

United Kingdom-Potters Bar: System quality assurance assessment and review services

OJ S 106/2018 06/06/2018

Contract notice

Services

Legal Basis:

Directive 2014/24/EU

Section I: Contracting authority

I.1. Name and addresses

Official name: Medicines and Healthcare Products Regulatory Agency (MHRA)

Postal address: NIBSC, Blanche Lane, South Mimms

Town: Potters Bar, Hertfordshire

NUTS code: UK United Kingdom

Postal code: EN6 3QG

Country: United Kingdom

E-mail: purchasing@nibsc.org

Telephone: +44 1707641000

Internet address(es):Main address: https://mhra.bravosolution.co.uk/web_mhra/login.html**I.3. Communication**

Access to the procurement documents is restricted. Further information can be obtained at:

https://mhra.bravosolution.co.uk/web_mhra/login.html

Additional information can be obtained from the abovementioned address

Tenders or requests to participate must be submitted electronically via: https://mhra.bravosolution.co.uk/web_mhra/login.html

Tenders or requests to participate must be submitted to the abovementioned address

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**

Notified body and ISO13485:2016 certification body

II.1.2. Main CPV code

72225000 System quality assurance assessment and review services

II.1.3. Type of contract

Services

II.1.4. Short description

The Medicines and Healthcare products Regulatory Agency is preparing to tender for a new Notified Body and ISO 13485 certifying body for one of its centre "National Institute for Biological Standards and Control (NIBSC)". NIBSC is a multi-disciplinary scientific establishment whose purpose is to safeguard and enhance public health by standardising and controlling biological substances used in medicines. One of its key roles is the production of reference materials including in vitro diagnostic devices (IVDs) and we are preparing to tender for a new Notified Body and ISO 13485:2016 certification body. We currently have 45 staff that are involved in the design and manufacture of 91 IVD products of which, 44 are currently Annex II List A and List B, and 47 are currently self-certified.

II.1.5. Estimated total value

II.1.6. Information about lots

This contract is divided into lots: no

II.2. Description

II.2.3. Place of performance

NUTS code: UK United Kingdom

II.2.4. Description of the procurement

The Medicines and Healthcare products Regulatory Agency is preparing to tender for a new Notified Body and ISO 13485 certifying body for one of its centre "National Institute for Biological Standards and Control (NIBSC)". NIBSC is a multi-disciplinary scientific establishment whose purpose is to safeguard and enhance public health by standardising and controlling biological substances used in medicines. One of its key roles is the production of reference materials including in vitro diagnostic devices (IVDs) and we are preparing to tender for a new Notified Body and ISO 13485:2016 certification body. We currently have 45 staff that are involved in the design and manufacture of 91 IVD products of which, 44 are currently Annex II List A and List B, and 47 are currently self-certified.

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

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

Duration in months: 36

This contract is subject to renewal: yes

Description of renewals:

Couple of extensions.

II.2.10. Information about variants

Variants will be accepted: no

II.2.11. Information about options

Options: no

II.2.13. Information about European Union funds

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

II.2.14. Additional information

Section IV: Procedure

IV.1. Description

IV.1.1. Type of procedure

Open procedure

IV.1.3. Information about a framework agreement or a dynamic purchasing system

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: 03/07/2018 Local time: 13:00

IV.2.3. Estimated date of dispatch of invitations to tender or to participate to selected candidates

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

Tender must be valid until: 30/09/2018

IV.2.7. Conditions for opening of tenders

Date: 04/07/2018 Local time: 13:00

Section VI: Complementary information

VI.1. Information about recurrence

This is a recurrent procurement: yes

VI.3. Additional information

VI.4. Procedures for review

VI.4.1. Review body

Official name: Medicines and Healthcare Products Regulatory Agency

Town: Potters Bar

Country: United Kingdom

VI.4.2. Body responsible for mediation procedures

Official name: Medicines and Healthcare Related Products Regulatory Agency

Town: South Mimms, Potters Bar, Herts

Country: United Kingdom

Telephone: +44 1707641000

VI.4.4. Service from which information about the review procedure may be obtained

Official name: Medicines and Healthcare Related Products Regulatory Agency

Town: South Mimms, Potters Bar, Herts

Country: United Kingdom

Telephone: +44 1707641000

VI.5. Date of dispatch of this notice

04/06/2018