Award

Consultancy Services relating to the design, validation and Qualification of Clean Rooms within Gene Therapy Innovation Manufacturing Centre

UNIVERSITY OF SHEFFIELD

F15: Voluntary ex ante transparency notice
Notice identifier: 2022/S 000-002231
Procurement identifier (OCID): ocds-h6vhtk-030f50
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Section I: Contracting authority/entity

I.1) Name and addresses

UNIVERSITY OF SHEFFIELD

Western Bank

SHEFFIELD

S102TN

Contact

Jamie Shaw

Email

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Telephone

+44 1142221516

Country

United Kingdom

NUTS code

UKE32 - Sheffield

Internet address(es)

Main address

www.sheffield.ac.uk

I.4) Type of the contracting authority

Body governed by public law

I.5) Main activity

Education

Section II: Object

II.1) Scope of the procurement

II.1.1) Title

Consultancy Services relating to the design, validation and Qualification of Clean Rooms within Gene Therapy Innovation Manufacturing Centre

II.1.2) Main CPV code

- 71530000 - Construction consultancy services

II.1.3) Type of contract

Services

II.1.4) Short description

The University of Sheffield (UoS) is establishing a new 'Gene Therapy Innovation Manufacturing Centre' (GTIMC) to advance scientific discoveries into life-changing treatments for patients with life threatening diseases. The Sheffield GTIMC will be one of three cutting edge hubs in the UK dedicated to advancing the clinical development of new genetic treatments. This facility is due to open in the Summer of 2022 and further details can be found at the following link:-

https://www.sheffield.ac.uk/news/new-gene-therapy-innovation-centre-advance-scientific-discoveries-life-changing-treatments

The services to be procured under this VEAT include the Qualification and Validation stages of the build completion of the Research and Development facilities including all Quality Control, Clean Room areas in grades C and grade D environments including obtaining full MHRA Licence.

II.1.6) Information about lots

This contract is divided into lots: No

II.1.7) Total value of the procurement (excluding VAT)

Value excluding VAT: £370,000

II.2) Description

II.2.3) Place of performance

NUTS codes

- UKE32 - Sheffield

Main site or place of performance

Gene Therapy Innovation and Manufacturing Centre, Faculty of Medicine Dentistry of Health, The University of Sheffield

II.2.4) Description of the procurement

Services are required for a number of tasks during the Qualification and Validation stages of the build completion of the Research and Development facilities including all Quality Control, Clean Room areas in grades C and grade D environments in addition to all process areas across the site and supporting site operations such as major infrastructure and support services such as logistics in addition to other areas.

These works are to cover the following areas / requirements:

Qualification Requirement Matrix prepared to track Validation Lifecycle and to support;

MHRA Audit. Used on previous MHRA audits and proved effective;

Validation Assessment, User Requirement Specifications, Validation Plan, Design Document Reviews;

Vendor Document Reviews, Factory Acceptance Tests Site Acceptance Tests (Commissioning);

COTS Installation/Operational Qualification Protocol, Installation Qualification Protocol;

Thermal Mapping Protocol (Empty and Loaded), Operational Qualification Protocol;

Performance Qualification Protocol, Validation Summary Reports.

It is envisaged that the majority of documentation preparation will be carried out remotely from the new build site however close working relationships will be required with attendance at site meetings for all aspects of the build and clean room fit outs will be required therefore an estimate of 50% site attendance is anticipated.

It will be a requirement that the provider will regularly visit the site throughout the construction period to ensure that the build is being documented to a suitable standard to allow for information leveraging into qualification. These visits will also be to ensure that the MHRA are suitably informed throughout all stages of the construction period.

Attendance by the provider and being that professional capacity for all engagement with the MHRA will be a major requirement and throughout the Licence application process and to assist the client in this application process through to successfully licence being granted.

Major recent experience is therefore a pre-request in interaction with the MHRA in the field of both Cell and Gene Therapy, Clean Room Manufacturing, Covid-19 Vaccine Response and recent demonstrated deployment / experience within Cell and Gene Therapy is of the highest importance.

As part of the process of validation and qualification, down stream training will be required to be delivered to allow for periodic validation of clean room areas by incumbent UoS GTIMC and UoS Estates and Facilities staff.

The project has extremely aggressive timelines with build construction due for completion in July 2022 and therefore standing up of this service will be required to be in place during the early stages of February 2022.

II.2.11) Information about options

Options: No

II.2.14) Additional information

Regulation 32 of PCR 2015 is being applied as in 32. (2) (b) (ii)

No contract will be entered into until after a 10 calendar day period from the submission of the VEAT notice date.

Section IV. Procedure

IV.1) Description

IV.1.1) Type of procedure

Negotiated without a prior call for competition

- The works, supplies or services can be provided only by a particular economic operator for the following reason:
    - absence of competition for technical reasons

Explanation:

The University of Sheffield signed an agreement with Cell and Gene Therapy Catapult (CGT Catapult) to tech transfer the Catapult AAV (Adeno-Associated Virus) manufacturing platform to Gene Therapy Innovation and Manufacturing Centre' (GTIMC). This task is one of the milestones under the funding award supporting the establishment of the GTIMC in Sheffield. The milestone must be completed within 12 months of the start of the GTIMC Project, i.e. by end July 2022. Any delay in the tech transfer will also impact on the milestone related to MHRA accreditation of GTIMC due by end Q4 2022.

The GTIMC and University of Sheffield will jointly acquire a technology license from CGT Catapult to be able to use their AAV manufacturing platform. This platform was established and optimised based on the processes developed using the proposed list of equipment.

A single source is therefore proposed to formalise the solution provided by Complete Technical Solutions Ltd for the following reasons: -

Significant recent (within the previous 6 months) experience is therefore a pre-request in interaction with the MHRA in the field of both Cell and Gene Therapy, Clean Room Manufacturing, Covid-19 Vaccine Response and recent demonstrated deployment / experience within Cell and Gene Therapy is of the highest importance.

To increase the U.K. capacity for GMP clinical vector manufacturing using the catapult process to allow for expansion of U.K. skills and training within the GTIMC space and increase partnerships with other academia which will create a fertile ecosystem for innovation and research excellence in this field across academia.

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

The procurement is covered by the Government Procurement Agreement: Yes

Section V. Award of contract/concession

A contract/lot is awarded: Yes

V.2) Award of contract/concession

V.2.1) Date of conclusion of the contract

25 January 2022

V.2.2) Information about tenders

The contract has been awarded to a group of economic operators: No

V.2.3) Name and address of the contractor/concessionaire

Complete Technical Solutions Limited

Manchester

Country

United Kingdom

NUTS code

- UKD36 - Greater Manchester North West

The contractor/concessionaire is an SME

Yes

V.2.4) Information on value of contract/lot/concession (excluding VAT)

Total value of the contract/lot/concession: £370,000

Section VI. Complementary information

VI.4) Procedures for review

VI.4.1) Review body

High Court of England, Wales & Northern Ireland

London

Country

United Kingdom