due to later amendments or changes shall be borne by the Client.

- 4.6 The correctness and plausibility of the Source Material or Source Text fall solely within the responsibility of the Client.
- 4.7 The Client may use the Deliverable only for the specified purpose (see **Item 4.2**). If the Client uses the Deliverable for another than the agreed-upon purpose, there shall be no liability on the part of the Service Provider, even if the Deliverable is in contradiction to the general rules for service providers.
- 4.8 Insofar as the Client requires use of a specific technology, the Client shall inform the Service Provider accordingly before preparation of the cost estimate and – if the application in question is not necessarily a common one for the Service Provider – shall provide the Service Provider with access to the required technology.
- 4.9 Insofar as the Client requires a specific terminology or specific styles or templates to be used, the Client shall inform the Service Provider accordingly before preparation of the cost estimate and simultaneously provide the Service Provider with the pertinent material.
- 4.10 The Service Provider shall be entitled to subcontract the order to qualified third parties. In this case, however, the Service Provider shall remain the Client's exclusive contractual partner and solely responsible towards the Client.
- 4.11 Unless otherwise agreed, the Service Provider shall transmit the Deliverable electronically as a single copy.
- 4.12 The name of the Service Provider may be added to the Deliverable only if the entire work was prepared by the Service Provider and no changes were made to the Deliverable as finalized in consultation and agreement with the Service Provider.
- 4.13 If the Deliverable is intended for print, the Client is obliged to provide the Service Provider, in a timely manner, with a galley proof before going to print, so that the Service Provider can remove any defects. Names and numbers shall be checked by the Client.

5 Prices and Invoicing

- 5.1 Prices charged shall be based on the current service rates of the Service Provider.
 - 5.2 Price calculations shall be based on the unit agreed upon on a case-per-case basis (e.g., hourly rate, source text, target text, or number of pages, lines, words, or characters).
 - 5.3 A cost estimate shall be considered binding only (Quotation) if given in writing, with the Service Provider having full knowledge of the exact scope of the project or having been provided with the Source Text, if explicitly marked as binding. Cost estimates made in a different form or under different circumstances shall be considered nonbinding and given for guidance only.
 - 5.4 Although cost estimates are prepared to the best of the Service provider's expert knowledge, they can be subject to change, e.g.,
 - if the Service Provider, after being provided with the complete Source Material or the Source Text, finds that the initial assumptions underlying the cost estimate were substantially inaccurate or
 - if, while working on the Deliverable, the Service Provider becomes aware of latent difficulties (e.g., inaccurate Source Material, discontinuous or incomprehensible Source Text, complex layout, instable document formatting, unexpectedly complex terminology requiring extensive research, &c.), which, at the time of estimate, were not foreseeable or reasonably predictable for either the Client or the Service Provider.
- If, after placement of an order, it becomes clear that a cost overrun exceeding the order amount will incur, the Service Provider shall, without delay, inform the Client of such increase.
- 5.5 A cost estimate shall remain valid for a period of 30 days from the date on which it was given.

- 5.6 Unless otherwise agreed, order changes or additional orders shall be charged at reasonable rates.
- 5.7 All accounts receivable shall be subject to value preservation. As a measure for the calculation of value preservation, the consumer price index published monthly by Statistics Austria or an index replacing it shall be used.
- 5.8 Express or weekend jobs can be invoiced at reasonable surcharges that have to be agreed upon in advance.
- 5.9 The Service Provider may request a reasonable advance payment.
- 5.10 Travel and ancillary expenses incurred by the Service Provider while fulfilling her contractual obligations and in consultation with the Client shall be reimbursed upon presentation of the corresponding receipts.

6 Due Dates and Delivery

- 6.1 The due date shall be agreed upon between the Service Provider and the Client. The due date is an essential contractual component of the order accepted by the Service Provider. A fixed delivery date in the sense of a fixed-date transaction shall be considered agreed-upon only if confirmed in writing. If no delivery date was agreed upon, the service shall be performed within a reasonable time frame. If the due date cannot be adhered to (e.g., due to latent difficulties as mentioned in **Item 5.4**), the Service Provider shall inform the Client immediately and specify by when the order will be able to be completed.
- 6.2 Prerequisites for being able to meet the due date, particularly in the case of fixed-date transactions, are the timely receipt, to the extent and in the format specified, of any data and documents to be provided by the Client (e.g., Source Material, Source Texts, any relevant background information) as well as compliance with the agreed payment conditions when delivery in installments or similar has been agreed and with any other obligations. If the Client fails to fulfill these prerequisites in time, the delivery period shall be extended by the period by which fulfillment was delayed.

In the case of fixed-date transactions, it is up to the Service Provider to decide whether the agreed due date is able to be met despite failure of the Client to provide the required data, documents, and other material. If meeting the due date results in surcharges for express or weekend jobs being incurred, the Service Provider shall inform the Client thereof without delay. If the Client cannot be reached, these surcharges shall be payable to the extent that they are required for the Service Provider to be able to honor the fixed-date transaction.

- 6.3 If the contracted order ends up being canceled for reasons falling within the Client's responsibility, e.g., because the Client fails to provide, or fails to provide in time, the Service Provider with the required data, documents, and other material or because the Client violates his duty to cooperate, the Service Provider shall be entitled to a cancellation fee of 50% of the order value of the agreed-upon work or installment, with any recourse to judicial mitigation being excluded. This shall not be offset against expenses the Service Provider was spared as a result of the contract not having materialized, against income generated through alternative use, or against income voluntarily forfeited (see Article 1168, Austrian Civil Code, [Allgemeines bürgerliches Gesetzbuch, ABGB]).
- 6.4 Any risks related to the transmission of the data, documents, and other material to be made available by the Client shall be borne by the Client; any risks related to the transmission of the Deliverable shall be borne by the Service Provider (see **Item 9.9**).
- 6.5 Unless otherwise agreed, the data, documents, and other material the Client supplied to the Service Provider shall, after completion of the order, remain with the Service Provider. The Service Provider shall undertake to securely file away the material so that access by unauthorized persons is prevented, the confidentiality obligation is not violated, and the material cannot be used in violation of the contract.

7 Force Majeure

- 7.1 Any instance of force majeure shall be communicated to the Client immediately. In case of force majeure, both the Service Provider and the Client shall have the right to rescind the contract. However, the Client undertakes to compensate the Service Provider for expenses already incurred or services rendered.
- 7.2 Instances of force majeure include labor conflicts, acts of war, civil war, unexpected events that demonstrably and significantly compromise the Service Provider's ability to carry out the order as agreed, and similar occurrences.

8 Confidentiality and Data Protection

- 8.1 The Service Provider undertakes to treat as confidential any business matters concerning the Client that become known to her, particularly any commercial and company secrets.
- 8.2 The Service Provider shall be exempt from her confidentiality obligation in relation to her subcontractors. However, the Service Provider undertakes to convey the confidentiality obligation to any subcontractor and shall be liable for any violation of the confidentiality obligation on the part of the subcontractor in the same way as if the violation was her own.
- 8.3 The confidentiality requirement shall be limited to a period of 5 years from the date of conclusion of the Work Order.
- 8.4 The Service Provider shall have the right to process the transmitted data or person-related data otherwise entrusted to her within the scope of the purpose of the contractual relationship and to continue to store these data after the termination of the contractual relationship, if such processing or storing is necessary to fulfill the order or statutory obligations (e.g., for the purpose of financial reporting).
- 8.5 With regard to the Client's contact details (e.g., email address), the Client agrees to these contact details being processed and stored or used to transmit notes for advertising purposes within the meaning of Section 107 of the Austrian Telecommunications Act (Telekommunikationsgesetz, TKG). The Client can revoke his consent hereto at any time.
- 8.6 The Client also has the right, under the preconditions set out in the Austrian Data Protection Act (Datenschutzgesetz, DSGVO), to demand that his personal data be deleted. However, any such demand will be honored only if the Service Provider is not legally required to store said person-related data.

9 Acceptance of the Deliverable and Liability for Defects (Warranty)

- 9.1 The Client shall be obliged to accept the Deliverable. Acceptance means the acknowledgment of the Deliverable prepared by the Service Provider being essentially in conformity with the contract.
- 9.2 Acceptance is generally by express declaration on the part of the Client. If express acceptance does not occur within 30 days after delivery of the Deliverable, the Deliverable shall be deemed to have been tacitly accepted.
- 9.3 Any defects have to be adequately detailed in writing and substantiated by the Client (error protocol). Such notice of defects shall be made within 30 days after delivery of the Deliverable. Hidden deficiencies must be reported to the Service Provider immediately upon discovery, but not later than 6 months after delivery of the Deliverable.
- 9.4 The Client shall grant the Service Provider a reasonable period to remedy or resolve the defects and an opportunity to correct and improve the Deliverable. If the Client refrains from doing so, this releases the Service Provider from any liability for defects. If the Service Provider remedies the defects within a reasonable time, the Client shall not be entitled to a price reduction.
- 9.5 If the Service Provider fails to remedy the defects within the granted period, the Client may either rescind the contract (redhibitory action) or demand a price reduction (abatement).

In case of minor defects, however, the Client shall have no right to rescission.

- 9.6 Warranty claims shall not entitle the Client to retain payment of the entire invoice amount, but only of an adequate portion thereof; in such an event, the Client also renounces the possibility of setoff.
- 9.7 For Deliverables intended for print, the Service Provider shall be liable for defects only if the Client expressly states in writing, in his Work Order, that he intends to publish the Deliverable and if the Service Provider is provided with galley proofs (author's correction) up to and including that version of the Deliverable after which no more changes are implemented. In this case, the Service Provider shall be adequately remunerated.
- 9.8 Stylistic changes or adaptations to specific terminologies (particularly company-specific terms) and the like shall not be considered defects.
- 9.9 The transmission of Deliverables via data transfer (e.g., email, modem, cloud solution, &c.) shall be performed by the Service Provider in accordance with state-of-the-art technological standards. In view of the nature of technological realities, the Service Providers shall neither assume any guarantee nor accept any liability for transfer-related defects or impairments (such as violation of confidentiality obligations, damaged files, &c.), unless the Service Provider acted in at least gross negligence.

10 Damages

- 10.1 Unless otherwise mandated by law, any claims for damages against the Service Provider shall be limited to the net amount invoiced. Excluded from this limitation of compensatory damages shall be cases in which the damage was caused by gross negligence or willful intent on the part of the Service Provider and cases of personal injury in accordance with the Austrian Product Liability Act (Produkthaftungsgesetz, PHG) that were demonstrably caused by a defective Deliverable.
- 10.2 Any claims for damages by the Client shall be asserted in court within 6 months after becoming aware of the damage and the damaging party, but not later than 12 months after the conclusion of the respective Work Order; otherwise, assertion of the claim shall be excluded. Prolongation of the cooperation does not extend this deadline. The Client has to provide evidence that the damage was due to the fault of the Service Provider.
- 10.3 In case the Client uses the Deliverable for a purpose other than the one specified (see **Item 4.2**), any liability of the Service Provider with regard to claims for damages shall be excluded.

11 Reservation of Title

- 11.1 Any files or documents related to the work order and provided to the Client shall remain the property of the Service Provider until full payment of all claims arising from the contract.
- 11.2 Any data, documents, and other material not contained in the work order, such as checklists, graphs, tables, translation memories, terminology lists or databases, parallel texts, software, brochures, catalogues, reports, publications, literature, or scripts, shall remain the property of the Service Provider and are subject to applicable legal regulations. These data, documents, and other material may only be distributed or reproduced with the permission of the Service Provider.

12 Intellectual Property Rights

- 12.1 The Service Provider shall not be obliged to verify whether the Client is entitled to process, or have processed, the Source Material or to translate, or have translated, the Source Text. The Client explicitly affirms that he has all necessary rights with respect to the execution of the Work Order.
- 12.2 With certain services, service providers hold moral rights in the material they create, and they therefore have the right to be credited as the creator of their work. Upon full payment of the invoice, the Client acquires the contractually agreed exploitation rights for the Deliverable. In principle, services protected

by moral rights should have the name of the service provider added to them. For the conditions for crediting the Service Provider, see **Item 4.12**.

- 12.3 In case of translations of works protected by moral rights, the Client shall clearly specify the purpose of the translation. The Client acquires only those rights that correspond with the specified purpose of the translation.
- 12.4 The Client undertakes to keep the Service Provider harmless from any claims from third parties arising from the infringement of moral rights, related rights (performance rights), copyright, and other commercial or personal intellectual property rights. This also applies in the event that no purpose had been specified by the Client or if the Client uses the Deliverable for other than the specified purposes. The Service Provider shall promptly notify the Client of any such claims and, if legal action is brought, shall give the Client notice of intervention. If, after being given notice of intervention, the Client fails to join the Service Provider as joint litigant, the Service Provider shall be entitled to accept the claim brought forth by the plaintiff and to seek recourse from the Client without regard to the legitimacy of the accepted claim.

13 Payment

- 13.1 Unless otherwise agreed, payment shall be effected at the time of delivery of the Deliverable and after invoicing (advance payments, see **Item 5.9**).
- 13.2 In the case of payment default, an adequate rate of default interest (8% above the base lending rate) as well as a reminder fee shall be charged.
- 13.3 If partial payments were agreed upon (e.g., when delivery is in installments or in case of advance payment) and the Client defaults on these payments, the Service Provider shall, after giving

advance notice, have the right to stop work on the Client's on-going orders without any legal consequences to the Service Provider until the Client has settled his payment obligations. This shall also apply to orders for which fixed-date deadlines have been agreed (see **Item 6.1**). The related suspension of work shall not entitle the Client to any legal claims, and the Service Provider shall in no way be prejudiced in her rights.

14 Severability

- 14.1 The invalidity of individual provisions of these GTC shall not affect the validity of the remaining provisions.
- 14.2 If any provision of these GTC should be, or become, invalid or unenforceable, both parties undertake to replace such provision with a legally admissible, effective, and enforceable provision that most closely matches the intent of the invalid or unenforceable provision.

15 Written Form

Any amendments or supplements of these GTC as well as any other agreements between the Client and the Service Provider must be in writing to be effective.

16 Venue and Applicable Law

- 16.1 The venue for all contractual relationships subject to these GTC shall be the place of business of the Service Provider.
- 16.2 The competent court for any disputes arising from this contract shall be the court of the place of business of the Service Provider.
- 16.3 Austrian law shall apply.

Mag. phil. Gabriele E. M. Berghammer, MA

the text clinic

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