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03/03/2011	AMMCLI (M. Piva)	AMMQUA (C. Bertollo)	DG (T. Conte)

General conditions for supply rev. 9

1. Introduction

Definitions:

Chelab” or “Laboratory”: Chelab S.r.l. company, registered office via Fratta, 25 Resana (TV), fiscal code and VAT number 01500900269, analysis laboratory accredited by ACCREDIA nr. 0051 in accordance with the norm UNI CEI EN ISO/IEC 17025, represented in this agreement by Dr. Tiziano Conte, chemist, registered in the chemist order nr. 148 of the Province of Treviso; Chelab operates in different sectors, listed in the website: www.chelab.it.

In the operative units of Chelab have been defined and implemented specific Systems of Quality management, in particular:

- Quality management system with reference to the regulation UNI CEI EN ISO/IEC 17025:2005, to prescriptible documents of ACCREDIA, to regulation UNI EN ISO 9001:2008 and other normative references applied in all the areas of Chelab S.r.l. displaced in Resana with the exception of Pharma Division, Assay centre and Clinical laboratory.
- Quality management system with reference to Italian and European legislation concerning GMP and GLP and to regulation UNI EN ISO 9001:2008, applied by Pharma Division, Assay centre and clinical laboratory of Chelab S.r.l.
- Quality management system with reference to regulation UNI CEI EN ISO/IEC 17025:2005, to prescriptible documents of ACCREDIA and other normative references, applied in other operative units specified in the area “Information about the company”.

“Client”: juridical, public or private person, identified in the client section of this contract and who requires Chelab S.r.l. to perform chemical, physical and/or microbiological analyses and/or biological and/or the execution of other services.

“Sample”: material which shall be analysed, not representative of other materials or lots except specific indications by an authority.

2. Application of the general conditions

These General Conditions concern the existing relationship between Chelab S.r.l. and the Client, unless otherwise agreed between the parties in writing.

Each contract can be concluded according to proper written agreements or by the acceptance of Chelab’s offers; anyway, the sending of the samples is considered as acceptance of this offer and of the general conditions. Chelab S.r.l. considers accepted the General conditions even the analyses requested or ordered directly by the Client.

Once the contract has been agreed, the Client accepts the General Conditions unless explicit exceptions or integrations deriving from the agreement itself.

3. Object of the contract

The business relation between Chelab S.r.l. and the Client is intended as a contract which includes the performance of services by Chelab S.r.l. within a complex activity that can include:

- Chemical, physical, microbiological, biological, mineralogical, toxic, ecotoxic and performance analysis on foodstuff, environmental, industrial samples and raw materials;
- Quality controls, in accordance with GMP, on medicines and pharmacological active raw materials, for human and veterinary use;
- Non clinical studies in accordance with GLP;
- Non clinical studies for cosmetic products according to international standards and in compliance with the standard UNI/CEI EN ISO/IEC 1025:20055;
- Development services and validation of methods, of contract research, stability studies;
- Legislative assistance and technical-scientific services in agrozootechnic, industrial sector (chemical, oil, petrochemical, mineral, building field) and environmental field (waters, soils, muds, fertilizers, wastes, emissions), no food goods (packaging, detergents, cosmetics, textile fibres, leathers), pharmaceutical products, raw materials and working places (industrial hygiene);
- Assistance for review analysis, expert surveys, technical assistance in case of civil and penal defence;
- Technical assistance services for labelling of the products.

4. Performing of the activity

The services concerning the above mentioned activity are performed by the competent section under the control of a chemist and/or biologist and/or physics who are registered in the competent professional order.

If the quality of the required performances to Chelab S.r.l. should comply the requisites of GMP or GLP, this request has to be communicated to Chelab S.r.l. before the drafting of the economical offer concerning the performance, and has to be agreed in writing before its execution by the pertinent laboratory.

The Client, subject to agreement of modality and time of execution with the competent technical director, can take part to the execution of the analysis of his sample. This activity constitutes an accessory performance and will be separately charged.

5. Delivery of samples to the laboratory

If it is not differently and explicitly agreed, the products to be analyzed have to be delivered to the Laboratory by the Client or by a delegate agent.

The sampling of the material from the Client's company (or somewhere else indicated by the Client) by Chelab's personnel is considered an additional service, with an extra price and which will be paid separately from the analyses.

In case of collection, Chelab S.r.l. guarantees the preservation of the original chemical, physical and microbiological characteristics of the products during the transfer to the Laboratory.

The Client is obliged to inform Chelab S.r.l. about the risks and dangers related to the material to be analysed; furthermore, he is obliged to indicate efficiently the correct modality for the managing of samples (elimination, reduction, protection).

The Client will be responsible for all legal purposes for damages to people or objects caused by the missing information as regards the risks and dangers of his products.

Provided and/or requested activities, procedures and/or methods for the creation, constitution or identification of the sample are intended as "sampling" and, unless otherwise agreed by writing, they are intended as performed or executed at the expense and under the responsibility of the Client or of the committee; if requested by the Client, Chelab S.r.l. can provide information on "sampling" and conservation procedures, techniques and/or methods according to legal and/or voluntary laws.

"Sampling" can be performed by and/or under Chelab S.r.l. responsibility if explicitly requested by the Client and with the possibility of an extra charge.

6. Beginning of the analyses

Generally, the "beginning of the analysis" (date of beginning) can be within two working days after the acceptance of the sample. Chelab S.r.l. has the duty to guarantee appropriate procedures for the preservation of the sample.

"Acceptance" is the receiving of the goods to be analysed by Chelab S.r.l.

7. Conservation of the sample and of the stock sample - residual sample and conservation of the raw data

When the laboratory receives the sample, it guarantees the preservation of the chemical, physical and microbiological characteristics of the product. Unless otherwise agreed in writing, Chelab S.r.l. acquires the property of the delivered sample. The Client can not require the restitution of the sample itself or of the residual part after the analysis.

The stock sample is kept by Chelab S.r.l. which guarantees the preservation of the original chemical, physical and microbiological characteristics of the product for a period agreed in writing in advance.

After this period, Chelab S.r.l. can destroy the stock sample, that is to deliver it to a third party for the disposal.

The residual part of the analysed sample (residual sample) is preserved for a period of 10 days after the issue of the analytical report, according to the matrix and the nature of the requested analyses.

The data are kept for a period of 4 years after the execution of the analysis, if not differently agreed between the parties

8. Analytical reports

The laboratory is responsible only for the analytical results referred to the samples subject of analysis. The client has to communicate to the laboratory all the necessary information (parameters to be researched, aim of the analysis, possible specific methods, etc.) for a correct choice of the analytical procedure to apply to the sample.

The analytical reports are issued in a unique copy.

The issue of a second copy in the original form, on request of the Client, shall be paid separately.

The analytical reports are issued in conformity with the general norms of the laboratory accreditation.

The issue of the analytical reports with a format corresponding to the Client's specifications shall be requested in writing; if this personalization is allowed by the general norms of the laboratory accreditation and is technically possible, it is an additional service which price is agreed with the Client in advance.

The analytical reports are normally issued on "Chelab S.r.l." form.

If applicable, the analytical reports can be issued on "Chelab S.r.l." form with ACCREDIA, ILAC logos, and if it is relevant the logo of QS in accordance with the Specifications of the norm. In this case the Client shall formulate this specific request before the Laboratory accepts the sample.

If applicable and on the Client's request (formulated before the acceptance of the sample), the analytical reports regarding the determinations of residues/traces can be integrated with the information concerning the recovery (or analytical performance) used in the calculation according to the applied method. This service may have an additional cost.

If the sampling activity is required and it is performed by and/or under Chelab's responsibility, in the analytical report and in accordance to the Client's request, there will be specific indications concerning the sampler (the technician responsible for the sampling), the sampling methods and conditions or other information.

If not differently agreed, the analytical reports are delivered to the client in electronic format with digital signature according to the applicable law. This document constitutes the original document. The original signature is not applied neither to analytical reports related to analytical activity performed in compliance with GMP requisites nor to final reports carried out in compliance with GLP requisites.

On the Client's request (formulated before the acceptance of the sample), the analytical reports can be sent by fax or by mail; this service shall be considered additional and may an additional cost.

On the Client's request, Chelab S.r.l. offers the service of treatment, transferring and consulting of the analytical data through telematics, in accordance with the applicable procedures; the service can be considered an additional service and so may have an additional cost. Chelab S.r.l. is not responsible for the loss, the change or not-intentionally divulgation of the data and/or information depending on the bad functioning of the telecommunication systems or events outside the direct control of Chelab S.r.l..

The use of communications and web services shall be regulated by Chelab S.r.l. specific supply conditions.

The duplication of the analytical reports is forbidden unless Chelab S.r.l. authorizes it by writing.

Chelab Sr.l. records electronically the analytical reports for 10 years according to the law in force; if not required by the law in force or if not agreed with the Client, Chelab S.r.l. keeps the raw data regarding the analytical reports at least for 4 years.

9. Identification of the analytical method

On the Client's request, the Laboratory gives explanations on the methods or on the procedures used in laboratory; this could be considered as an additional service and will be separately charged.

Specific requests concerning the analytical methods shall be agreed with Chelab S.r.l. by writing before the acceptance of the sample.

Chelab quality system updates constantly the adopted analytical methods to optimize the services.

In case of analysis carried out in accordance with GMP or GLP, the updated methods are used only after the approval by the Client, unless they are methods of the official Pharmacopoeia.

10. Further services related to the analytical reports

Any other Client's request related to the analytical reports (such as, opinions, interpretations, reports, comments, comparisons with the limits of law and/or specifications) is a separate service and could have an additional cost. All the information in the analytical report refer exclusively to the analysed sample and analysed parameters and cannot be considered as inspection and/or product certification.

The additional services connected to the analytical reports shall be considered performed by Dr. Tiziano Conte, registered in the Chemists' Order of the province of Treviso with nr. 148 or at least under his direct supervision and control or by a qualified and regularly registered person.

Any other particular request shall be formalized in the Quality System of the Client.

Modifications and integrations: for any modification and integration not formally requested and/or not agreed by writing, only the registrations made by Chelab S.r.l. are considered valid.

11. Observance of the industrial injury legislation

By performing its activities and services, Chelab S.r.l. applies and observes all the prescriptions and duties concerning the safety and health of workers in accordance with the Legislative decree nr. 81/2008 and following modifications; the law is valid even when Chelab's Personnel is working by a Client as regards the risks connected to the use of equipments, plants, safety dispositions, etc.

12. Privacy policy (D. Lvo. nr. 196/2003 and following modifications).

Observing the Legislative Decree nr. 196 of 30/06/2003 (treatment of the personal data), Chelab S.r.l. informs that in the Laboratory archives are collected data concerning the Client, which are used to perform the activity expressed in the contract of supply.

With reference to the treatment of those data, the Client can exercise the rights mentioned in article 7 of the Legislative Decree nr. 196 of 30/06/2003.

The data can be treated by manual, computer and telecommunication systems, always guaranteeing the safety and the privacy and without disclosing the information to any third party.

As established by the Legislative Decree nr. 196 of 30/06/2003, here enclosed find an informative report which is considered approved once the contract has been accepted, unless otherwise agreed by writing.

13. Privacy obligation and information

The parties ensure that they do not communicate to third party the documents connected to this contract and any other information related to the contract during the service and even after the interruption of the contract.

The parties ensure that they maintain the maximum privacy and the official secret about the organization company structure of the other party.

Each party shall take all the necessary precautions to safeguard the official secret and shall impose this duty to its employees and/or collaborators, included those of third parties: they shall not abuse of the received information.

14. Claims/controversies

Applying the general principles of Chelab's certified quality management system, the Laboratory considers binding only written claims and controversies received within 8 days after the receiving of the document object of the controversy.

Different terms of time limit shall be agreed in advance by writing.

15. Term of payments

If not differently agreed, Chelab services have to be paid within 30 days after the receiving of the invoice. In case of delay in the payment, Chelab S.r.l. will apply the moratory measures according to art. 4 and 5 of Legislative Decree 231 of 9/10/2002, if not differently agreed by writing.

16 Express termination clause

Chelab S.r.l. can rescind this contract, without any notice, in case the Client will not respect the payment terms.

17. Place of Jurisdiction

Any controversy (about interpretation, execution or interruption of the contract) between the parties shall be resolved in Treviso court of jurisdiction.

Read, confirmed and signed.

Place and date

CHELAB SRL

THE CLIENT

According to the law of articles 1341 1342 c.c., the parts declare to have read, take knowledge and approved the following clauses: 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 13, 14, 15, 16, 17, 18,.

CHELAB SRL

THE CLIENT

Attachment: Informative report ex art. 13 of the Legislative Decree 196/2003.

Informative ex art. 13 Legislative Decree 196/2003

Dear Sir/Madam,

We would like to inform you that the Legislative Decree 196 of June 30th 2003 (Code in subject of protection of the personal data) provides for the safeguard of person and other subjects regarding the treatment of the personal data.

In accordance with the above mentioned norm, the treatment of the information will be based on correctness, lawfulness, transparency and safeguard of your privacy and rights.

According to the article 13 of the Legislative Decree nr. 196/2003, we inform you that:

1) Your data will be treated for the following purposes:

- a) execution of the contract
- b) execution of performances connected to the contract, included fiscal and tax fulfilment, in public or private offices
- c) statistics and/or managerial activities
- d) e-mailing of advertising materials concerning services offered by Chelab S.r.l.

For the above mentioned purposes, the treatment of the personal data does not need the agreement of ex article 24, comma 1, letters a), b), c), d), f) of the Legislative Decree nr. 196/2003.

2) The treatment shall be performed, for the above mentioned purposes, by writing and/or on paper, magnetic, electronic or telecommunication support, by using automatized instruments which memorize, handle and communicate the data and always guarantee the privacy and the safety of the data.

3) The conferring of the data is mandatory for legal and contractual purposes and the possible refusal to furnish those data could cause the loss or the partial execution of the contract

4) Besides the communication of data to meet legal purposes, the data could be communicated to third parties which perform certain functions on the behalf of Chelab S.r.l. (banks, assurance agencies, adviser, carrier, etc.) and to the following agents and/or responsible persons:

- a) commercial office agents/employees
- b) Technical Scientific Assistance employees

The data will not be diffuse

5) The company Chelab S.r.l. is the holder of the data treatment

6) The person responsible for the data treatment is Dr. Conte Tiziano – legal representative

7) Unless otherwise agreed by writing, the personal data, which you have already given to us, are treated as described in this informative report

8) The data may be held on our contacts because of the work we are currently engaged in order to satisfy any law, regulation, legal request or any future commercial activity

9) In every moment you may assert your rights towards the holder of the treatment, according to the law 7 of the legislative decree 196/2003, that we integrally reproduce

Legislative decree nr. 196/2003, Article nr.7 - access right to the personal data and other rights

1. The interested party has the right to get the confirmation of the existence of his own personal data, even if not yet filed, and their communication in intelligible form

2. The interested party has the right to get the indication:
 - a) of the origin of the personal data
 - b) of the finalities and way of the treatment
 - c) of the logic applied in case of treatment carried out by electronic tools
 - d) of the identification of the holder, of the persons responsible for the treatment and of the designate representative according to the article 5, paragraph 2
 - e) of the subjects or of the categories of subjects to which the personal data can be communicated or that can become acquainted of the data as designate representative in the territory of the State, of responsible or entrusted persons

3. The interested party has the right to get:
 - a) the updating, the rectification or, if interested, the integration of the data
 - b) the cancellation, the transformation in anonymous form or the block of the data treated in violation of law, including those which are not necessary for the purposes for which the data have been collected or afterwards treated
 - c) the attestation that the operations indicated at the letters a) and b) have been brought to knowledge, with their content as well, of those people to which the data have been communicated or diffused, excepted the case in which such fulfilment is impossible or it needs an employment of means disproportionate in comparison to the protected right

4. The interested party has the right to disagree, entirely or partly:
 - a) for legitimate reasons concerning the treatment of his/her personal data, even if relevant to the purpose of the collection of the data
 - b) with the treatment of personal data concerning him/her in order to receive advertising information or direct sale or for market researches or commercial communication

Resana, on the.....

Chelab S.r.l.

For information, the Client