SPECIFICATIONS ATTACHED TO THE INVITATION TO TENDER

General invitation to tender n° SANCO/2007/C6/005 concerning a quality system guide for establishments in the field of substances of human origin

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1. Title of contract

Tender No SANCO/2007/C6/005 concerning a quality system guide for establishments in the field of substances of human origin.


2. Purpose and context of contract

To maintain public and professional confidence in the safety and efficacy of substances of human origin, careful attention must be paid to all aspects of the quality of the blood, tissues and cells. Article 152 of the Treaty, in particular paragraph (4) (a), requires the European Parliament and the Council to adopt measures that set high standards of quality and safety of blood, organs and substances of human origin. Safety and quality requirements have been adopted in 2003 for blood and blood components (Directive 2002/98/EC) and in 2004 for tissues and cells (Directive 2004/23/EC).

The Blood Directive and the Tissues and Cells Directive oblige Member States to take all necessary measures to ensure that each blood establishment and tissue establishment establishes and maintains a quality system based on the principles of good practice. Quality management systems enable the blood, tissues and cells to meet the quality and safety requirements with confidence. They define and document a series of systematic processes that are to be followed by all those working within an organisation. These processes are designed to ensure that quality is evident in every part of the organisation. The objective is to avoid mistakes. However, if a mistake does happen, the cause should be identified and the process amended so that it is not repeated.

The Commission has established the Community standards and specifications for the activities relating to a quality system to be carried out by a blood establishment in Commission Directive 2005/62/EC of 30 September 2005 implementing Directive 2002/98/EC as regards Community standards and specifications relating to a quality system for blood establishments. It has also established Community standards and specifications for the activities relating to a quality system to be carried out by a tissue establishment in Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells.

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Although the Commission has already introduced provisions on quality systems, these could be interpreted differently and tissue establishments could have difficulties in knowing how to put in place these requirements concretely.

Therefore, there is a need for developing guidelines for the application of the Community standards and specifications in relation to quality systems for blood/blood components and tissues and cells. These guidelines will be a tool to help blood and tissue establishments in putting into practice the current technical requirements with regard to quality systems. This will not preclude blood and tissue establishments to use an alternative approach if such approach satisfies the requirements of the applicable regulatory framework. When developing this quality system guide for establishments in the field of substances of human origin, the principles and guidelines of good manufacturing practice as referred to in Article 47 of Directive 2001/83/EC shall be fully taken into account.

In order to establish good practice guidelines for the of the Community standards and specifications in relation to quality systems for blood and tissues and cells, the Commission has decided to enlist the services of an organisation, institution, company or body (hereinafter referred to as ‘contractor’) to carry out a number of tasks and produce a report and a quality system guide for establishments in the field of substances of human origin as described in the following section.

3. Subject of contract

3.1 Objectives and expected outcome

The contract has the following objectives.


- To obtain an overview of existing relevant general guidelines on quality systems such as ISO and GMP, and of existing relevant specific guidelines on quality systems for blood establishments and tissues and cells establishments as specified under 3.3. task (a).

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3 See also Article 2 of Commission Directive 2005/62/EC implementing Directive 2002/98/EC as regards Community standards and specifications relating to a quality system for blood establishments which stipulates that good practice guidelines shall be developed by the Commission for the of the Community standards and specifications.
To analyse and compare the contents of the existing guidelines with each of the specific requirements of the Community standards and specifications as defined in the Tissue and Cells and in the Blood Directives in order to determine how to interpret best from the point of view of quality management those requirements and to provide for a rationale for the choices made.

To evaluate the applicability of the chosen interpretations in the 27 EU Member States while making sure that different types of blood and tissues/cell establishments as specified under 3.3. task (b) have participated in the evaluation and to propose an alternative in case the proposed interpretation raises significant problems.

To produce a ready-to-use and user-friendly Quality system guide for establishments in the field of substances of human origin, which will offer guidance for the application of the Community standards and specifications as set out by the Annex to Commission Directive 2005/62/EC and Commission Directive 2006/86/EC, and which will offer a practical help to blood and tissue establishments on how to implement the Community standards and specifications.

The contractor is required:

a) To prepare an overview of existing relevant general guidelines on quality systems such as ISO and GMP, and of existing relevant specific guidelines on quality systems for blood establishments and tissues and cells establishments as specified under 3.3. task (a). The contractor will consult the Commission on the list of the guidelines.

b) To propose an optimal interpretation of the Community standards and specifications in relation to quality systems for substances of human origin based on an analysis and comparison of the existing guidelines and fully taking into account the detailed principles and guidelines of good manufacturing practice as referred to in Article 47 of Directive 2001/83/EC as amended, and to provide for a rationale for the choices made.

c) To contact in cooperation with the Commission the competent authorities of the 27 Member States and a representative sample of blood and tissue establishments as specified under 3.3. task (b) in order to evaluate the proposed interpretation/guidelines. The evaluation will have as a purpose to assess the clarity, adequacy, helpfulness and applicability of each of the proposed interpretations of the Community standards and specifications in the EU Member States. In case the chosen interpretation raises significant

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problems, the contractor will explain the different positions to the Commission and will identify and document alternative interpretations. The contractor will then make a proposal for an optimal solution which balances the need for optimal guidelines with the concerns of the Member States and tissue and blood establishments.

d) To write and submit to the Commission in English, French and German a Quality system guide for establishments in the field of substances of human origin.

e) To write and submit to the Commission a comprehensive report summarising the results of the tasks and providing a rationale for the final choices of interpretation of the Community Standards and specifications made.

The contractor shall carry out the tasks specified above in close cooperation with the Commission (DG Health and Consumer Protection).

3.2 Data sources to be used

The contractor will review existing relevant general guidelines on quality systems such as ISO and GMP, and existing relevant specific guidelines on quality systems for blood establishments and tissues and cells establishments:

- in the EU, Council of Europe, WHO, the FDA, and
- from a sample of national authorities within and outside of the EU, and
- from the key representative scientific and professional societies such as JACIE, EBA, EACC, EATB, ESHRE, NETCORD, AATB, EEBA, ISBT... ⁵

The contractor will also review the preparatory work for the Commission Directives in relation to quality systems and other relevant material which will be provided by the Commission. He will take into account Commission interpretations of the regulatory framework; these will be provided to the contractor by the Commission.

3.3 Activities to be carried out

The tasks to be executed by the contractor(s):

**Task a** consists in gathering information and providing an overview of the existing relevant general guidelines on quality systems such as ISO and GMP, and existing

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relevant specific guidelines on quality systems for blood establishments and tissues and cells establishments:

- in the EU, Council of Europe, WHO, the FDA, and
- from a sample of national authorities within and outside of the EU, and
- from the key representative scientific and professional societies such as JACIE, EBA, EACC, EATB, ESHRE, NETCORD, AATB, EEBA, ISBT…

Task a) also involves the identification of guidelines providing an optimal interpretation of the Community standards and specifications in relation to quality systems for substances of human origin based on an analysis and comparison of the information gathered and fully taking into account the detailed principles and guidelines of good manufacturing practice as referred to in Article 47 of Directive 2001/83/EC as amended.

Task a) involves also convening a meeting with the Commission to discuss the study under deliverable 1.

For task a) the following deliverable must be provided:

**Deliverable 1**: Study providing an overview of the existing guidelines on quality systems for blood establishments and tissue establishments, which systematically analyses and compares their contents and which identifies those guidelines which provide an optimal (in terms of quality management) application of the Community standards and specifications in relation to quality systems for substances of human origin. The study shall be presented in the form of a table which lists in the first column every requirement from the Community standards and specifications and which lists the corresponding existing guidelines which were identified for review in the following columns. The last column shall list the optimal interpretation of the Community standards and specifications as proposed by the contractor based on the analysis and comparison of existing guidelines.

At least the following areas shall be covered in the guidelines:

1. **Introduction and general principles**
   1.1. Quality system
   1.2. Quality assurance
   Including guidelines in relation to a change control system.
2. **Personnel and organisation**

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Including guidelines on the contents of training for personnel and on delegation of responsibilities.

3. Premises, including guidelines on procurement sites, ancillary areas and mobile sites
   3.1. General
   3.2. Donor area
   3.3. Collection area
      Including guidelines on safe and clean environment, designed to minimise errors, means of communication to ensure that emergency help is available.
   3.4. Testing and processing area
      Including guidelines on air quality, equipment and ventilation.
   3.5. Storage area
      Including guidelines on access, lighting, equipment, monitoring, separate areas and quarantine storage.
   3.6. Waste disposal area

4. Equipment and materials
   Including guidelines on computers.

5. Documentation
   Including guidelines on document control procedures.

6. Collection/procurement, testing and processing
   6.1. Donor eligibility
   6.2. Collection / procurement
   6.3. Laboratory testing
      Including guidelines on confirmatory testing, on which type of samples, accordance with recommendations of the test kit manufacturer, using in-house protocols, records, blood group serology testing.
   6.4. Processing and validation
   6.5. Labelling
   6.6. Release
      Including guidelines on release subject to computer derived information, comparison with previous records from donor, quarantine.

7. Storage and distribution
   Including guidelines on storage, dispatch, quality monitoring, microbiological contamination monitoring, environmental control, storage conditions, hygiene.

8. Contract management

9. Non-conformance
   9.1. Deviations
   9.2. Complaints
   9.3. Recall
   9.4. Corrective and preventive actions
      Including guidelines on documentation and investigation of errors and accidents (including near miss events) and routine analysis of quality data to identify problems.

10. Self-inspection, audits and improvements
    Including guidelines on documentation of corrective actions, assessment of preventive and corrective actions for effectiveness,
stimulation of inter-institutional audits and the process for continuous and systematic improvement.

**Task b)** involves evaluating the proposed guidelines in the 27 EU Member States and in a representative sample of blood and tissue establishments. The evaluation will have as a purpose to assess the clarity, adequacy, helpfulness and applicability of each of the proposed interpretations of the Community standards and specifications in the EU Member States.

Task (b) involves contacting the competent authorities of the 27 Member States and a representative sample of blood and tissue establishments. The Commission will assist in contacting the competent authorities with this request. The competent authorities will be informed of the list of establishments in their country which are participating in the evaluation. The selection of blood and tissue establishments should include a balance between establishments that have been accredited under an existing scheme and establishments that have not. It should also ensure that different organisational models/sizes of establishments are covered. The selection will include the following types of blood and tissue establishments, and no two establishments of the same type can be selected from the same Member State:

- reproductive cells (at least 5)
- blood (at least 15)
- stem cells (at least 5 including at least 1 cord blood bank)
- general tissues (at least 15 representing in a balanced way all tissue types such as heart valves, bones, skin, cornea…)

Task (b) also involves explaining the different positions of the Member States and of the blood and tissue establishments to the Commission. In case one of the proposed guidelines raises significant problems, the contractor will identify and document alternative interpretations. The contractor will then make a proposal for an optimal solution which balances the need for optimal guidelines with the concerns of the Member States and tissue and blood establishments.

For task b) the following deliverables must be provided:

- **Deliverable 2**: Action plan for evaluating the proposed guidelines with the competent authorities of the 27 Member States and a representative sample of blood and tissue establishments as described above. This action plan shall be submitted to the Commission and needs to be accepted by the Commission before proceeding with the evaluation.

- **Deliverable 3**: Two questionnaires that have been tested and validated for assessing the clarity, adequacy, helpfulness and applicability of each of the proposed guidelines: one for the evaluation of the proposed guidelines by the competent authorities and one for the evaluation of the proposed guidelines by the representative selection of tissue and blood establishments.

- **Deliverable 4**: Study which provides an overview of the positions of the 27 competent authorities and of the blood and tissue establishments on each of the guidelines. In case one of the proposed guidelines raises
significant problems, the study will identify and document alternative interpretations and will present a proposal for an optimal solution which balances the need for optimal guidelines with the concerns of the Member States and tissue and blood establishments and which provides for a rationale for the chosen solution.

Task b) involves also convening a meeting with the Commission to discuss the study under deliverable 4.

**Task c)** consists of writing and submitting to the Commission a draft table of contents and a quality system guide for establishments in the field of substances of human origin.

For task c) the following deliverables must be provided:

- **Deliverable 5**: a draft table of contents in English of the “Quality system guide for establishments in the field of substances of human origin”.

- **Deliverable 6**: a draft “Quality system guide for establishments in the field of substances of human origin” in English.

- **Deliverable 7**: a ready-to-use and user-friendly “Quality system guide for establishments in the field of substances of human origin” in English, French and German.

Task c) involves also sending the draft table of contents to the Commission for agreement prior to writing the Quality system guide, and sending the draft “Quality system guide for establishments in the field of substances of human origin” for approval.

**Task d)** involves preparing and submitting to the Commission a comprehensive report containing a description of all the work carried out and results obtained in execution of the tendered job.

For Task d) the following deliverable must be provided:

- **Deliverable 8**: To prepare and submit to the Commission a comprehensive report containing a description of all the work carried out and results obtained in execution of the tendered job.

If the execution of the contract requires any acquisition of material (especially hardware or software) the relevant material will be the property of the Commission (and should be delivered to the Commission at the end of the contract) unless otherwise agreed.

Tenders must submit a **working plan and a detailed list and description step-by-step of activities, preferably in the form of work packages**, including a full list of data-sources, and a time table appraisal for the completion of the various activities with associated milestones and deployment schedule of the various resources (personnel, etc).
3.4 Meetings

To ensure close cooperation with the Commission services concerned, at least three meetings will have to be organised. The funding of these meetings has to be foreseen in the tender. Meetings will take place in Brussels.

3.5 Geographical coverage

The contractor should ensure that the guidelines proposed to interpret the Community standards and specifications on quality systems for blood establishments and tissue and cells establishments have been evaluated in the 27 EU Member States.

3.6 Timeframe for carrying out the work

The work shall be carried out during a period of 12 months.

4. Volume of contract

The total price is estimated at maximum 250,000 euro (two hundred and fifty thousand euro, excluding VAT and other taxes, as specified under 16 below).

The price includes all costs and cover costs of a team of experts, consultancies, meetings, secretarial support, data-processing, translations, printing etc. as set out in this tender.

The contract will be awarded under the best-value-for-money procedure.

5. Participation in the tendering procedure

Participation in tendering procedures is open on equal terms to all natural and legal persons coming within the scope of the Treaties and to all natural and legal persons in a third country which has a special agreement with the Communities in the field of public procurement on the conditions laid down in that agreement.

6. Reports and documents to be submitted

The work carried out by the Contractor under the contract will be the subject of the following reports, which must be sent to the Commission by the Contractor in English. The “Quality system guide for establishments in the field of substances of human origin” itself has to be provided in English, French and German. All documents with accompanying documents must be submitted also in electronic form suitable for Microsoft Word XP, and Adobe Acrobat reader and in a format ready for use on the internet.

These documents are subject to the approval of the Commission.
- a final version of the detailed work plan, as defined in 3.3, must be sent within one week of the start of the contract to the Commission.

- a study 4 months after the start of the contract providing an overview of the existing guidelines on quality systems for blood establishments and tissue establishments, which systematically analyses and compares their contents and which identifies those guidelines which provide an optimal (in terms of quality management) application of the Community standards and specifications in relation to quality systems for substances of human origin. The study shall be presented in the form of a table which lists in the first column every requirement from the Community standards and specifications and which lists the corresponding existing guidelines which were identified for review in the following columns. The last column shall list the optimal interpretation of the Community standards and specifications as proposed by the contractor based on the analysis and comparison of existing guidelines.

- an action plan for evaluating the proposed guidelines, 5 months after the start of the contract which takes into account that the proposed guidelines must be evaluated with the competent authorities of the 27 Member States and a representative sample of blood and tissue establishments as described under 3.3. task (b).

- two questionnaires 5 months after the start of the contract that have been tested and validated, for assessing the clarity, adequacy, helpfulness and applicability of each of the proposed guidelines: one for the evaluation of the proposed guidelines by the competent authorities and one for the evaluation of the proposed guidelines by the representative selection of tissue and blood establishments.

- a study 8 months after the start of the contract which provides an overview of the positions of the 27 competent authorities and of the blood and tissue establishments on each of the guidelines. In case one of the proposed guidelines raises significant problems, the study will identify and document alternative interpretations and will present a proposal for an optimal solution which balances the need for optimal guidelines with the concerns of the Member States and tissue and blood establishments and which provides for a rationale for the chosen solution.

- a table of contents, 8 months after the start of the contract, in English of the “Quality system guide for establishments in the field of substances of human origin”.

- a draft “Quality system guide for establishments in the field of substances of human origin” (electronically and 10 paper copies, in English), are to be submitted within 10 months after the start of the contract.

- a ready-to-use and user-friendly “Quality system guide for establishments in the field of substances of human origin” within 12 months after the start of the contract, (electronically and 100 paper copies in English, written by or corrected by a native English speaker; and an electronic and each time 100 paper copies of the Guide in French and German):
• The Guide shall contain more than 30 pages and less than 50 (excluding Annexes).
• This will be one guide covering blood and tissues and cells simultaneously, but respecting where necessary the specificities of blood and tissues and cells.
• In case of non-approval of the Guide the contractor will have a month to revise the Guide following the Commission’s written observations and to submit a revised version of the Guide to the Commission for its approval. The approval/revision process may be repeated if the Commission considers it necessary or useful.

- the final report after 12 months after the start of the contract; 5 copies of the final report are to be submitted. The Commission will inform the contractors either that it approves the report or will give its observations. The final report will be deemed to have been approved by the Commission if it does not expressly inform the Contractor of any comments within 45 days of its receipt.

• In case of non-approval of the final report, the contractor will have a month to revise the report following the Commission’s written observations and to submit a revised version of the report to the Commission for its approval. The approval/revision process may be repeated if the Commission considers it necessary or useful.

7. Terms of payment

- Pre-financing:

Following signature of the Contract by the last contracting party7, within forty-five days of the receipt by the Commission of a request for pre-financing with a relevant invoice.

A pre-financing payment equal to 30% of the total amount shall be made.

- Interim payment:

Within forty-five days of the date on which the study which provides an overview of the positions of the 27 competent authorities and of the blood and tissue establishments on each of the guidelines (eight months after the start of the contract) is approved by the Commission, an interim payment equal to 30% of the total amount shall be made.

- Payment of the balance:

7 Where the Contractor is the last to sign, this clause should be worded as follows: “the date on which the signed Contract was received by the Commission”.

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Within forty-five days of the date on which the final report is approved by the Commission, payment of the balance equal to 40% of the total amount shall be made.

- Payment for travel and subsistence expenses:

Reimbursement will be made on presentation of statements of reimbursable expenses, and after their approval.

8. **Standard contract and general conditions**

In drawing up his bid, the tenderer should bear in mind the provisions of the standard contract attached to this invitation to tender (Annex VI).

Submission of a tender implies acceptance of all the terms specified in the present specifications and in particular in the attached standard contract including the general conditions applicable to contracts (Annex VI).

All documents presented by the tenderer become the property of the European Commission and are deemed confidential.

The Commission will not reimburse expenses incurred in preparing and submitting offers.

9. **No obligation to award the contract**

Completing the adjudication or the procedure of the call for tenders in no way imposes on the Commission an obligation to award the contract.

The Commission shall not be liable for any compensation with respect to tenderers whose tenders have not been accepted, nor shall it be liable when deciding not to award the contract.

10. **Administrative and financial penalties**

1. Without prejudice to the application of penalties laid down in the contract, candidates or tenderers and contractors who have been guilty of making false declarations or have been found to have seriously failed to meet their contractual obligations in an earlier procurement procedure shall be excluded from all contracts and grants financed by the Community budget for a maximum of two years from the time when the infringement is established, as confirmed after an adversarial procedure with the contractor.

That period may be extended to three years in the event of a repeat offence within five years of the first infringement.

Tenderers or candidates who have been guilty of making false declarations shall also receive financial penalties representing 2 % to 10 % of the total value of the contract being awarded.
Contractors who have been found to have seriously failed to meet their contractual obligations shall receive financial penalties representing 2 % to 10 % of the total value of the contract in question.

That rate may be increased to 4 % to 20 % in the event of a repeat offence within five years of the first infringement.

2. In the cases referred to in paragraph 12.1 points (a), (c) and (d) of these specifications, the candidates or tenderers shall be excluded from all contracts and grants for a maximum of two years from the time when the infringement is established, as confirmed after an adversarial procedure with the contractor.

In the cases referred to in paragraph 12.1 points (b) and (e) of these specifications, the candidates or tenderers shall be excluded from all contracts and grants for a minimum of one year and a maximum of four years from the date of notification of the judgment.

Those periods may be extended to five years in the event of a repeat offence within five years of the first infringement or the first judgment.

3. The cases referred to in paragraph 12.1 point (e) of these specifications shall be the following:

(a) cases of fraud as referred to in Article 1 of the Convention on the protection of the European Communities' financial interests drawn up by the Council Act of 26 July 1995⁸;

(b) cases of corruption as referred to in Article 3 of the Convention on the fight against corruption involving officials of the European Communities or officials of Member States of the European Union, drawn up by the Council Act of 26 May 1997⁹;

(c) cases of participation in a criminal organisation, as defined in Article 2(1) of Joint Action 98/733/JHA of the Council¹⁰;

(d) cases of money laundering as defined in Article 1 of Council Directive 91/308/EEC¹¹.

11. Requirement as to the tender

The tender must include:

(a) an administrative part including all the information and documents required by the contracting authority for the appraisal of tenders on the basis of the exclusion and selection criteria set out under paragraphs 12 and 13 respectively of these specifications;

(b) a technical part including all the information and documents required by the contracting authority for the appraisal of tenders on the basis of the award criteria set out under paragraph 15 of these specifications;

(c) a financial part setting out prices in accordance with paragraph 16 of these specifications.

Administrative part

12. Exclusion criteria

12.1. Candidates or tenderers shall be excluded from participation in a procurement procedure if:

(a) they are bankrupt or being wound up, are having their affairs administered by the courts, have entered into an arrangement with creditors, have suspended business activities, are the subject of proceedings concerning those matters, or are in any analogous situation arising from a similar procedure provided for in national legislation or regulations;

(b) they have been convicted of an offence concerning their professional conduct by a judgment which has the force of res judicata;

(c) they have been guilty of grave professional misconduct proven by any means which the contracting authority can justify;

(d) they have not fulfilled obligations relating to the payment of social security contributions or the payment of taxes in accordance with the legal provisions of the country in which they are established or with those of the country of the contracting authority or those of the country where the contract is to be performed;

(e) they have been the subject of a judgment which has the force of res judicata for fraud, corruption, involvement in a criminal organisation or any other illegal activity detrimental to the Communities' financial interests;

(f) following another procurement procedure or grant award procedure financed by the Community budget, they have been declared to be in serious breach of contract for failure to comply with their contractual obligations.

Candidates or tenderers must certify that they are not in one of the situations listed above by completing and signing the form in Annex IV, “Certification with respect to the Exclusion Criteria”.
Tenderers must also provide evidence that they are not in any of the situations described in points (a), (b), (d) and (e) above. This evidence must be in one of the forms described in paragraph 12.2 below.

12.2. Evidence

a) The Commission shall accept, as satisfactory evidence that the candidate or tenderer is not in one of the situations described in point (a), (b) or (e) of paragraph 12.1, production of a recent extract from the judicial record or, failing that, a recent equivalent document issued by a judicial or administrative authority in the country of origin or provenance showing that those requirements are satisfied.

b) The Commission shall accept, as satisfactory evidence that the candidate or tenderer is not in the situation described in point (d) of paragraph 12.1, a recent certificate issued by the competent authority of the State concerned. Where no such certificate is issued in the country concerned, it may be replaced by a sworn or, failing that, a solemn statement made by the interested party before a judicial or administrative authority, a notary or a qualified professional body in his country of origin or provenance.

c) Depending on the national legislation of the country in which the tenderer or candidate is established, the documents referred to in points (a) and (b) of paragraph 12.2 shall relate to legal persons and natural persons.

12.3. Contracts may not be awarded to candidates or tenderers who, during the procurement procedure:

(a) are subject to a conflict of interest;

(b) are guilty of misrepresentation in supplying the information required by the contracting authority as a condition of participation in the contract procedure or fail to supply this information;

Candidates or tenderers must certify that they are not in the situation in point (a) by completing and signing the form in Annex IV, “Certification with respect to the Exclusion Criteria”.

13. Selection criteria

13.1 Evidence of access to contracts (proof of eligibility)

The tenderer indicates in which State it has its headquarters or domicile and presents the supporting evidence normally acceptable under its own law (see Annex I).

Moreover, the tenderers are requested to:

- indicate their VAT number (see Annex I);
- indicate the name and position of the person authorised to sign the contract (see Annex I);
- indicate their account number and bank address (R.I.B. or standard form in Annex II);
- for natural persons, the standard form in Annex III must also be completed and returned.

13.2 Economic and financial capacity

1. Proof of economic and financial capacity may be furnished by one or more of the following documents:

(a) appropriate statements from banks or evidence of professional risk indemnity insurance;

(b) the presentation of balance sheets or extracts from balance sheets for at least the last two years for which accounts have been closed, where publication of the balance sheet is required under the company law of the country in which the economic operator is established;

(c) a statement of overall turnover and turnover concerning the works, supplies or services covered by the contract during the last three financial years.

2. If, for some exceptional reason which the contracting authority considers justified, the tenderer or candidate is unable to provide the references requested by the contracting authority, he may prove his economic and financial capacity by any other means which the Commission considers appropriate.

13.3 Technical and professional capacity

1. Technical and professional capacity of economic operators shall be evaluated and verified in accordance with paragraphs 2 and 3.

2. The tenderer will provide evidence of experience of at least five years in quality systems and quality management, and the capacity to put together a team with at least three years of relevant professional activity in the following areas (enclose curricula vitae and a reference list of projects carried out in this area):

- in the field of blood establishments, and
- in the field of tissue and cell establishments, and
- in the field of reproductive cells, and
- in the field of stem cells.

The tenderer will provide proof of capacity to work in several community languages (particularly English, French and German, enclosed curricula vitae should specify languages abilities).
Evidence of the technical and professional capacity of economic operators may be furnished on the basis of the following documents:

a) the educational and professional qualifications of the service provider or contractor and/or those of the firm's managerial staff and, in particular, those of
the person or persons responsible for providing the services or carrying out the
works;
b) a list of the principal services provided and supplies delivered in the past three
years, with the sums, dates and recipients, public or private;
c) a description of the measures employed to ensure the quality of supplies and
services, and a description of the firm's study and research facilities;
d) an indication of the technicians or technical bodies involved, whether or not
belonging directly to the firm, especially those responsible for quality control;
e) a statement of the average annual manpower and the number of managerial staff
of the service provider or contractor in the last three years;
f) an indication of the proportion of the contract which the service provider may
intend to subcontract.

Where the services or supplies referred to in point (b) of the first subparagraph are
provided to contracting authorities (incl. the Commission), evidence of
performance shall be in the form of certificates issued or countersigned by the
competent authority.

3. Where the services or products to be supplied are complex or, exceptionally, are
required for a special purpose, evidence of technical and professional capacity may
be secured by means of a check carried out by the Commission or on its behalf by
a competent official body of the country in which the service provider or supplier
is established, subject to that body's agreement. Such checks shall concern the
supplier's technical capacity and production capacity and, if necessary, its study
and research facilities and quality control measures.

14. Tenders from consortiums of firms or groups of service providers,
contractors or suppliers

Tenders from consortiums of firms or groups of service providers, contractors or
suppliers must specify the role, qualifications and experience of each member or
group.
Proof of eligibility, Certification with respect to the Exclusion Criteria and
documents on exclusion and selection criteria must be supplied by each member of
the consortiums of firms or groups of service providers (or contractors or suppliers,
depending on the type of contract) submitting a single tender.

Technical part

15. Award criteria
The contract will be awarded to the tenderer who submits the most
economically advantageous bid, as assessed on the basis of the following
factors:
(a) Technical evaluation criteria in their order of importance as weighted by percentage:

<table>
<thead>
<tr>
<th>No</th>
<th>Qualitative Award criteria</th>
<th>Weighting (max. points)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Understanding of the nature, the scope and objectives of the work to be done and of the means needed to be deployed for its development and conduct.</td>
<td>20</td>
</tr>
<tr>
<td>2.</td>
<td>Organisational structure within the team and breakdown of the work plan so as to perform the work within the time scale required.</td>
<td>20</td>
</tr>
<tr>
<td>3.</td>
<td>Methodology of the work; the manner in which the work will be carried out, including the schedule of tasks and description of the activities to be undertaken, availability and gaps in data strategy and steps to fill the gaps.</td>
<td>40</td>
</tr>
<tr>
<td>4.</td>
<td>Scientific quality of the tender, clarity and precision</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td><strong>Total points</strong></td>
<td><strong>100</strong></td>
</tr>
</tbody>
</table>

A tender must achieve a minimum score of 65% of the award criteria to be eligible for selection.

(b) Price.

The total price is estimated at maximum 250,000 euro (two hundred and fifty thousand euro, excluding VAT and other taxes, as specified under 16 below).

The price includes all costs and cover costs of a team of experts, consultancies, meetings, secretarial support, data-processing, translations, printing etc. as set out in this tender.

The contract will be awarded under the best-value-for-money procedure.

**Financial part**

16. Prices
- Prices must be quoted in Euro using, if necessary, the conversion rates published in the C series of the Official Journal of the European Union on the day when the contract notice was published (if no notice was published, on the day when the invitation to tender was sent out).
- Prices must be fixed amounts in euro.
- Estimated travel and subsistence expenses must be indicated separately. This estimate should be based on Article I.3.2 of the contract annexed to these specifications and include any travel required to meet representatives of DG Health and Consumer Protection. In any event, it should represent the maximum amount of travel and subsistence expenses payable for all the services provided.

- Prices should be quoted free of all duties, taxes and other charges, including VAT, as the Communities are exempt from such charges under Articles 3 and 4 of the Protocol on the privileges and immunities of the European Communities; the amount of VAT should be shown separately.

- Prices are firm and not subject to revision until the contract is signed.

- **Prices must be presented in the standard format of Annex V.**

**Annexes:**

I: Tender submission form  
II: Financial identification form  
III: Form for natural persons only  
IV: Certification with respect to the exclusion criteria  
V: Budget  
VI: Contract and Annexes