

**A. General provisions**

**I. Scope of application**

- (1) These General Terms and Conditions apply to all fields of business activities of Schrack & Partner. The General Terms and Conditions therefore shall apply in particular to
- (a) all our consultancy services, including but not limited to establishing, supporting and optimizing quality management systems for medical devices, supporting and designing, setting up, optimizing and expanding manufacturing processes. Further to consulting on technical and other product documentation, including but not limited to support of development and product testing, advice on conformity assessment procedures, and advice / declaration on product approvals, further to
- (b) conduct training, seminars and in-house seminars.
- (2) In our relationship with the customer, these General Terms and Conditions shall apply exclusively. These General Terms and Conditions shall also apply to all future transactions and in all cases in which contact is taken up with a customer for business purposes, as for example the entry into contractual negotiations or in the preliminary stage before conclusion of a contract, even if these General Terms and Conditions are not expressly agreed again or if no express reference is made to them again.
- (3) If, in an individual case, obligational relationships are also established towards persons or businesses who or which are not themselves intended to become a party to the contract, then the conditions regarding liability contained in these General Terms and Conditions shall also apply against them, to the extent that these General Terms and Conditions were incorporated against the third parties when the obligational relationship came into existence. This is the case, above all, if, when the obligational relationship came into existence, the third parties obtained, or already had, knowledge of these General Terms and Conditions .
- (4) We do not accept any terms or conditions of the customer which deviate or contradict our General Terms and Conditions. The acceptance of our services by the customer is regarded as acknowledgment of the validity of these General Terms and Conditions. Previously agreed agreements and earlier versions of our General Terms and Conditions shall be abolished by these General Terms and Conditions

**II. Conclusion of a contract**

- (1) Unless otherwise agreed, our offers are free and non-binding.

- (2) An order shall not become binding upon us, unless it has been confirmed by us in writing or if we start to carry it out.

**III. Scope of services, periods for performance**

- (1) The scope of our services is determined by our written offer or, as appropriate, by our confirmation of the order. Modifications and alterations require our written confirmation.
- (2) If our offer or our confirmation of the order was based on information from the customer (data, numbers, pictures, drawings, details of weights and measurements etc.), then our offer is only binding, if such information was correct. If, after conclusion of the contract, it turns out that the order cannot be carried out in accordance with the information provided by the customer, then we are entitled to withdraw from the contract, if and so far as the customer is not prepared to accept the alternative solution which is suggested by us and, if necessary, to assume the additional incurred costs.
- (3) We shall be entitled to undertake acts of partial performance in respect to all orders to a reasonable and fair extent. We are entitled to use subcontractors to fulfill our contractual obligations.
- (4) Time-periods and dates for performances are always as accurate as possible, but are not generally legally binding unless otherwise agreed. The start of the period for performance and compliance with performance dates are subject to the following prerequisites: that the customer punctually and properly performs the acts of cooperation which are incumbent on the customer; that the customer makes available all necessary documentation and that the customer makes all prepayments which had been agreed.
- (5) We shall not come into delay in cases of force majeure or in situations which arise without fault on our part or in extraordinary circumstances. In such cases, we are also entitled to withdraw from the contract if we were already in delay. We do not come into delay if default of supply is caused by non-delivery or late delivery by our suppliers, provided we are not responsible for such non-delivery or late delivery. As such, we shall not be held responsible in cases of slight negligence caused by us. In case of temporary supply problems, the timelines for our supply are extended for a term equal to the time of the temporary problems plus a reasonable term for catching up with supply.
- (6) If we are under a contractual obligation to undertake an act of performance in advance, we shall be entitled to decline to carry out such act of performance which is incumbent on us, if, after conclusion of the contract, it becomes apparent that our claim to the act of counter-performance is endangered by the customer's inability to perform. In par-

ticular, this is the case if the counter-performance to which we are entitled is endangered due to the customer's bad commercial circumstances or if other impediments to performance threaten, such as, for example, export- or import bans, armed conflicts, insolvency of suppliers or non-availability of necessary members of staff due to illness.

- (7) Unless expressly agreed otherwise, when rendering consultancy services and seminars, it shall not be our obligation to reach an actual success.

**IV. Prices**

- (1) Our prices are net prices. When an invoice is issued, Value Added Tax will be added to the price at the statutory rate respectively applicable. In the event we send documents or other goods to the customer, the customer shall bear the shipping costs.
- (2) In such cases where there is a time period of more than 4 months in between conclusion of the contract and agreed and / or actual performance, we shall be entitled to charge costs based on our cost rates respectively applicable at the time of actual delivery or performance. If such costs exceed the initially agreed sum by more than 10%, then the customer is entitled to withdraw from the contract within ten days after being informed of such higher costs.
- (3) The remuneration of services rendered by us shall be invoiced upon on an hourly rate based on the actual time spent, even in case of a previously given cost estimate. This shall not apply in case of an explicitly agreed lump sum. The units of the time recording and the current hourly rates can be found in our offer or our order confirmation.

Unless otherwise agreed travel expenses are billed separately. Payment of travel and accommodation expenses (after deduction of the VAF-amount of invoices relative to such expenses) by the customer shall be due upon presentation of the relevant documents in a copy. For our applicable travel expenses rates please refer to our offer or our order confirmation.

**V. Terms of payment**

- (1) Our remuneration is due by the time of performance of the service. If we render parts of our services separately, we shall be entitled to charge a corresponding portion of the remuneration.
- (2) In respect to new customers and customers situated abroad, we reserve the right to ask for full payment in advance.
- (3) Unless otherwise expressly agreed the customer shall not be entitled to any deductions whatsoever.
- (4) Unless otherwise expressly agreed payment by bill of exchange or acceptance shall not be permitted, and even in case of permissance, shall be deemed only on account of payment. If

such payments cause additional costs, they must be borne by the customer.

- (5) If we have agreed on installments the following shall apply: If the customer falls into arrears in whole or in part for more than two weeks, the entire outstanding balance is due for immediate payment.
- (6) If the customer is in default of payment, he shall be obliged to compensate us for the damage caused by default, in particular he shall be obliged to pay interest of 9 percentage points above the basic interest rate of the European Central Bank prevailing during the time of default of payment.
- (7) The assignment of claims against us by the customer requires our prior consent, which we will only refuse for an important reason.

#### **VI. Reservation of title, copyrights**

We reserve to ourselves the property in goods, papers and documents and in all user-rights under copyright law until the customer has completely paid the remuneration which is due to us in respect of the order. If, at the time of supply, other claims still exist against the customer, apart from the claim which is owed to us in respect of the relevant order, then we reserve to ourselves the property and all user rights under copyright law in the goods delivered by us until all claims as specified above are settled (extended reservation of title). Insofar as the effectiveness of (2) this reservation of title is dependent on its registration, for example in public registers in the country of the customer, then we are entitled, and are so authorised by the customer, to effect such registration at the cost of the customer. The customer is obliged, on its part, to provide all such cooperation as is necessary for the purpose of such registration free of charge.

#### **VII. Duties of the customer to cooperate with us**

- (1) It is the duty of the customer to support us and our members of staff to a fair and reasonable and usual extent. Insofar as project-related work has to be done or services have to be performed by our members of staff in the business premises of the customer, then, if we so request, the support which is due from the customer can also include the provision of workspaces and workplace facilities with PCs and telephones; the costs thereof shall be borne by the customer.
- (2) The customer shall make available to us the materials, information and data which we require in order to perform our work. Data and data-carriers must be technically faultless. If there are any special statutory- or office-safety regulations which are applicable in the business of the customer, then the customer must indicate these to us before our work is performed.

- (3) The customer has no right to give our members of staff instructions regarding the specific form of performance of their work, except insofar as instructions are necessary in connection with safety requirements and internal company regulations which are applicable in the customer's business. Instructions on individual points regarding the work to be done by us or regarding the services to be performed by us are not to be given to the members of staff who are entrusted with the particular job, but to those contact persons who are nominated by us for the project. Decisions regarding the measures which are necessary are always taken by us on our own responsibility and within the framework of our contractual duties of performance.

#### **VIII. Liability**

- (1) If we provide documents, opinions, documentations or comparable services to the customer, then the customer must examine them for obvious defects and shall notify such defects without undue delay. Non-obvious defects are also to be notified without undue delay after recognition. If the customer fails to send off the notice of defect without undue delay, but at the latest within 7 days after recognition, then our performance shall be deemed to be approved, even in case of defects.
- (2) The result of our consultation and / or the content of the documents and documentation provided by us is based upon the status quo of the applicable rules and regulations at the time of processing the relevant order. Any changes of such applicable rules and regulations must be monitored by the customer. We are not obliged to inform the customer about any changes that may occur after the completion of our order.
- (3) If the act of performance or the act of supply which is due from us is not performed at all or is performed late or defective, then, for a period of one year from the statutory commencement of limitation the customer shall be entitled to demand for damages. However, after the period of one year, we shall be entitled to refuse subsequent performance and the customer shall have no rights for reduction in price, withdrawal from the contract or damages. This limitation period does not apply to claims for damages other than those due to refusal of subsequent performance or in the event of fraudulent concealment of a defect.
- (4) The customer shall only be entitled to claim for damages:
  1. if damages are based on
    - an intentional or grossly negligent breach of non-essential contractual duties by us or
    - by one of our statutory representatives, senior members of staff or assistants in performance

(essential contractual duties - cardinal obligations - are understood as duties which have to be observed to allow correct fulfilment of the contract and in respect to which the customer can trust in observation of those duties).

2. if damages are based on an intentional or negligent breach of essential contractual duties (cardinal obligations) by us or by one of our statutory representatives, senior members of staff or assistants in performance.
3. if damages are based on an intentional or negligent breach of our other contractual duties (supplementary or additional obligations).
4. If damages fall within the protective scope of a guarantee (warranty) given by us or within the protective scope of a guarantee of condition or durability.
- (5) In the event that a breach of an essential contractual obligation is caused by simple negligence, liability is limited to the loss which is typically to be expected in applying reasonable care.
- (6) Claims for damages against us which are based on a breach of an essential contractual obligation caused by simple negligence, shall become time-barred one year from commencement of statutory period of limitation. This shall not be applicable in respect of losses arising from injury to life, body, or health.
- (7) Claims for damages against us which are based on mandatory statutory liability, for example under the Product Liability Act, and claims for damages because of injury to life, body or health shall be unaffected by the provisions in this section VIII and shall exist as provided by law.
- (8) If instructions are given to a third party or if a third party is involved in the preliminary stage of the contractual relationship or for the purpose of its performance, then the abovementioned limitations regarding guarantees and liability shall also apply for the benefit of the third party.

#### **IX. Special provisions for contracts under which a successful result is owed**

- (1) If the achievement of a specific successful outcome is owed by us, as for example the production of a particular item of work or the preparation of specific documentation, then, after we have given the relevant notice of completion, the customer is obliged to declare in writing by way of acceptance that we have performed our contractual obligations.
- (2) If acceptance is delayed without blame on our part, then, after the expiry of seven calendar days from the time of the notice of completion, our act of performance shall be deemed to be accepted.

**X. Special provisions for contracts for the provision of a service**

- (1) A contract for the provision of a service can only be terminated for a serious reason.
- (2) A serious reason shall be deemed to exist, in particular, if
  - obligations, in particular duties of cooperation, which are to be performed within contractually-agreed time-periods, have not been performed, despite the fact that a time-period for performance has been set drawing attention to the existing right of termination;
  - there is a breach of duties to maintain secrecy;
  - significant parts of the contract are not performed at all or, despite the fact that an additional time-period for performance has been set, are not performed in full.
- (3) Termination must be made in writing or in text form for example via e-mail to the address info@schrack-partner.eu.
- (4) If we terminate the contract for an important reason without notice, then the customer shall be obliged to pay for remuneration in respect to the part which has been already provided by us by the time of termination. This also applies if, as a result of the termination, the customer has no use or interest in the performance. In the event that the remuneration was agreed as a lump sum payment, of an agreed remuneration package, the customer shall, in case of every termination be entitled to provide evidence that the lump sum is unreasonably high.

**XI. Confidentiality**

- (1) During the term of the contract, the parties undertake to keep confidential all received information, including but not limited to such information which becomes accessible to the parties during carrying out their contractual obligations or which is marked as confidential or which recognizably contains business secrets. Unless prior written consent is obtained neither party shall be entitled to record such information or disclose it to third parties or use it in any other way than for the purpose of the conducted contract. The obligation to keep confidential all information received hereunder shall terminate five years after the expiration of the conducted contract.
- (2) Notwithstanding clause XI. (1) the obligation to keep confidential all information shall not or no longer apply to information for which evidence can be furnished that it:
  - had already been known to the receiving party prior to such disclosure or was, after such disclosure, lawfully obtained from a third party without the obligation to keep it confidential, or

- has been or is being developed by the receiving party independent of any such information disclosed by the other party, or
- was publicly known by the time of disclosure by one party or, through no wrongful act of the receiving party, became publicly known thereafter, or
- had to be disclosed on the basis of statutory obligations or an official or court order.

In the latter case, the disclosing party shall immediately notify the other party prior to such disclosure. Any further statutory obligations regarding confidentiality shall remain unaffected. If a contracting party refers to one of the above exceptions subject to clause XI. (2) such party shall be obliged to provide evidence thereof.

**XII. Miscellaneous**

- (1) The place of performance and the exclusive court of jurisdiction for all disputes between the parties arising out of the contractual relationship is Reutlingen. As an exemption hereto, we are also entitled to proceed against the customer at the customer's general legal venue.
- (2) The customer is aware that data in connection with the transaction and also personal data (relating to the customer) will be electronically stored and that, consistent with business needs, such information must also be processed and transmitted to third parties. The customer agrees to this storage and processing of data.
- (3) If a provision of these General Terms and Conditions should be or become ineffective or if, within the framework of other agreements, a provision hereof should be or become ineffective, then the effectiveness of all other provisions or agreements shall not be affected thereby.
- (4) The contractual and other legal relations between ourselves and our customers are governed by German law, to the exclusion of the UN Convention on Contracts for the International Sale of Goods (CISG) dated 11<sup>th</sup> April 1980.

**B. Specific provisions for trainings, seminars and in-house seminars**

**I. Scope of application**

The hereinafter contained special conditions for trainings, seminars and in-house seminars apply in addition to the provisions as set out in section A.

**II. Scope of training, documents for training**

- (1) The scope of training is determined by the contractual agreement based on our offer or order confirmation.
- (2) Termination must be made in writing or in text form for example via e-mail to the address info@schrack-partner.eu.

- (3) We reserve all rights to our seminar papers, including reprint, duplication, editing and translation. The dissemination or storage of the seminar papers, either in parts or in total, is prohibited. In the event we use software for our seminars, the participants in the seminar are obliged to protect the copyrights of the software and shall not copy, reproduce or distribute the software.

**III. Participants in training courses**

- (1) The maximum number of persons to participate in a training course will be determined by us in consent with the customer.
- (2) Training will be provided solely for the customer and its employees at the customer's premises. If it is desired that additional persons participate in the training, then prior, individual agreements between us and the customer have to be reached.

**IV. Termination, reschedule of training**

- (1) An agreed and scheduled training course can only be terminated for serious reasons.
- (2) Our training courses will be provided by an in-house or external trainer. Details are set out in our offer or order confirmation. In the event a trainer fails to attend the agreed and scheduled training course for reasons which are beyond our control, then, we shall be entitled to appoint at our discretion a suitable substitute in-house or external trainer or reschedule a new training-course in consent with the customer.

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