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Planning

Qualified Person Service for Investigational Medicinal Product (IMP)

NHS Blood and Transplant

F01: Prior information notice

Prior information only

Notice identifier: 2023/S 000-022326

Procurement identifier (OCID): ocids-h6vhtk-03ec0d

Published 1 August 2023, 1:38pm

Section I: Contracting authority

I.1) Name and addresses

NHS Blood and Transplant

500 North Bristol Park

Bristol

BS34 7QH

Contact

Richard Athay-Hunt

Email

richard.athay-hunt@nhsbt.nhs.uk

Country

United Kingdom

Region code

UKK11 - Bristol, City of

Internet address(es)

Main address

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

Buyer's address

<https://www.nhsbt.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

Section II: Object

II.1) Scope of the procurement

II.1.1) Title

Qualified Person Service for Investigational Medicinal Product (IMP)

Reference number

C197288

II.1.2) Main CPV code

- 73100000 - Research and experimental development services

II.1.3) Type of contract

Services

II.1.4) Short description

NHSBT are looking to appoint a suitable Qualified Person (QP) on a contract basis to work alongside its existing in-house QPs to support a very active and rapidly growing portfolio of Investigational Medicinal Product (IMP) manufacturing projects.

II.1.5) Estimated total value

Value excluding VAT: £260,000

II.1.6) Information about lots

This contract is divided into lots: No

II.2) Description

II.2.3) Place of performance

NUTS codes

- UKK1 - Gloucestershire, Wiltshire and Bristol/Bath area

II.2.4) Description of the procurement

NHSBT are looking to appoint a suitable Qualified Person (QP) on a contract basis to work alongside its existing in-house QPs to support a very active and rapidly growing

portfolio of Investigational Medicinal Product (IMP) manufacturing projects. NHSBT has developed the capability over at least 20 years to manufacture a range of Biotechnology, Gene Therapy, Cell Therapy and Tissue Engineered Medicinal Products for Phase I/II clinical Trials. Many of these are categorised as Advanced Therapy Medicinal Products (ATMP) in accordance with EU Regulations. IMP manufacture is focused at NHSBT facilities in Barnsley, Bristol, Birmingham, and Liverpool holding appropriate MIA(IMP). NHSBT manufacture IMP for both internally sponsored Clinical Trials and under contract for academic and commercial clients.

The services we require the Qualified Person (QP) to support are as follows:

- Advice on regulatory and quality compliance requirements for specific Biological and ATMP manufacturing projects.
- Input to selected regulatory submissions
- Input to design of selected processes and facilities
- QP Certification of batches of biological & ATMP for use in approved clinical trials
- Mentoring of selected NHSBT staff through the process of obtaining QP registration

II.3) Estimated date of publication of contract notice

20 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: No