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Tender

eCTD Solution

MHRA

F02: Contract notice

Notice identifier: 2022/S 000-033565

Procurement identifier (OCID): ocds-h6vhtk-038895

Published 25 November 2022, 4:53pm

Section I: Contracting authority

I.1) Name and addresses

MHRA

10 South Colonnade

London

E14 4PU

Contact

Purchasing

Email

Purchasing@mhra.gov.uk

Telephone

+44 2030806000

Country

United Kingdom

Region code

UK - United Kingdom

Internet address(es)

Main address

<https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency>

Buyer's address

<https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency>

I.3) Communication

The procurement documents are available for unrestricted and full direct access, free of charge, at

<https://health-family.force.com/s/Welcome>

Additional information can be obtained from the above-mentioned address

Tenders or requests to participate must be submitted electronically via

<https://health-family.force.com/s/Welcome>

Tenders or requests to participate must be submitted to the above-mentioned address

Electronic communication requires the use of tools and devices that are not generally available. Unrestricted and full direct access to these tools and devices is possible, free of charge, at

<https://health-family.force.com/s/Welcome>

I.4) Type of the contracting authority

National or federal Agency/Office

I.5) Main activity

Health

Section II: Object

II.1) Scope of the procurement

II.1.1) Title

eCTD Solution

II.1.2) Main CPV code

- 72261000 - Software support services

II.1.3) Type of contract

Services

II.1.4) Short description

MHRA is embarking on the development of a next generation Regulatory Management System (RMS) that will replace multiple legacy systems with converged technology platforms to support the agency regulation of medicinal products and medical devices.

In order to support medicinal regulatory management, one component of the new platform identified is a technology solution to facilitate the management of information using the eCTD format (ICH electronic Common Technical Document).

II.1.5) Estimated total value

Value excluding VAT: £6,000,000

II.1.6) Information about lots

This contract is divided into lots: No

II.2) Description

II.2.2) Additional CPV code(s)

- 48517000 - IT software package
- 48100000 - Industry specific software package

II.2.3) Place of performance

NUTS codes

- UKI - London

II.2.4) Description of the procurement

Please see section VI.3 of this notice.

II.2.5) Award criteria

Price is not the only award criterion and all criteria are stated only in the procurement documents

II.2.6) Estimated value

Value excluding VAT: £6,000,000

II.2.7) Duration of the contract, framework agreement or dynamic purchasing system

Duration in months

60

This contract is subject to renewal

Yes

Description of renewals

The Contract will have an initial duration of 5 years, with an option for the Agency to extend it for a further period of up to 5 years more.

II.2.9) Information about the limits on the number of candidates to be invited

Envisaged minimum number: 3

Maximum number: 5

Objective criteria for choosing the limited number of candidates:

Criteria to be used for selecting the candidates appear in the Standard Selection Questionnaire Guidance document.

II.2.10) Information about variants

Variants will be accepted: Yes

II.2.11) Information about options

Options: Yes

Description of options

Please see section VI.3 of this notice.

II.2.13) Information about European Union Funds

The procurement is related to a project and/or programme financed by European Union funds: No

Section III. Legal, economic, financial and technical information

III.1) Conditions for participation

III.1.2) Economic and financial standing

List and brief description of selection criteria

Selection criteria as stated in the procurement documents

III.1.3) Technical and professional ability

List and brief description of selection criteria

Selection criteria as stated in the procurement documents

Section IV. Procedure

IV.1) Description

IV.1.1) Type of procedure

Competitive procedure with negotiation

IV.1.4) Information about reduction of the number of solutions or tenders during negotiation or dialogue

Recourse to staged procedure to gradually reduce the number of solutions to be discussed or tenders to be negotiated

IV.1.5) Information about negotiation

The contracting authority reserves the right to award the contract on the basis of the initial tenders without conducting negotiations

IV.1.8) Information about the Government Procurement Agreement (GPA)

The procurement is covered by the Government Procurement Agreement: Yes

IV.2) Administrative information

IV.2.2) Time limit for receipt of tenders or requests to participate

Date

28 December 2022

Local time

4:00pm

IV.2.4) Languages in which tenders or requests to participate may be submitted

English

IV.2.6) Minimum time frame during which the tenderer must maintain the tender

Duration in months: 9 (from the date stated for receipt of tender)

Section VI. Complementary information

VI.1) Information about recurrence

This is a recurrent procurement: No

VI.2) Information about electronic workflows

Electronic ordering will be used

Electronic invoicing will be accepted

Electronic payment will be used

VI.3) Additional information

The Agency is seeking an eCTD solution and subsequent support for that solution. Bidders must be aware that there are; supply, implementation, and support requirements.

Please indicate your interest by registering at <https://health-family.force.com/s/Welcome>, this is the address at which the procurement documents will be available for unrestricted and full direct access, free of charge.

Options for the procurement are shown in the procurement documents.

The contracting authority is not a centralised purchasing body, and no other form of joint procurement is or may be involved.

Estimated nature and quantity or value of supplies: Industry specific software package, Software support services; between £5,000,000.00 and £6,000,000.00.

Please note, the above value is for the initial period; depending on the renewals and options taken the total contract value over the entire term may be up to £12,000,000.00.

Please contact purchasing@mhra.gov.uk and quote "Procurement Project Ref: eCTD Solution" for further information.

The Agency reserves the right to terminate, discontinue, suspend and/or abandon this Procurement Exercise (in whole or in part) at any time prior to contract award without incurring any liability to the affected Applicants and/or Bidders.

The Agency may have an affordability cap but this is not currently known. Bidders will be made aware of any known affordability caps that affect evaluation when evaluation exercises are undertaken

VI.4) Procedures for review

VI.4.1) Review body

Royal Courts of Justice

Strand

London

WC2A 2LL

Email

royalcourtsofjustice.jc@gov.uk

Country

United Kingdom

Internet address

<https://www.gov.uk/>

VI.4.2) Body responsible for mediation procedures

Centre for Effective Dispute Resolution

70 Fleet Street

London

EC4Y 1EU

Email

info@cedr.com

Country

United Kingdom

Internet address

<https://www.cedr.com/>