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Planning

Quality Management System (MDR Compliance)

The Common Services Agency (more commonly known as NHS National Services Scotland) ("NSS")

F01: Prior information notice

Prior information only

Notice identifier: 2022/S 000-012232

Procurement identifier (OCID): ocds-h6vhtk-033665

Published 11 May 2022, 11:20am

Section I: Contracting authority

I.1) Name and addresses

The Common Services Agency (more commonly known as NHS National Services Scotland) ("NSS")

Gyle Square (NSS Head Office), 1 South Gyle Crescent

Edinburgh

EH12 9EB

Contact

Ope Ore

Email

ope.ore@nhs.scot

Telephone

+44 7866157482

Country

United Kingdom

NUTS code

UKM - Scotland

Internet address(es)

Main address

<http://www.nss.nhs.scot/browse/procurement-and-logistics>

Buyer's address

https://www.publiccontractsscotland.gov.uk/search/Search_AuthProfile.aspx?ID=AA11883

I.2) Information about joint procurement

The contract is awarded by a central purchasing body

I.3) Communication

Additional information can be obtained from the above-mentioned address

I.4) Type of the contracting authority

Body governed by public law

I.5) Main activity

Health

Section II: Object

II.1) Scope of the procurement

II.1.1) Title

Quality Management System (MDR Compliance)

Reference number

NP605721

II.1.2) Main CPV code

- 72000000 - IT services: consulting, software development, Internet and support

II.1.3) Type of contract

Services

II.1.4) Short description

NSS occupies a unique place in the delivery of Health and Social Care across Scotland in that it manufactures (as defined by the MHRA), owns, manages, procures, maintains, uses, stores and disposes a large variety of Medical Devices (both hardware and software), which are subject to the UK Medical Device Regulations. As part of the process to achieve and maintain compliance with the Regulations, a Quality Management System (consistent with ISO 13485) is required. While the regulations do not define the nature of the Quality Management System (QMS), which may be paper based or electronic, NSS is interested in discovering available electronic QMS solutions that will complement the QMS processes.

II.1.6) Information about lots

This contract is divided into lots: No

II.2) Description

II.2.2) Additional CPV code(s)

- 72000000 - IT services: consulting, software development, Internet and support

II.2.3) Place of performance

NUTS codes

- UKM - Scotland

Main site or place of performance

Scotland

II.2.4) Description of the procurement

NHS Scotland is exploring all the available options of Quality Management Systems to ensure compliance with the new and evolving requirements of the Regulations.

The objective of this exercise is to obtain up-to-date information and feedback from the market in order to:

Understand the capabilities and solutions in relation to the functionality and usability required;

Understand where innovation and the “state of the art” may provide opportunities for NSS to improve efficiency, effectiveness and Patient Safety; and

Provide NSS with a deployment overview and indicative costs associated with the implementation and on-going support of a suitable solution

The information to be provided will help us better understand the market and consider the way forward. Views and suggestions will not be disclosed to third parties or used for any other purpose.

II.2.14) Additional information

For further information please review the attached document titled 'MDR Compliance QMS PIN v.1.0'

II.3) Estimated date of publication of contract notice

1 September 2023

Section IV. Procedure

IV.1) Description

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

The procurement is covered by the Government Procurement Agreement: Yes

Section VI. Complementary information

VI.3) Additional information

NOTE: To register your interest in this notice and obtain any additional information please visit the Public Contracts Scotland Web Site at

https://www.publiccontractsscotland.gov.uk/Search/Search_Switch.aspx?ID=692447.

(SC Ref:692447)