



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 December 2014
EMA/700115/2014

Dear Tenderer

Subject: Procurement Procedure EMA-2014-49-AUD for the provision of audit services advertised in OJEU no. S 238 of 10 December.

1. Please find enclosed the tender documents relating to the above-mentioned invitation to tender. Attached to this letter you will find a "tender acknowledgement form". I would be grateful if you would complete and return it to me within seven days of receipt of this letter to indicate whether or not you intend to submit a tender.
2. If you are interested in participating in this tender, please submit one tender in one original paper copy with one copy of all documents on CD-ROM. Please note only one tender per tenderer can be submitted (this includes only one financial tender (costing sheet)). Any tenderer submitting more than one tender shall be eliminated from the procedure. In case of any discrepancy the paper copy shall prevail over the copy on CD-ROM. Please submit to the following address which should be clearly marked as follows on the outer envelope:

Edit Weidlich
Head of Audit
European Medicines Agency
Procurement Procedure – Reference: EMA-2014-49-AUD
30 Churchill Place
Canary Wharf
London E14 5EU

Please note that no tender may be submitted by electronic mail. Any tender submitted in such a way will be immediately eliminated from the procedure.

Tenderers should note that the Agency is unable to accept electronic signatures on the paper copy.

3. Tenders must be submitted in one of the following ways:
 - Either by **registered post or by courier service**, dispatched no later than 23 January 2015, the postmark or the date of the deposit slip with the courier service serving as proof of posting date/time.
 - **Or by hand delivery** to the Agency no later than 1200H on 23 January 2015, directly or by a representative of the tenderer.
 - In the case where deliveries are effected by hand, the deadline to be respected shall be the date and time of **delivery** cited above and not the date of transmission/deposition by the tenderer to its representative. The said delivery must be effected against a dated and signed receipt given by a member of staff of the Agency or its representative.



- Please note that in the case of delivery by hand or by courier service, the envelope should be addressed as in point 2 above but delivery must be made to the following address:

European Medicines Agency
30 Churchill Place
Loading Bay
Canary Wharf
London, E14 5EU

4. Tenders must be submitted in one or more envelopes which are sealed, each enclosed inside a second sealed envelope. The following must be written on the inner envelope(s) in addition to the name and address as given in point 2 above:

Tender Procurement Procedure – Reference: EMA-2014-49-AUD Attn. of Edit Weidlich, Head of Audit NOT TO BE OPENED BY THE INTERNAL MAIL SERVICE

If self-adhesive envelopes are used, they must be sealed with adhesive tape and the sender must sign across this tape.

Boxes may be used instead of envelopes if the size or weight of the tender so requires.

Labels are attached to this letter which you may use for the submission of your tender for both the inner and outer envelopes.

Any financial element (including costing sheet) must be submitted in separate binders or folders and on separate CD-ROM, which must be clearly labelled. Information relating to this element should be given nowhere else in the tender.

All documents in electronic copy on the CD-ROM should be in either Adobe Portable Document Format (.pdf) or in standard Office 2003/7 format (i.e. doc and .xls).

In order to reduce the amount of paper submitted, the Agency requests that tenders are presented in the following way:

- (1) always using double-sided printing;
- (2) avoiding use of unnecessary plastic folders or binders;
- (3) avoiding inclusion of attachments (brochures, booklets, general publicity material etc) which are not requested by the Agency;
- (4) choosing a simple and clear structure.

The technical specifications for this tender as well as the draft contract are attached to this invitation to tender letter. The technical specifications indicate clearly which documents are required to submit a tender as well as the supporting documents which must be enclosed.

5. All tenders must:

- Be signed by the tenderer or his authorised representative.
- Be perfectly legible in order to avoid any doubt about terms and/or figures included.

- Include the costing sheet or other model documents as indicated in the technical specifications.
6. All tenders submitted must be valid for a period of six months from the closing date for receipt of tenders during which the tenderer may not modify the terms of the tender in any respect.
 7. The submission of a tender in response to this invitation to tender automatically implies the tenderer's acceptance of all the terms and conditions stipulated in the invitation to tender, the current technical specifications and annexes including the draft contract. It also implies that the tenderer renounces his own terms and conditions. This is binding on the tenderer to whom the contract is awarded for the duration of the contract. You are requested to confirm acceptance of the draft contract and terms and conditions of this tender as part of your tender response.
 8. Contacts between the Agency and tenderers are prohibited throughout the procedure save in exceptional circumstances and under the following conditions only:

Before the final date for submission of tender:

At the request of the tenderer, the Agency may provide additional information solely for the purpose of clarifying the nature of the contract. Should a tenderer have a question, this should be submitted in writing (by letter or by e-mail) to:

Edit Weidlich
Head of Audit
European Medicines Agency
30 Churchill Place
London E14 5EU
E-mail: EMA-2014-49-AUD@ema.europa.eu

Requests for additional information received less than five calendar days before the closing date for submission of tenders will not be processed for practical reasons.

The attention of tenderers is drawn to the fact that the Agency will remain closed from 24/12/2014 until 02/01/2015. Any requests for clarification submitted during this period will be answered as soon as possible after the Agency has re-opened on 5 January 2015. Please also note that the response time for this tender has been extended due to the Christmas closure.

The Agency may also, on its own initiative, inform tenderers of any error, inaccuracy, omission or other clerical error in the text of the contract notice, invitation to tender letter or technical specifications and their annexes.

Any additional information including that referred to above will be made available in an identical manner simultaneously to all tenderers.

After the opening of tenders:

If clarification is required or if obvious clerical errors in the tender need to be corrected, the Agency may contact the tenderer provided the terms of the tender are not modified as a result.

9. This invitation to tender does not constitute any contractual obligation on the part of the Agency. The Agency's obligation commences only upon signature of a contract with the successful tenderer.

The Agency may, until the contract is signed, withdraw from the contract or cancel the procurement procedure without any compensation to tenderers. In such a situation a decision to cancel would be notified to all tenderers.

10. Processing your reply to the invitation to tender may involve the recording and processing of personal data (such as names, addresses and Curricula Vitae). Such data will be processed pursuant to Regulation (EC) No 45/2001 on the protection of individuals with regard to the

processing of personal data by the European Union institutions and bodies and on the free movement of such data. Unless indicated otherwise, your replies to the questions and any personal data requested are required to evaluate your tender in accordance with the specifications of the invitation to tender and will be processed solely for that purpose and, if necessary, for any other relevant purposes which may be specified by the Agency. Details concerning the processing of your personal data are available on the privacy statement on the Agency's website at:

http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/12/WC500136168.pdf

11. You are informed that for the purposes of safeguarding the financial interest of the European Union, your personal data may be transferred to internal audit services, to the Court of Auditors, to the Financial Irregularities Panel and/or to the European Anti-Fraud Office (OLAF).

Data of economic operators which are in one of the situations referred to in Articles 106, 107, 109(1)(b) and 109(2)(a) of the general Financial Regulation¹ may be included in a central database and communicated to the designated persons of the European Commission, other institutions, agencies, authorities and bodies mentioned in Article 108 (1) and (2) of the general Financial Regulation. This refers as well to the persons with powers of representation, decision making or control over the said economic operators. Any party entered into the database has the right to be informed of the data concerning it upon request to the Agency. The Agency will obtain the requested information from the accounting officer of the European Commission. The privacy statement for the central database of the European Commission is available at:

http://ec.europa.eu/budget/library/explained/management/protecting/privacy_statement_ced_en.pdf

12. Tenders will be opened at the Agency's premises on 28 January 2015 at 10.30am. One representative per tenderer is permitted to be present at the opening of the tenders. The name of any such representative is to be notified in advance in writing to the Agency to the address given in point 2 of this letter.

All tenderers will be informed of the outcome of their tender.

I inform you that the Agency has published a Guidebook for Tenderers which may be downloaded from its external website at <http://ema.europa.eu/>. It is recommended that you read this Guidebook before preparing your tender submission.

Yours faithfully



Andreas Pott

Authorising Officer

Encs:

1. Labels for submission of a tender
2. Tender acknowledgement form
3. Technical Specifications and draft contract

¹ Council Regulation (EC, Euratom) N° 996/2012 of 25 October 2012.

Label for the outer envelope

Edit Weidlich, Head of Audit

Audit – AF-AUD

European Medicines Agency

Procurement Procedure – Reference: EMA-2014-49-AUD

30 Churchill Place

Canary Wharf

London E14 5EU

NOT TO BE OPENED BY THE INTERNAL MAIL SERVICE

Label for the inner envelope

Tender

Procurement Procedure – Reference: EMA-2014-49-AUD

Attn. Edit Weidlich, Head of Audit (AF-AUD)

NOT TO BE OPENED BY THE INTERNAL MAIL SERVICE

Tender acknowledgement form

To: Edit Weidlich, Head of Audit European Medicines Agency 30 Churchill Place Canary Wharf LONDON E14 5EU UK	From:
--	-------

Date: [complete]

Dear Ms Weidlich

Subject: Procurement Procedure no. EMA-2014-49-AUD for provision of audit services – OJEU reference no. S 238.

- * We intend to submit a tender in accordance with your instructions².
- * We are unable/do not wish to submit a tender. Our reasons are set out below. The invitation to tender documentation is enclosed/is being returned under separate cover³.

Please submit your reasons here (or in a separate letter) for declining the opportunity to submit a tender.

Yours sincerely

For and on behalf of:

Note to tenderers: completion and return of this form is requested but is not mandatory. Responses received are treated in confidence for internal evaluation purposes only and will have no consequences for the tenderers.

² Delete as applicable.

³ Delete as applicable.