

## **General Terms and Conditions of Contract for analytical tests of vivo Science GmbH and its Subsidiaries ("vivo Science")**

### **0. Preamble**

vivo Science GmbH is an internationally operating biotechnology company. Its business purpose is the implementation of quality control analysis of biopharmaceutical, chemical or related products. In the process, vivo Science conducts test development, test validation and testing for quality control in connection with the development of pharmaceutical products as well as with the approval and manufacturing processes. vivo Science's test equipment is certified in accordance with Good Laboratory Practice (GLP) or Good Manufacturing Practice (GMP) guidelines.

### **1. Subject matter**

These General Terms and Conditions of Contract determine the responsibilities of the parties. The contract implementation and the organization of vivo Science's pharmaceutical analysis division are carried out in accordance with the EU -Good Manufacturing Practice- Directives and the US-Code 21 CFR 210/211 or with Good Laboratory Practice (GLP) pursuant to Annex 1 of the German Chemicals Act and the OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring, insofar as nothing to the contrary has been agreed upon.

### **2. Scope**

These General Terms and Conditions of Contract shall apply to all deliveries and performances rendered by vivo Science within the scope of the respective order. These General Terms and Conditions of Contract shall become part of the contract upon the placing of an order with vivo Science, though at the latest when the order is confirmed by vivo Science. These General Terms and Conditions of Contract shall also apply in the event vivo Science subject to the provisions within section 5.4 below awards part of its duties to partner laboratories as subcontractors for the purpose of fulfilling the contract. The customer's general terms and conditions of business shall only apply in the event vivo Science has explicitly agreed to such general terms and conditions in writing.

### **3. Offers and Order Confirmation; Written Form**

vivo Science's offers are subject to confirmation (invitatio ad offerendum). An offer shall first be considered as accepted when it is available in written form and has been confirmed in writing by vivo Science. In determining the scope of vivo Science's contractual obligations solely the written order confirmation shall be decisive, unless vivo Science submits a binding offer with an acceptance deadline and the customer accepts such offer in writing prior to such deadline. Any collateral agreements must be confirmed in writing by vivo Science. The offers and the documents accompanying the offers such as cost estimates, calculations, expert opinions, reports, etc. shall remain the property of vivo Science and are to be returned upon request.

### **4. Duties of the Customer**

- 4.1. For the purpose of tests and -if necessary- repetition of tests the customer shall provide vivo Science free of charge with an adequate number of test samples together with a Test Item Submission Form in which pursuant to guidelines of vivo Science all information relevant for the tests, particularly Acceptance Limits (Specifications), is listed. A Specification according to these General Terms and Conditions of Contract is a set of criteria the test specimen must meet for the respective batch to be released and ready for further use. The single criterion forms an Acceptance Limit. The customer shall ensure that all test samples and materials provided correspond to the characteristics laid down in the Test Item Submission Form. In the event the customer does not comply with its duty to cooperate in full or in due time, vivo Science's performance obligation shall accordingly cease to exist or be delayed without vivo Science's being in delay or default of performance.
- 4.2. The customer shall advise vivo Science of the purpose of the test, particularly of whether the supervision duties in accordance with the Medicines Act or other international approval standards are to be adhered to.
- 4.3. The customer shall advise in its order of all characteristics of the test substances that could represent a risk for the personnel, equipment, premises, test substance itself or for other materials (e.g., explosive, infectious, carcinogenic, refrigeration required). The customer shall be liable for any damage to property or bodily injury occurring as the result of a failure to inform of the nature of its test substances. Any liability of vivo Science, its legal representatives, employees or vicarious agents resulting from such risks is hereby excluded, unless vivo Science, its legal representatives, employees or vicarious agents can be accused of intent or gross negligence or unless injuries to life, body or health have occurred culpably.

- 4.4. The proper transport of test specimens shall be the responsibility of the customer. The Customer shall bear the costs for the transport (free delivery to destination).

## 5. Duties of vivo Science

- 5.1. vivo Science shall carry out the analysis orders and test orders according to the agreed information relevant to the test and pursuant to the agreements and, upon conclusion, shall provide the customer with the results in the form of a Certificate of Analysis or a Final Report in English or German language, as mutually has been agreed upon. In case the customer wishes to receive a draft report and does not raise an objection within a period of 14 calendar days after its receipt and although the period was pointed out to the customer at delivery the draft report will be treated as acknowledged and the final report will be finished by vivo Science.

The customer shall be responsible for the conclusive analysis of the test results, particularly for the release of the batches. vivo Science shall operate in accordance with Standard Operating Procedures (SOP) that are to be cleared in advance by the customer. vivo Science shall not be obligated to turn over the laboratory methods it has developed (Standard Operating Procedure) to the customer.

The study result shall be compared with the Acceptance Limit/Specification. If the result does not meet the Acceptance Limit/Specification, it is called an "out-of-specification result" ("OOS result"). In this case vivo Science shall conduct a failure investigation. If the result cannot be invalidated as a result of this investigation (e.g. mistake in laboratory) vivo Science shall inform the customer on this still unconfirmed OOS result. Further action must be determined between vivo Science and the customer in writing. Normally, the respective standard operating procedure established at vivo Science for such investigation shall be applied.

- 5.2. vivo Science shall be responsible for ensuring that the test specimens are properly stored and for regular inspection of the test specimen storage facilities for the term of the contractual obligations. In the event nothing has been specified to the contrary, any non-used test substances shall be preserved by vivo Science after acknowledgement for a reasonable period, usually 6 weeks, for possible subsequent tests and then destroyed. Excess specimens shall be given back to the customer upon special request. The shipment shall in such case be made at customer's costs. The risk of transport shall pass to the customer as soon as the deliverables have been handed over to the commissioned transport company. The customer shall store reserve specimens.
- 5.3. The written documents, especially the originals of all raw data, shall be archived by vivo Science for 2 years (GMP) or 15 years (GLP). After the expiration of this period, further action shall be coordinated between vivo Science and the customer. However, after the Certificate of Analysis or a Final Report has been delivered, the customer shall not be entitled to compensation for damage based on a loss of data occurring as a result of unforeseen circumstances, unless such loss of data resulted due to intent or gross negligence on the part of vivo Science.
- 5.4. vivo Science shall place subcontracts for full or partial performances only after prior written consent of the customer. In such cases, vivo Science shall obligate the subcontractor to maintain secrecy regarding the information and data received from the customer. § 664 S. 2 of the Civil Code shall apply accordingly. For the specific conditions for the transport of the test specimens to the subcontractors the provisions in the written order apply.

## 6. Deviations

In the terms of this Agreement, "deviations" shall exist if a work stage proceeds in an unplanned fashion contrary to written instructions. A deviation shall be considered "critical" if an effect on the analytical result cannot be ruled out. Any deviation appearing during a test shall be assessed by vivo Science based on the aforementioned criteria. Only if a deviation is classified as "critical", the further procedure is agreed upon by vivo Science and the customer and documented in writing. In any case the customer shall be informed about all deviations in the Certificate of Analysis or the Final Report.

## 7. Change Control

In the terms of this Agreement, a "change" shall exist if a work stage proceeds in a planned fashion contrary to written instructions. A change shall be designated as "critical" if an effect on the analytical result cannot be ruled out. If a change must be made, the change shall be assessed by vivo Science before it is carried out. Only if a change is classified as critical the customer must approve the change before it is carried out. Approval by fax shall be sufficient in urgent events. In any case the customer shall be informed about all changes in the Certificate of Analysis or the Final Report.

## 8. Audits

- 8.1. Following prior arrangement of dates with vivo Science, the customer shall be entitled to subject those vivo Science facilities used for work ordered by the customer to routine audits or to carry out audits for

specific immediate reasons (e.g., because of unusual observations or occurrences).

The customer shall be entitled to be present at the single procedures and to review relevant documentation. vivo Science shall provide the customer with necessary assistance and the required information.

- 8.2. At customer's request and cost, vivo Science shall provide access to its facilities to representatives of the supervisory or authorization authorities responsible for the customer in relation to GMP or GLP monitoring following prior arrangement of dates. vivo Science shall give said official representatives any support and information required.

## 9. Delivery / Appointed Dates

The appointed dates for the services to be rendered by vivo Science shall be set jointly in the written order. Appointed dates shall only be deemed fixed dates when they have been expressly agreed upon in writing as binding. In the event non-adherence to a binding date or a binding time limit is attributable to an action or lack of action of the customer for which vivo Science is not responsible, the date or the time limit shall be extended by a reasonable time span. Any reduction of the fee, payment of a contractual penalty or other damage compensation claims against vivo Science shall be excluded in such cases.

Insofar as non-adherence to an appointed date that has been agreed upon in writing as binding or to a binding time limit is the fault of vivo Science, the customer shall set a reasonable grace period for vivo Science in writing. After expiration of such grace period, the customer may demand lump-sum compensation for delayed performance as a contractual penalty. Such lump-sum compensation shall amount to 0.5% of the value of the order at the time of expiration of the grace period for each full week of delay. The compensation for delayed performance shall be limited to 5% of the value of the order, or EUR 25,000.00 at the most. Payment of compensation for delayed performance shall discharge all claims for damage compensation due to delay. vivo Science shall not assume any further liability in the case of delay.

## 10. Prices and Payment Conditions

Prices for consulting services shall correspond with expenditure on the basis of the rates agreed upon at the time of conclusion of the contract. Provided nothing has been expressly specified to the contrary, vivo Science shall invoice the ancillary costs that it incurs (expenses, including travel expenses, etc.) in addition to the daily fees or other remuneration.

In the event delivery first occurs more than four months after the conclusion of the contract -based on an agreement or due to circumstances for which the customer is responsible-, and in the event vivo Science's laboratory costs have increased in the meantime, vivo Science shall be entitled to invoice the customer for the increased costs or for the prices applicable on the date of delivery.

Invoices shall be due 14 days after the date of invoice without deduction.

In the event the customer falls into arrears, vivo Science shall be entitled -without sending a special reminder- to charge interest of 8 percentage points over the current base lending rate (§ 247 of the Civil Code) starting on the day following the due date (§§ 280, 286 of the Civil Code). In the event the customer does not meet its payment obligations, stops payment or in the event insolvency proceedings are initiated on the customer's assets, all of vivo Science's claims from the business relation shall be due immediately. In such case, vivo Science shall be entitled to withhold delivery until all claims have been met. This shall not be considered as rescission of the contract.

The customer may only set off undisputed or legally established counterclaims against claims of vivo Science. Any right of retention is hereby excluded, particularly in the event the customer asserts warranty claims that have not yet been reviewed and acknowledged by vivo Science.

## 11. Shipping

The deliveries and performances shall be shipped by vivo Science at the cost and at the risk of the customer. Packing shall occur in the form customary in the trade under consideration of the climatic conditions in Western and Central Europe. The transport risk shall pass over to the customer as soon as the subject matter of the contract has been transferred to the transport company commissioned.

## 12. Reservation of Ownership

vivo Science shall retain ownership and all rights of use to the deliveries and performances rendered, including the Certificates of Analysis or Final Reports, expert opinions, laboratory findings and other documents, until the customer has settled all claims from the business relation in full. In the event the customer falls into arrears with payments, vivo Science shall be entitled to withhold any material received from the customer and to reclaim and take into custody the deliveries and performances delivered to the customer until payment has been made in full. This shall not be considered as rescission of the contract.

### 13. Industrial Property Rights

- 13.1. vivo Science is and shall remain the holder of its industrial property rights and copyrights existing upon the date of conclusion hereof ("Prior Copyrights"). vivo Science shall automatically inform the customer of the existence of industrial property rights if such rights are applicable to the tests. In the event any Prior Copyrights of vivo Science are required in order to exploit the results of the contractual deliveries, the customer shall receive a non-exclusive license limited in time and place free of charge.
- 13.2. Legal ownership of all results which are obtained by vivo Science within the framework hereof and which are included in the Certificate of Analysis or in the Final Report shall pass to the customer when obtained.

### 14. Force Majeure

Circumstances of force majeure such as accident, illness, fire, unusual personnel shortages, power breakdown and other supply bottlenecks, strikes, serious defects in the testing apparatus, changes in health and genetic status of biologic test systems that are beyond vivo's reasonable control or non-delivery of laboratory materials shall release vivo Science from adherence to the agreed-upon delivery dates, insofar as vivo Science is not responsible for such circumstances. In the event of continuous force majeure, vivo Science shall be entitled to rescind the contract without the customer being able to assert any damage compensation claims based upon such rescission.

### 15. Warranty and Damage Compensation

- 15.1. vivo Science's performances shall be considered as accepted in the event no lack of readiness for acceptance has been reported within 10 days of receipt by the customer.
- 15.2. The warranty period shall comprise one year from the delivery of the Certificate of Analysis or the Final Report. The warranty shall extend to performance of the contract while exercising scientific and customary care as well as to the potentially warranted characteristics of the performances to be delivered. vivo Science shall not assume any warranty or liability for test results that are erroneous due to the fact that the samples and materials provided by the customer did not have the characteristics specified by the customer. The results delivered to the customer by vivo Science shall be based exclusively on the purpose stipulated in the contract. No warranty shall be assumed for the use of any results of the test series or any other performances of vivo Science for other purposes and conclusions outside of the contract.
- 15.3. In the event of justified complaints, the statutory claims in accordance with § 634 of the Civil Code shall apply. However, notice of defects shall be given to vivo Science without delay, at the latest within the warranty period pursuant to section 15.2 above. Notice of defects shall include a description of the defect with utmost details. The customer shall be excluded from any claim based on breach of duty due to malfeasance (Pflichtverletzung wegen Schlechtleistung) if the notice is not given in due time or form.
- 15.4. vivo Science shall be liable unlimited for its own intentional or grossly negligent breach of duty and for intentional or grossly negligent breach of duty by its legal representatives or vicarious agents as well as for the breach of essential contractual duties (wesentliche Vertragspflichten) and in case of impossibility of performance and material breach of duty for which vivo Science is responsible. vivo Science shall also be liable unlimited in case of injuries to life, body or health also by its legal representatives or vicarious agents. The same applies to the extent vivo Science has provided guarantees for its performance or the existence of a performance result and in case of breach of other duties pursuant to § 241 sect. 2 of the Civil Code, provided that the performance of vivo Science is no longer reasonable for the customer.

In other cases vivo Science shall not be liable in case of slight negligence for any claims for compensation based on culpable breach of duties within the scope of the contractual relationship -irrespective of the legal basis-.

In cases of liability as mentioned above and liability without fault, particularly in case of initial frustration (anfängliche Unmöglichkeit) and defects of title, vivo Science shall be liable only for typical and foreseeable damages.

Unless liability cannot be based on sentence 1 vivo Science's liability for each damage event shall be limited to the indemnification covered by the commercial third party liability insurance held by vivo Science. vivo Science shall be obligated to deliver a copy of the insurance policy to the customer on first demand. The insurance protection provides coverage for bodily injury and property damage up to EUR 2.500.000 for each damage event and for financial loss up to EUR 500.000 for each damage event. This limitation does not apply as far as vivo Science's actions do not lie against the insurance company (exclusion of risks etc.). In this case vivo Science's liability is limited to the amount of EUR 25.000 for each damage event.

A single "damage event" is understood as the sum of damage claims of all claimants which arise from a single, definable, chronologically connected and insofar integrative performance.

Any further liability is excluded.

The aforementioned limitations or exclusions of liability, other than the liability pursuant to sentence 1 above, also apply to the same extent for the benefit of executive and non-executive staff, other vicarious agents and subcontractors of vivo Science.

No reversal of the burden of proof shall be associated with the aforementioned provisions.

## 16. Term, Rescission and Consequences of Rescission

- 16.1. The Agreement can be terminated any time without notice for good cause. "Good cause" shall exist particularly in the event: of intentional, grievous or persistent breaches of any provision of the Agreement which make it appear unreasonable to continue this Agreement with due regard to all circumstances of the specific case; of the initiation of bankruptcy or composition proceedings concerning the assets of either party or the dismissal of such proceedings due to a lack of assets; the payment of performances rendered by vivo Science is delayed twice for more than four weeks
- 16.2. Following the termination hereof, both parties shall no longer use the technical information and documentation, which each received from the other party and each shall return it to the other party; however, either Party may retain a copy of said technical information and documentation for purpose of evidence.

## 17. Confidentiality

vivo Science and the customer shall be mutually obligated to treat the technical information, the documentation of the tests as well as the Certificates of Analysis or the Final Reports received from the other party as confidential, to use such information, documentation and certificates or reports only for their own purposes in accordance with the contract and to only allow access to such information, documentation and certificates or reports to those of their employees and subcontractors which must be familiar with the information, documentation and certificates or reports for testing purposes. The transfer to third parties shall only be permitted in cases in which this ensues from the purpose of the tests, for instance to public authorities in the case of drug approval procedures. The duty to maintain secrecy shall also apply after termination of the contract. The receiving party shall be entitled to disclose technical information to the extent necessary to the supervisory authorities or courts. As far as it is possible (e.g. not with unheralded ad hoc inspection) the receiving party in such cases shall inform the other party in writing prior to disclosure as to which extent information and documentation will be disclosed to which institution.

## 18. Data Protection

vivo Science shall be entitled to process and store data of the customer (in particular company name, address, contact person, telephone and fax number, banking account) in its computing system and to forward it to third persons, as far as it is necessary and/or appropriate within the scope of the delivery / performance of this contract.

## 19. Place of Jurisdiction and Place of Performance, Applicable Law, Final Provisions

- 19.1. Duesseldorf shall be the exclusive place of jurisdiction and place of performance for all mutual obligations based on contracts between vivo Science and the customer. German law shall prevail.
- 19.2. Any modifications to the contract or collateral agreements must be made in writing. This written form requirement for its part may only be waived by written declaration of vivo Science and the customer.
- 19.3. The customer will be informed about any changes of this General Terms and Conditions of Contract in writing. They are deemed agreed by the customer if the customer does not object in time in writing. vivo Science shall point out this legal consequence together with the information about the change. The customer shall send its objection to vivo Science within four weeks after receipt of the information of change.
- 19.4. In the event any individual provisions hereof are or become invalid, all the remaining provisions shall remain valid. Both parties shall then agree upon valid provisions such that the purpose of the invalid provisions can be fulfilled as nearly as possible.

Gronau, 02 November 2020