

## **General Terms and Conditions of the Aurigon Group (ATRC Aurigon Ltd and Aurigon GmbH)**

**This version is valid from 14 February 2020 and replaces all previous versions.**

### **1. Scope of Validity**

(1) The terms and conditions herein shall apply to all services and offers from ATRC Aurigon Ltd and Aurigon GmbH (hereafter the name "AURIGON" covers both companies where applicable). The terms and conditions are an integral part of all contracts that are concluded between us and our contract partners (hereafter named "PARTNER") for our services. This is valid for orders confirmed by telephone, fax or email.

(2) Should a Master Service Agreement for preclinical development of a medicinal substance or a galenics preparation be concluded with PARTNER or a cooperation partner, the conditions in the master service agreement prevail when the conditions differ from those in these general terms and conditions. The validity of all other points in the general terms and conditions remain unchanged.

(3) Specific business terms and conditions that differ from these general terms and conditions of business agreed upon with PARTNER or a third party will remain unbinding unless they are specifically agreed upon in writing. A specific acknowledgement of other general terms and conditions of business is especially not given when another document is referred to when it contains or refers to the general terms and conditions of PARTNER or of a third party.

(4) These terms and conditions apply to all future business relations with PARTNER, as well as when they are not separately agreed upon. They replace any previous general terms and conditions that were in place with PARTNER.

### **2. Object of Agreement, Termination**

(1) The subject matter of the development projects and the exact scope of the services to be provided by or to AURIGON. are determined in the confirmation of order, descriptions of services, experimental plans, trial plans or study plans.

(2) Before the execution of the services agreed upon, the document(s) mentioned in §2 point (1), must be confirmed in writing to ATRC Aurigon Ltd or Aurigon GmbH. and by a person authorised from PARTNER, vis-à-vis ATRC Aurigon Ltd or Aurigon GmbH.

(3) An extraordinary termination of the contract according to § 626 BGB due to important breach of duty is reserved. Precondition for the legitimacy of the termination is that the party having caused the damages be entitled to a reasonable time period to discontinue the violation of the contract, or to reverse the consequences thereof. This does not apply, when the violation of the contract is so serious that further maintenance of the contract would be at any rate unacceptable. The termination must be given in writing and state the reason. The date of termination will be the date that the letter of termination is received by post by the addressee.

(4) In the case where regulations of any provisions of these general terms of business exceed the term of the contract in time, these general terms and conditions remain valid, even after the term of the contract has been exceeded or expired. This specifically applies to § 8.

### **3. Delivery Times for Services**

(1) Respites and time lines for the implementation of the services, including the final date and those for each phase are detailed in the pertaining confirmations of orders, descriptions of services, experimental plans, trial plans or study plans. They are unbinding and only approximate, unless binding respites and deadlines are explicitly agreed upon in writing, but material changes from the approximations must be agreed upon in writing.

(2) If circumstances beyond the reasonable control of AURIGON, hinder the services or render the completion of services impossible, AURIGON reserves the right to withdraw from the contract, when these circumstances are not of a temporary nature. When the circumstances are of a temporary nature, then the delivery time will be extended by the duration of these circumstances plus an adequate time period.

(3) If the acceptance of the services is unreasonable for PARTNER due to circumstances cited in §3 Para. 2, PARTNER may withdraw from the contract by immediate notification to ATRC Aurigon Ltd. or Aurigon GmbH in writing. In this case, damage claims against AURIGON are excluded.

### **4. Payment**

(1) The payment schedule for services will be made according to the regulations agreed upon by individual contracts, service descriptions or quotations.

(2) Unless nothing else is agreed - referred to the §4. Para. 1- , the §4 3-8 shall apply.

(3) If applicable projects are divided as follows:

- First milestone is the placement of order and/or starting of project activities (for example preparing study plan, ordering study materials, obtaining approvals etc.)
- Second milestone is the end of in-life phase (exclusive eventual recovery groups)
- Third milestone is the delivery of draft report to prepare the final report (Draft of the final report) or delivery of the tabulated report.
- Fourth milestone is the delivery of the final report. (Final report). If no remark or request of change is submitted by PARTNER within 6 weeks after delivery of the draft report, the draft report will be finalized and a final report will be issued.

(4) Invoice will be issued after the reaching the respective milestone.

(5) In general, the first milestone is calculated as 40 % of the project volume, the second milestone is calculated as 50 % of the project volume and the third milestone is calculated as 10 % of the project volume. In general, no invoice is issued when reaching the fourth milestone.

(6) Payments are due within 14 days after receipt of invoice.

(7) Complaints and claims referring to invoices can be accepted within 2 weeks after receipt of invoice.

(8) After ordering of the study, the appropriate resources will be reserved for the project. Any subsequent alteration to the study outline/assumptions, delay/postponement or cancellation of the study may be

subject to additional charges that will be invoiced separately. The final study price will be calculated on the authorized definitive study protocol.

(9) In case of the delayed payment (for at least 2 weeks after the due date of the respective instalment/invoice), AURIGON reserves the right to suspend any activities on this specific project. This especially applies for cases where PARTNER does not inform AURIGON about a presumed delay before the due date.

## **5. Property Rights**

(1) All material, data (such as study records, study protocols, study plans, reports), rights to data and research results of ATRC Aurigon Ltd. shall remain the sole and untransferable property of AURIGON and shall not be transferred to anyone and shall be returned or destroyed at AURIGON's request.

(2) All material, data (such as study records, study protocols, study plans, reports), rights to project-related data and research results of PARTNER transferred to AURIGON shall remain the sole and untransferable property of PARTNER and shall not be transferred to anyone and shall be returned or destroyed at PARTNER's request.

(3) All project-related material, data (such as study records, study protocols, study plans, reports), rights to project-related data and research results shall be fully owned by PARTNER upon full payment of the remuneration as specified in the valid individual study contract.

## **6. Transport and Transfer of Perils**

(1) The risk for material or samples sent lies with PARTNER from the moment of hand-over to a courier or a transport company. This shall be the case regardless of which party pays the transport costs and from where and to whom the samples are shipped.

(2) All shipping is provided by a third-party vendor and is not considered to be the part of services provided by AURIGON. Shipping costs included into the current proposal are valid if the shipping is performed by a company chosen by AURIGON (e.g. DHL, FedEx or EasyGot). The PARTNER has the possibility to choose a different courier, but the potential increase of shipping costs resulted by PARTNER's requirements will be charged by ATRC Aurigon Ltd or Aurigon GmbH.

## **7. Reporting and report formats**

- [1] The "**tabulated report**" only consists of a
- a cover sheet listing the basic study information and signatures
  - copy of the signed study plan
  - list of deviations from study plan (if any)
  - the tabulated study data.

From these reports no draft report versions are issued.

- [2] The "**short report**" contains
- a cover sheet listing the basic study information and signatures
  - a brief description and design of the study
  - conclusion, short summary of results and a list of abbreviations,
  - list of deviations from study plan (if any)
  - the tabulated study data.

- [3] The “**full report**” is the most detailed version of reporting at AURIGON, including
- a cover sheet listing the basic study information and signatures
  - a detailed description and design of the study
  - detailed descriptions and interpretation of results including conclusion, summary
  - a list of abbreviations,
  - amendments and a list of deviations from the study plan (if any)
  - the tabulated study data.
  - additional information (e.g. about the test item) as addendi.
- Studies under GLP require the “full report”.
- [4] After delivery of short or full draft report (excluding tabulated report) PARTNER gets one review occasion to send queries to AURIGON. Any further queries will be billed on time and material basis. If no queries of the PARTNER occur within 6 weeks after delivery of draft and at least one week after a proper notice sent to the PARTNER via email, Aurigon is entitled to finalize the report.

## **8. Conductance of bioanalytics on external site**

- (1) If bioanalytics is not performed by AURIGON and bioanalytical report is not received within 6 weeks after delivery of samples to the analytical laboratory contracted by the PARTNER, the draft or final report will be sent to the PARTNER without the bioanalytical data or evaluation thereof.
- (2) For all GLP sample measurements order of the corresponding method transfer/development, validation and stability testing is required. If formulation- or bioanalytics is not performed by AURIGON and the outsourcing is performed on PARTNER's request, GLP studies are considered to be multi-site studies and a multi-site management fee will be charged (e.g. EUR 1.350,00 per external test site).
- (3) If any other GLP-compliant part of a GLP study is performed on an external site on PARTNER's request (such as histology, histopathological evaluation or peer review), the study is considered to be multi-site study and a multi-site management fee will be charged (e.g. EUR 1.350,00 per external test site).

## **9. Warranty and Liability**

- (1) Contract for Work and Labour:

The services are only subjected to law of contract for work and labour if explicitly the creation of a product defined in advance is agreed upon.

- (2) Liability Limitation:

In so far as hereinafter nothing else is specified, further claims of PARTNER are excluded, regardless of the legal grounds on which they are based. In particular, AURIGON is not liable for PARTNER's profit losses or other financial losses. This liability limitation for damages will not apply for contracts for work and labour if the damages are caused by the absence of a property that AURIGON has guaranteed. If AURIGON neglects a cardinal obligation or an essential contractual duty, the liability is limited to the obligation of replacement and the predictable damages.

AURIGON takes no liability for damages for breach of the rules in §11, in particular concerning accidents or damages to property or physical injury to PARTNER's personnel during a visit to AURIGON's premises.

The time periods stated in §9 1) and 2) are limitations; they are not valid for claims resulting from unlawful acts.

(3) PARTNER's Liability:

Damages to AURIGON's premises, facilities, machines that are caused by the acts of the PARTNER's employees will be repaired or replaced by PARTNER.

**10. Secrecy, access to data, information and documents**

(1) PARTNER will forward to AURIGON in a timely manner, all information and documents that are necessary for the implementation of the service. They are to be used exclusively for the service. At the end of the service, all tangible and intangible items must be returned to PARTNER.

(2) PARTNER and AURIGON will maintain confidentiality over business or company secrets, technical information, in particular intentions, experiences, expertise and designs, as well as financial information such as calculation basis, costs and financial structures that will be entrusted to either party or that become known during the collaboration. They will be used exclusively for the implementation of the services and not communicated to any third party, nor used in PARTNER's own interest. These obligations will survive for the following ten (10) years after the end of the contractual period. These confidentiality obligations are also applicable when dealing with companies that are affiliates of PARTNER. These obligations do not apply to information:

- a. which was demonstrably already known prior to signature of contract or placing the order, or which was generally known prior to signature of contract or placing the order, or which became generally known after signature of the contract through no breach of the confidentiality obligations by one of the contracting parties
- b. which is demonstrably lawfully acquired from third parties who have a right to disclose such information;
- c. which was already known to the contracting parties at the time of disclosure

(3) Data and research results obtained during the implementation of services shall be considered as business/work secrets and handled as such. Data and research results obtained by AURIGON which are obtained independently and have no reference to information or materials received from PARTNER or the project shall be handled as AURIGON's business/work secrets.

(4) Records, documents and data, which are required to remain with AURIGON due to legal requirements or guidelines (such as Chemical law, GLP, ICH, EMEA, OECD) are excluded from the rules stated in § 10 Para. 1.

(5) Raw data and documents will be retained electronically by ATRC Aurigon Ltd for 5 or 15 years for non-GLP and GLP studies, respectively, unless otherwise agreed in the Study Plan. Physical archiving of documents and samples of GLP studies will be performed according to GLP regulations. The archiving period can be extended at an additional charge.

**11. Animal housing, work procedures in the establishments of ATRC Aurigon Ltd.**

(1) PARTNER and his personnel recognize ATRC Aurigon Ltd.'s regulations concerning occupational health and safety, animal protection and hygiene. Within the establishments of ATRC Aurigon Ltd., PARTNER's personnel will follow the directives of ATRC Aurigon Ltd.'s personnel concerning dispositions for work procedures for animal protection or safety and hygiene.

(2) PARTNER's personnel may not enter ATRC Aurigon Ltd.'s facilities or laboratories without the prior knowledge of the responsible representative of ATRC Aurigon Ltd., nor leave the area agreed upon, once entered.

(3) Only PARTNER's personnel who have been previously identified to ATRC Aurigon Ltd. by name, and who have been briefed on ATRC Aurigon Ltd.'s rules and SOP's are allowed to enter the facilities or laboratories.

(4) When entering ATRC Aurigon Ltd.'s facilities or laboratories PARTNER's personnel is responsible and ensures, that all pertaining regulations are adhered to (e.g. regulations concerning occupational safety, genetic engineering law, radiation safety) for the protection of the personnel and facilities of both the PARTNER and ATRC Aurigon Ltd.

(5) ATRC Aurigon Ltd. reserves the right to refuse the PARTNER's personnel entry to the establishment if the rules in § 11 Para. 1 – 5 are not adhered to.

## **12. Other Provisions**

(1) Place of fulfilment is Dunakeszi or Budapest for services performed at ATRC Aurigon Ltd or Munich for services performed at Aurigon GmbH, unless nothing else is agreed upon. Should any disagreement over this contract arise the place of jurisdiction is the district court of Budapest and Hungarian law is applicable for services performed by ATRC Aurigon Ltd. For services performed by Aurigon GmbH (exclusively services mediated to ATRC Aurigon Ltd.) the place of jurisdiction is Munich and Germany law is applicable. The UN sales convention does not apply.

(2) In the event that any clause hereof should be invalid or non-compliant to the law, this shall not affect the validity of the remaining terms. Instead of the invalid or non-compliant clause the parties shall endeavour to find a clause that is compliant to the law, and which comes closest to the intention of the parties.

(3) For everything that is not regulated in these general terms and conditions the latest version of the Hungarian Civil Code (2013 évi V. törvény) shall apply for services performed at ATRC Aurigon Ltd. For services performed by Aurigon GmbH (exclusively services mediated to ATRC Aurigon Ltd.) the latest version of the German Civil Code (2002, Bürgerliches Gesetzbuch BGB).