SPECIFICATION OF TECHNICAL REQUIREMENTS

SERVICE FOR THE CONDUCTING OF TOXICITY STUDIES UNDER GOOD LABORATORY PRACTICE BY OPEN PROCEDURE

1. PURPOSE OF THE CONTRACT

The purpose of this contract is to procure the service of "Preclinical toxicological studies to evaluate the safety of a gas", in accordance with the conditions set forth in these specifications.

The service covers all the services needed to conduct a "Single dose inhalation toxicity study of sulphur hexafluoride in rats under Good Laboratory Practice (GLP) standards", including all necessary pre- and post-activities.

Lot split:
In accordance with the provisions of article 99.3 of Spanish Law 9/2017, of 8 November, on Public Sector Contracts, in this case, the contract is tendered in a single lot given the need for a coordinated development of the planned service, which could be made impossible by a number of different contractors.

File: BMG 2023-07-SERV. Services for the conducting of toxicity studies under good laboratory practice

The purpose of these Specifications is to determine the technical characteristics to be met by the provision of the service that must consequently be carried out in accordance with these Specifications and in accordance with the provisions of the Specific Administrative Clauses.

2. TECHNICAL CHARACTERISTICS OF THE SERVICE

- Dose analysis and validation for GLP inhalation studies.
  - Gas to evaluate, SF_6:

Molecule	Sulphur hexafluoride
Administration method	Controlled atmosphere

Development of the atmosphere	The validation of an analytical method (filters, trapping solvent, cascade impactor slides, as appropriate) will be required prior to testing for the characterisation of the atmosphere before the animal study. Common analytical method: HPLC/UPLC; assumes a single analyte.
Characterisation of the atmosphere	Preliminary tests. Tests for the atmosphere generation methodology will be required prior to the animal study.
Monitoring of the concentration of the atmosphere	At least 2 aerosol samples will be collected during each exposure.
Chemical analysis of the atmosphere	During the dosing phase, all samples will be chemically analysed.

- Single dose inhalation toxicity study in Wistar Han rats with a 2-week recovery.
  General information:
  - Regulatory compliance: GLP
  - Guidelines: Based on current applicable regulatory guidelines
  - Minimum duration of the study: ~4 weeks (~2 weeks acclimatisation, 1 day dosing phase, 2 weeks recovery)
  - Experimental groups:

	Number of animals	
Groups	**Male**	**Female**
1 (Control)	15	15
2 (High dose)	15	15

4. CONDITIONS OF THE SERVICE

The contractor undertakes to provide professional staff with the appropriate experience and training to perform the service.
The service will be carried out with quality, rigour and efficiency and in full compliance with all legal provisions, regulations, standards and specifications in force that directly or indirectly regulate it.
Specifically, the contractor undertakes, vis-a-vis CIC biomaGUNE, to develop and organise its professional activity in accordance with its own criteria and guidelines, assuming the full risk of its activity. For its part, CIC biomaGUNE will establish the means of control it deems appropriate to verify the contractor's full and correct compliance with the service provided.

5. ORGANISATION AND WORK TEAM

The staff members performing the service will depend solely on the service provider and the latter will have all the rights and duties inherent to their status as employer and must comply under their exclusive

responsibility with the provisions in force, or which may be enacted in the future, in labour, Social Security, Health and Safety and tax matters, with CIC biomaGUNE being exempt from any liability that may arise as a result of the service provider's failure to comply with the aforementioned obligations.
The service provider will be responsible for all expenses needed to fulfil the contract, as well as for any compensation for damages that may be caused as a result of the fulfilment of the contract.
During the term of the contract, the service provider is obliged to present, at the request of CIC biomaGUNE, any documentation requested and that proves the fulfilment of the obligations of this contract.

5. ORGANISATION AND WORK TEAM

The service provider must have at its disposal all the staff and material means needed to fulfil the obligations of the contract.

For its part, CIC biomaGUNE will establish the means of control it deems appropriate to verify the provider's full and correct compliance with the service provided.

The service will be carried out with quality, rigour and efficiency, as well as in full compliance with all legal provisions, regulations, standards and specifications in force that directly or indirectly regulate it.

The successful bidder will be responsible, in its capacity as employer, for the staff assigned to the contract, and must comply, under its exclusive responsibility, with the provisions in force or to be issued in the future on labour, Social Security, Health and Safety and tax matters, with CIC biomaGUNE being exempt from any liability that may arise as a result of the contractor's failure to comply with the aforementioned obligations, whether the service covered by the contract is carried out by staff who depend exclusively on the contractor or by subcontracted staff.

The service provider will be responsible for all expenses needed to fulfil the contract, as well as for any compensation for damages that may be caused as a result of the fulfilment of the contract.

During the term of the contract, the service provider is obliged to present, at the request of CIC biomaGUNE, any documentation requested and that proves the fulfilment of the obligations of this contract.