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Planning

Supply of Viral Vector Plasmids

NHS Blood and Transplant

F01: Prior information notice

Prior information only

Notice identifier: 2024/S 000-029545

Procurement identifier (OCID): ocds-h6vhtk-049b21

Published 16 September 2024, 1:16pm

Section I: Contracting authority

I.1) Name and addresses

NHS Blood and Transplant

500 North Bristol Park

Bristol

BS34 7QH

Contact

James Marshall

Email

james.marshall2@nhsbt.nhs.uk

Telephone

+44 7386961244

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

Supply of Viral Vector Plasmids

II.1.2) Main CPV code

• 33698000 - Clinical products

II.1.3) Type of contract

Supplies

II.1.4) Short description

Viral Vector Plasmids. Please note this is not the start of a procurement process. A separate contract notice will be published to cover this requirement.

II.1.5) Estimated total value

Value excluding VAT: £3,000,000

II.1.6) Information about lots

This contract is divided into lots: No

II.2) Description

II.2.3) Place of performance

NUTS codes

• UK - United Kingdom

II.2.4) Description of the procurement

NHS Blood & Transplant (NHSBT) are seeking to engage with suppliers of plasmids for Adeno-associated Viral (AAV) vectors, Lentiviral (LV) vectors and other clinically relevant viral vector types via an early market engagement exercise.

NHSBT Clinical Biotechnology Centre (CBC), Filton is part of the Cellular and Molecular Therapies (CMT) function and one of the Innovation Hubs for Gene Therapies in the UK. The CBC, is part of the strategic business CMT function of NHSBT, providing specialist

advanced therapy manufacturing services for clinical trials such as gene therapies. CBC services are part of a national network of four laboratories across England which have a Medicines and Healthcare products Regulatory Agency (MHRA) regulated license for the manufacturing of investigational medicinal products. NHSBT offers viral vector manufacturing services to the Advanced Therapy Medicinal Product (ATMP) sector. NHSBT operates on a not-for-profit basis to support the gene therapy clinical translation from academic and other organisations, therefore cost effectiveness of plasmids is a key factor.

NHSBT seeks to engage with suppliers who provide plasmids with a proven transfection system suitability to produce high titre of viral vectors with greater ratios of full capsids by maintaining required quality standards for the use of these products in clinical use.

NHSBT's requirement is likely to include the following:

- Plasmids must meet the quality standards for viral vector production for clinical use.
- Plasmids should be available at different quality standards including Research and Development (R&D) grade, High-Quality and Good Manufacturing Practices (GMP) grade.
- It is recognised that newer and innovative viral vector plasmids/plasmid systems may become available and that NHSBT may wish to take advantage of these. The supplier must notify NHSBT of any such new developments which are relevant and, where mutually agreed, work with NHSBT to introduce these and make them available to NHSBT.
- AAV Plasmids should be available for all common AAV serotypes. along with any newer and innovative serotypes.
- Plasmids need to be available in different pack sizes from 1mg to 2g.
- All necessary plasmids should be available.
- Plasmids should demonstrate high titre/yield and packaging efficiency.
- AAV Plasmids should demonstrate high ratio of full capsids.
- Demonstration of suitability of the plasmids with different transfection systems is critical.
- Availability of different qualified plasmid identification tests and residual plasmid detections test to satisfy required regulatory authority is advisable.

As part of the early market engagement exercise, NHSBT would like to discuss our requirement with suppliers along with: time frame for supply; whether plasmid suppliers also provide consumables etc; and what innovative plasmids may be available.

It should be noted that other health authorities may be permitted to use any agreements awarded.

It is NHSBT's intention to hold the early market engagement exercise supplier meetings the week of 28th October 2024 (note: dates are subject to change). The meetings will be held remotely. To enable NHSBT to finalise arrangements (e.g. send meeting details and agree time slots), interested organisations are required to send an expression of interest

via email to <u>james.marshall2@nhsbt.nhs.uk</u> by no later than 17:00 hrs (GMT) on Wednesday 16th October. This should include a list of your requested attendees and a brief overview (or a website link) of the Goods / Services which might be of interest to NHSBT in relation to this requirement. Please include options, if available, for a managed service contract.

There is no guarantee that a formal procurement process will be launched as a result of this early market engagement exercise, nor that any contract(s) will be placed. No remuneration or compensation etc will be paid to organisations who take part in this early market engagement exercise. Suppliers should take part in this process only on the basis that they fully understand and accept this position.

II.3) Estimated date of publication of contract notice

16 September 2024

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

We are currently considering whether to award this requirement in lots and reserve the right to do so.