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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](mailto: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](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

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## **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

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## **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

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## **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](https://www.publiccontractsscotland.gov.uk/Search/Search_Switch.aspx?ID=692447).

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