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Planning

## **GMP compliant Radiopharmaceutical Production Unit**

Guy's and St Thomas' NHS Foundation Trust

F01: Prior information notice

Prior information only

Notice identifier: 2023/S 000-012915

Procurement identifier (OCID): ocids-h6vhtk-03c69e

Published 5 May 2023, 11:20am

### **Section I: Contracting authority**

#### **I.1) Name and addresses**

Guy's and St Thomas' NHS Foundation Trust

Great Maze Pond

London

SE1 9RT

#### **Contact**

Adam Crowe

#### **Email**

[adam.crowe@gstt.nhs.uk](mailto:adam.crowe@gstt.nhs.uk)

#### **Country**

United Kingdom

## **Region code**

UKI44 - Lewisham and Southwark

## **Internet address(es)**

Main address

<https://www.guysandstthomas.nhs.uk>

Buyer's address

<https://www.guysandstthomas.nhs.uk>

## **I.3) Communication**

Additional information can be obtained from 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**

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**

GMP compliant Radiopharmaceutical Production Unit

Reference number

ST23-P028

#### **II.1.2) Main CPV code**

- 85121200 - Medical specialist services

#### **II.1.3) Type of contract**

Services

#### **II.1.4) Short description**

To develop a new, purpose-built, GMP compliant Radiopharmaceutical Production Unit for the aseptic manufacture of radiopharmaceuticals. The unit is to realise the productivity and commercial potential of the Radiopharmacy department and become an exemplar NHS Nuclear Medicine Unit providing training and education opportunities to the next generation of Radiopharmacists.

The Unit will ensure equity of patient access to the increasing pipeline of RP diagnostics and therapeutics over the next 15-20 years and deliver the most innovative clinical research at its Investigational Medicinal Products (IMP) and Specials licensed facilities.

#### **II.1.5) Estimated total value**

Value excluding VAT: £40,000,000

#### **II.1.6) Information about lots**

This contract is divided into lots: No

### **II.2) Description**

## **II.2.2) Additional CPV code(s)**

- 85111200 - Medical hospital services

## **II.2.3) Place of performance**

NUTS codes

- UKI44 - Lewisham and Southwark

Main site or place of performance

St Thomas' Hospital, Westminster Bridge Road, London, SE1 7EH

## **II.2.4) Description of the procurement**

The Authority, Guy's and St Thomas' NHS Foundation Trust (GSTT) is seeking expressions of interest from strategic and operational industry partners for the provision of Radiopharmacy (RP) services which ensure the realisation of the service's ambition:

To develop a new, purpose-built, GMP compliant Radiopharmaceutical Production Unit for the aseptic manufacture of radiopharmaceuticals. The unit is to realise the productivity and commercial potential of the Radiopharmacy department and become an exemplar NHS Nuclear Medicine Unit providing training and education opportunities to the next generation of Radiopharmacists.

The Unit will ensure equity of patient access to the increasing pipeline of RP diagnostics and therapeutics over the next 15-20 years and deliver the most innovative clinical research at its Investigational Medicinal Products (IMP) and Specials licensed facilities.

Radiopharmacy sits in the Integrated and Specialist Medicine (ISM) directorate at GSTT, within CLIMP (Clinical Imaging and Medical Physics), and is part of the Nuclear Medicine Department based in the Borough Wing at Guy's Hospital. The unit manufactures tracers used in diagnostics scans, which are used to detect a wide range of conditions (including injuries; infections; tumours; heart disease; thyroid abnormalities; and kidney conditions) and also guide some cancer procedures.

Commerical Opportunity

RP has seen significant growth in recent years. Manufacturing service lines have generated £2.5m in billings (fy21/22) and is forecast to generate circa £3m in revenues for fy22/23. We plan to double this within five years and treble revenues within 10 years.

RP is currently unable to realise its potential and increase capacity due to ageing facilities, lack of space and lack of resources. The unit frequently has to turn down opportunities to

increase production. This equates to £x00,000s of missed opportunity and unfulfilled orders, per annum. There is huge potential to increase production of radiopharmaceuticals as a number of market forces are currently driving up demand of RP's services, including:

- Increased use of theranostic combinations involving Gallium-68 e.g. prostate cancer and neuroendocrine tumours (NET) where radiopharmaceuticals are required for screening prior to therapy.
- Increased demand for routine Gallium-68 based radiopharmaceuticals including Ga-68-PSMA (prostate cancer) and Ga-68-DOTATATE (Neuroendocrine tumours (NETs) for diagnostic imaging, (both are commissioned by NHS England).
- Increased interest in research-based Gallium-68- tracers coming into clinical studies e.g. Ga-68-FAPI.
- Compromised supply while other units are shut (Guildford, Addenbrookes), due to tighter compliance and regulations, decreasing national capacity to supply radiotracers and increasing demand in compliant units.
- Lack of capacity in London for blood labelling driving up demand for those able to supply this service.
- Increased interest in cell tracking for Advanced Therapy Medicinal Products including CAR-T cell therapy.
- Lack of capacity elsewhere for producing radiopharmaceuticals for clinical trials.
- Increased interest in radiotracers for clinical trials (including novel radiopharmaceuticals emerging from the Imaging Sciences research laboratories at King's College London).
- Increased interest in radiopharmaceutical therapies in clinical trials, including Lu-177, Ac-225 and Pb-212

#### Current Client Base

Our current client base is centred around Guy's and St Thomas' NHS Foundation Trust (Nuclear Medicine Department, Guy's Cancer Centre and the PET centre at St Thomas' Hospital). Radiopharmaceuticals are also provided daily to King's College NHS Foundation Trust; their Princess Royal Hospital site in Orpington; and a broad diverse range of private hospitals.

#### Existing RP services include:

Manufacture of Diagnostic Tc-99m based radiopharmaceuticals

Tc-99m is the most commonly used radioisotope for radiolabelling radiopharmaceuticals and is used for diagnosis of a wide range of medical conditions. The unit currently produces approximately c7000 vials per annum.

Dispensing of diagnostic and therapeutic radiopharmaceuticals

The unit prepares non-Tc-99m diagnostic and therapeutic radiopharmaceuticals (including I-123, In-111, Se-75 and Ra-223 based radiopharmaceuticals),

Manufacture of Ga-68 based radiopharmaceuticals

The unit manufactures routine and research Ga-68 radiopharmaceuticals, the most important of which are Ga-68 DOTATE (imaging of neuroendocrine tumours) and Ga-68

PSMA (imaging of prostate cancer).

Blood Cell Labelling

White cells and denatured red cells are radiolabelled on site and then provided to a range of internal departments and external clients. The most common cell labelling conducted is for Red Cell Mass studies and ad hoc white cell-labelling.

Clinical Trials

RP holds a Manufacture of Investigational Medicinal Products licence (MIA(IMP)) and has manufactured novel radiopharmaceuticals for clinical trials, as well as producing radiopharmaceuticals for clinical studies.

eGFR (kidney function) services

RP supports the eGFR service by processing and counting blood samples.

RP's current manufacturing portfolio can be found in appendix #1

RP current cost modelling

RP costing model considers consumables, staff time, overheads and running costs for the unit in order to calculate cost per unit dose before applying a profit margin to facilitate future investment, maintenance and growth.

## **II.2.14) Additional information**

Please contact Adam Crowe for a fuller draft project brief and for a questionnaire to assist us.

Adam Crowe (B.A.Hons, ACIM, ABPI)

Commercial Service Directorate

Guy's and St Thomas' NHS Foundation Trust

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## **II.3) Estimated date of publication of contract notice**

1 June 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

