

United Kingdom-London: Pharmaceutical products

OJ S 98/2014 22/05/2014

Contract notice

Services

Directive 2004/18/EC

## Section I: Contracting authority

---

### I.1. Name and addresses

Official name: Cell Therapy Catapult

Postal address: 12th Floor, Guy's Tower, Great Maze Pond

Town: London

Postal code: SE1 9RT

Country: United Kingdom

For the attention of: Jodie Hill

E-mail: [ojeu@ct.catapult.org.uk](mailto:ojeu@ct.catapult.org.uk)

#### Internet address(es):

General address of the contracting authority: <http://catapult.org.uk/celltherapy>

#### Additional information can be obtained from:

the abovementioned address

**Specifications and additional documents (including documents for competitive dialogue and a dynamic purchasing system) can be obtained from:**

the abovementioned address

**Tenders or requests to participate must be submitted:** the abovementioned address

### I.2. Type of the contracting authority

Other: Private Company Limited by Guarantee

### I.3. Main activity

Other: Cell Therapies

### I.4. Contract award on behalf of other contracting authorities

The contracting authority is purchasing on behalf of other contracting authorities: no

## Section II: Object of the contract

---

### II.1. Description

#### II.1.1. Title attributed to the contract by the contracting authority

Cell Therapy Catapult GMP Manufacturing Partners.

#### II.1.2. Type of contract and place of performance or delivery

Services

Service category No 8: Research and development services

Main site or place of performance: UK.

NUTS code UK United Kingdom

#### II.1.3. Information about a framework agreement or a dynamic purchasing system

The procurement involves the establishment of a framework agreement

#### II.1.4. Information about framework agreement

Framework agreement with several operators

Maximum number Envisaged maximum number of participants to the framework agreement  
: 30

**Duration of the framework agreement**

Duration in years: 4

**Estimated total value of purchases for the entire duration of the framework agreement**

Estimated value excluding VAT: 25 000 000 GBP

**II.1.5. Short description of the contract or purchase(s)**

The Cell Therapy Catapult has recognised the need to engage with established Manufacturing Partners to leverage existing expertise across the Cell Therapy industry in its pursuit of the rapid development, delivery and commercialisation of cell therapies.

The Cell Therapy Catapult has internal activities for analytical, process development and manufacturing proving with its facilities on the 12th Floor of Guy's Hospital. It is desired to partner with centres of excellence for clinical manufacturing activities.

The Cell Therapy Catapult is engaged in numerous projects with an array of diverse products, and therefore wishes to engage in a framework agreement with several suppliers covering a wide range of skills and capabilities in order that these can be leveraged when required.

In order to fulfil its mission, the Cell Therapy Catapult needs to have access to sufficient manufacturing outsource providers to be able to confidently deliver on current and future projects across the entirety of the cell therapy industry. These projects could be internal Cell Therapy Catapult projects or those for which the Cell Therapy Catapult is acting on behalf of a client or partner. For this reason the Cell Therapy Catapult is looking to engage with outsource providers who may be able to offer one or more desired services in the following lots:

Lot 1: Immune cell therapy manufacture (including gene modified immune cell therapy).

Lot 2: Pluripotent derived cell therapy manufacture (iPS or hES).

Lot 3: MSC and other multi-potent cell therapy manufacture.

Lot 4: Other somatic cell therapy manufacture.

Lot 5: 3D culture based cell therapy manufacture.

To enable the manufacture in the specific lots the organisation should have experience, expertise and technology that includes the following activities where relevant to the particular lot:

— MHRA MIA(IMP) license for cell therapy applications (or equivalent local license outside of the UK);

— HTA license for donor material procurement testing (or equivalent local license outside of the UK);

— Hosting of GMP audits;

— Tech transfer support for incoming processes, including ability to absorb Catapult staff into the facility to aid tech transfer;

— Preparation of batch documentation;

— Manufacturing technologies and capability to enable processes may include but should not be limited to:

- Non-enclosed processing (using MBSCs within grade B background or isolators within grade C or grade D background);

- Enclosed processing (using closed systems in a grade C or grade D background);

- Adherent cell culture in T-flasks, cell factories and on microcarriers in bioreactors;

- Suspension culture of cells in static mode and in bioreactors;

- 3D culture of cells on surfaces;

- Cell separation;

- Cell activation;

- Differentiation;
- Volume reduction and washing of cells;
- Aseptic vial/bag filling;
- Product labelling;
- Cryopreservation;
- QC analytical testing of final products, in-process controls and raw materials;
- QA batch review;
- QP release of clinical material;
- Regular project meetings to report progress.

#### **II.1.6. CPV code(s)**

33600000 Pharmaceutical products, 71900000 Laboratory services, 73111000 Research laboratory services, 73120000 Experimental development services, 33620000 Medicinal products for the blood, blood-forming organs and the cardiovascular system

#### **II.1.7. Information about the Government Procurement Agreement (GPA)**

The procurement is covered by the Government Procurement Agreement: no

#### **II.1.8. Lots**

This contract is divided into lots: yes  
Tenders may be submitted for one or more lots

#### **II.1.9. Information about variants**

Variants will be accepted: yes

### **II.2. Scope of the procurement**

#### **II.2.1. Total quantity or scope**

The total estimated value of call offs under the framework is GBP 25,000,000.  
Estimated value excluding VAT: 25 000 000 GBP

#### **II.2.2. Information about options**

Options: no

#### **II.2.3. Information about renewals**

This contract is subject to renewal: no

### **II.3. Duration of the contract or time limit for completion**

Duration in months: 48 (from the award of the contract)

Information about lots

Lot No: 1

Lot title: Immune cell therapy manufacture (including gene modified cell therapy)

#### **1) Short description**

#### **2) CPV code(s)**

33600000 Pharmaceutical products, 71900000 Laboratory services, 73111000 Research laboratory services, 73120000 Experimental development services, 33620000 Medicinal products for the blood, blood-forming organs and the cardiovascular system

#### **3) Quantity or scope**

#### **4) Indication about different time frame or duration**

#### **5) Additional information about lots**

Lot No: 2

Lot title: Pluripotent derived cell therapy manufacture (iPSC or hESC)

**1) Short description**

**2) CPV code(s)**

33600000 Pharmaceutical products, 71900000 Laboratory services, 73111000 Research laboratory services, 73120000 Experimental development services, 33620000 Medicinal products for the blood, blood-forming organs and the cardiovascular system

**3) Quantity or scope**

**4) Indication about different time frame or duration**

**5) Additional information about lots**

Lot No: 3

Lot title: MSC and other multi-potent cell therapy manufacture

**1) Short description**

**2) CPV code(s)**

33600000 Pharmaceutical products, 71900000 Laboratory services, 73111000 Research laboratory services, 73120000 Experimental development services, 33620000 Medicinal products for the blood, blood-forming organs and the cardiovascular system

**3) Quantity or scope**

**4) Indication about different time frame or duration**

**5) Additional information about lots**

Lot No: 4

Lot title: Other somatic cell therapy manufacture

**1) Short description**

**2) CPV code(s)**

33600000 Pharmaceutical products, 71900000 Laboratory services, 73111000 Research laboratory services, 73120000 Experimental development services, 33620000 Medicinal products for the blood, blood-forming organs and the cardiovascular system

**3) Quantity or scope**

**4) Indication about different time frame or duration**

**5) Additional information about lots**

Lot No: 5

Lot title: 3D culture based cell therapy manufacture

**1) Short description**

**2) CPV code(s)**

33600000 Pharmaceutical products, 71900000 Laboratory services, 73111000 Research laboratory services, 73120000 Experimental development services, 33620000 Medicinal products for the blood, blood-forming organs and the cardiovascular system

**3) Quantity or scope**

**4) Indication about different time frame or duration**

## 5) Additional information about lots

### Section III: Legal, economic, financial and technical information

---

#### III.1. Conditions related to the contract

##### III.1.1. Deposits and guarantees required

Tenderers may be requested to sign a Parent Company Guarantee, depending on the evaluation of Financial Information.

##### III.1.2. Main financing conditions and payment arrangements and/or reference to the relevant provisions governing them

##### III.1.3. Legal form to be taken by the group of economic operators to whom the contract is to be awarded

##### III.1.4. Contract performance conditions

The performance of the contract is subject to particular conditions: yes

Description of particular conditions: Any conditions will be detailed in the tender documents.

#### III.2. Conditions for participation

##### III.2.1. Suitability to pursue the professional activity, including requirements relating to enrolment on professional or trade registers

List and brief description of conditions: Please see the PQQ.

##### III.2.2. Economic and financial ability

List and brief description of conditions: Please see the PQQ.

Minimum level(s) of standards possibly required: Please see the PQQ.

##### III.2.3. Technical and professional ability

List and brief description of conditions:

Please see the PQQ.

Minimum level(s) of standards possibly required:

Please see the PQQ.

##### III.2.4. Information about reserved contracts

#### III.3. Conditions specific to services contracts

##### III.3.1. Information about a particular profession

Execution of the service is reserved to a particular profession: no

##### III.3.2. Information about staff responsible for the performance of the contract

Obligation to indicate the names and professional qualifications of the staff assigned to performing the contract: no

### Section IV: Procedure

---

#### IV.1. Type of procedure

##### IV.1.1. Type of procedure

Restricted

#### **IV.1.2. Information about the limits on the number of candidates to be invited**

Envisaged minimum number 25: and Maximum number 48  
Objective criteria for choosing the limited number of candidates: Please see the PQQ.

#### **IV.1.3. Information about reduction of the number of solutions or tenders during negotiation or dialogue**

#### **IV.2. Award criteria**

##### **IV.2.1. Award criteria**

The most economically advantageous tender in terms of Price is not the only award criterion and all criteria are stated only in the procurement documents

##### **IV.2.2. Information about electronic auction**

An electronic auction will be used: no

#### **IV.3. Administrative information**

##### **IV.3.1. File reference number attributed by the contracting authority**

CON-0038

##### **IV.3.2. Previous publication concerning this procedure**

no

##### **IV.3.3. Conditions for obtaining specifications and additional documents or descriptive document**

Time limit for receipt of requests for documents or for accessing documents: 23.6.2014 - 10:00  
Payable documents: no

##### **IV.3.4. Time limit for receipt of tenders or requests to participate**

23.6.2014 - 10:00

##### **IV.3.5. Estimated date of dispatch of invitations to tender or to participate to selected candidates**

##### **IV.3.6. Languages in which tenders or requests to participate may be submitted**

English.

##### **IV.3.7. Minimum time frame during which the tenderer must maintain the tender**

##### **IV.3.8. Conditions for opening of tenders**

#### **Section VI: Complementary information**

---

##### **VI.1. Information about recurrence**

This is a recurrent procurement: no

##### **VI.2. Information about European Union funds**

The procurement is related to a project and/or programme financed by European Union funds:  
no

##### **VI.3. Additional information**

To express interest and request a copy of the PQQ please email [ojeu@ct.catapult.org.uk](mailto:ojeu@ct.catapult.org.uk)

The deadline for completed PQQs is 23.6.2014 at 10:00 hours.  
Prior to the deadline, Candidates will be able to attend a briefing session on the procurement process.

**VI.4. Procedures for review**

**VI.4.1. Review body**

**VI.4.2. Review procedure**

**VI.4.3. Service from which information about the review procedure may be obtained**

Official name: Cell Therapy Catapult

E-mail: [ojeu@ct.catapult.org.uk](mailto:ojeu@ct.catapult.org.uk)

**VI.5. Date of dispatch of this notice**

20.5.2014