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Tender

## **Framework for QC Analytical Testing Requirements**

Centre for Process Innovation Limited

F02: Contract notice

Notice identifier: 2024/S 000-025441

Procurement identifier (OCID): ocds-h6vhtk-0489eb

Published 12 August 2024, 2:35pm

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

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

Centre for Process Innovation Limited

Wilton Centre

Redcar

TS10 4RF

#### **Contact**

E-Tendering

#### **Email**

[e-tendering@uk-cpi.com](mailto:e-tendering@uk-cpi.com)

#### **Telephone**

+44 1642455340

#### **Country**

United Kingdom

**NUTS code**

UK - United Kingdom

**Internet address(es)**

Main address

[www.uk-cpi.com](http://www.uk-cpi.com)

Buyer's address

[https://www.publiccontractsscotland.gov.uk/search/Search\\_AuthProfile.aspx?ID=AA30305](https://www.publiccontractsscotland.gov.uk/search/Search_AuthProfile.aspx?ID=AA30305)

**I.2) Information about joint procurement**

The contract is awarded by a central purchasing body

**I.3) Communication**

The procurement documents are available for unrestricted and full direct access, free of charge, at

<https://in-tendhost.co.uk/uk-cpi.aspx/Home>

Additional information can be obtained from the above-mentioned address

Tenders or requests to participate must be submitted electronically via

<https://in-tendhost.co.uk/uk-cpi.aspx/Home>

**I.4) Type of the contracting authority**

Body governed by public law

**I.5) Main activity**

Other activity

Research And Development

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## **Section II: Object**

### **II.1) Scope of the procurement**

#### **II.1.1) Title**

Framework for QC Analytical Testing Requirements

Reference number

3345

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

- 71620000 - Analysis services

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

Services

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

You are invited to submit a tender for the following requirements; analytical services for multiple modalities drug substances and drug products required for early phase clinical trials. This tender is to cover the analytical services required for release analysis of drug substance (DS) and drug product (DP).

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

This contract is divided into lots: Yes

Tenders may be submitted for maximum number of lots

6

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

#### **II.2.1) Title**

Water Testing (Glasgow Area)

Lot No

1

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

- 71620000 - Analysis services

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

NUTS codes

- UKM83 - Inverclyde, East Renfrewshire and Renfrewshire

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

The MMIC facility near Glasgow will require microbiological testing of water samples in accordance with Ph. Eur. [0169]. The following analysis techniques are required and have been included in pricing schedule for comparison:

-Microbiological monitoring (Ph. Eur.)

-Bacterial endotoxin testing (Ph. Eur.)

### **II.2.5) Award criteria**

Quality criterion - Name: GMP Questionnaire / Weighting: 5

Quality criterion - Name: Technical Specification / Weighting: 20

Quality criterion - Name: Turnaround timescales (Lead Time) / Weighting: 20

Quality criterion - Name: Qualification and Experience / Weighting: 20

Quality criterion - Name: Order Processing, Account Management & Customer Service / Weighting: 5

Price - Weighting: 30

### **II.2.7) Duration of the contract, framework agreement or dynamic purchasing system**

Duration in months

48

This contract is subject to renewal

Yes

Description of renewals

48 months with 1 additional 12 months period extension options

at the discretion of the Authority.

#### **II.2.10) Information about variants**

Variants will be accepted: Yes

#### **II.2.11) Information about options**

Options: No

#### **II.2.13) Information about European Union Funds**

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

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

#### **II.2.1) Title**

RNA Therapeutic/Vaccines

Lot No

2

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

- 71620000 - Analysis services

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

NUTS codes

- UKM83 - Inverclyde, East Renfrewshire and Renfrewshire

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

Our facility in Darlington currently manufactures RNA-LNP vaccines and therapeutics for Phase 1 clinical trials. Both the drug substance and drug product are presented as liquid formulations.

The requirements for RNA-LNP analysis include:

- Method development, verification and Phase appropriate validation (as required)
- Integrity analysis for RNA In-process samples, RNA-LNP drug substance and drug product (release and stability analysis)
- Process impurity testing for RNA-LNP drug substance and drug product

#### **II.2.5) Award criteria**

Quality criterion - Name: GMP Questionnaire / Weighting: 5

Quality criterion - Name: Technical Specification / Weighting: 20

Quality criterion - Name: Turnaround timescales (Lead Time) / Weighting: 20

Quality criterion - Name: - Qualification and Experience / Weighting: 20

Quality criterion - Name: Order Processing, Account Management & Customer Service / Weighting: 5

Price - Weighting: 30

#### **II.2.7) Duration of the contract, framework agreement or dynamic purchasing system**

Duration in months

48

This contract is subject to renewal

Yes

Description of renewals

48 months with 1 additional 12 months period extension options

at the discretion of the Authority.

#### **II.2.10) Information about variants**

Variants will be accepted: Yes

#### **II.2.11) Information about options**

Options: No

### **II.2.13) Information about European Union Funds**

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

## **II.2) Description**

### **II.2.1) Title**

Recombinant Protein Therapeutics

Lot No

3

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

- 71620000 - Analysis services

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

NUTS codes

- UKM83 - Inverclyde, East Renfrewshire and Renfrewshire

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

Our facility in Darlington will, in the future, manufacture Recombinant protein vaccines and therapeutics produced in Microbial cell lines, for Phase 1 clinical trials. Both the drug substance and drug product are presented as liquid formulations.

The requirements for Recombinant Protein analysis include:

- Method development, verification and Phase appropriate validation (as required)
- Integrity analysis for Recombinant Protein drug substance and drug product (release and stability analysis)
- Process impurity testing for Recombinant Protein drug substance and drug product

### **II.2.5) Award criteria**

Quality criterion - Name: GMP Questionnaire / Weighting: 5

Quality criterion - Name: Technical Specification / Weighting: 20

Quality criterion - Name: Turnaround timescales (Lead Time) / Weighting: 20

Quality criterion - Name: Qualification and Experience / Weighting: 20

Quality criterion - Name: Order Processing, Account Management & Customer Service / Weighting: 5

Price - Weighting: 30

#### **II.2.7) Duration of the contract, framework agreement or dynamic purchasing system**

Duration in months

48

This contract is subject to renewal

Yes

Description of renewals

48 months with 1 additional 12 months period extension options

at the discretion of the Authority.

#### **II.2.10) Information about variants**

Variants will be accepted: Yes

#### **II.2.11) Information about options**

Options: No

#### **II.2.13) Information about European Union Funds**

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

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

#### **II.2.1) Title**

Process and Product Microbiology (Teesside Area)

Lot No



4

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

- 71620000 - Analysis services

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

NUTS codes

- UKM83 - Inverclyde, East Renfrewshire and Renfrewshire

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

Our facility in Darlington will require Microbiology testing to support the RNA-LNP and Recombinant Protein GMP manufacture.

The following analysis is required, all under Ph.Eur:

- Endotoxin (Buffers)
- Endotoxin (Process product Protein)
- Endotoxin (Process product RNA and RNA-LNP)
- Bioburden (Buffers)
- Bioburden (Process product Protein)
- Bioburden (Process product RNA and RNA-LNP)

## **II.2.5) Award criteria**

Quality criterion - Name: GMP Questionnaire / Weighting: 5

Quality criterion - Name: Technical Specification / Weighting: 20

Quality criterion - Name: Turnaround timescales (Lead Time) / Weighting: 20

Quality criterion - Name: Qualification and Experience / Weighting: 20

Quality criterion - Name: Order Processing, Account Management & Customer Service / Weighting: 5

Price - Weighting: 30

### **II.2.7) Duration of the contract, framework agreement or dynamic purchasing system**

Duration in months

48

This contract is subject to renewal

Yes

Description of renewals

48 months with 1 additional 12 months period extension options

at the discretion of the Authority.

### **II.2.10) Information about variants**

Variants will be accepted: Yes

### **II.2.11) Information about options**

Options: No

### **II.2.13) Information about European Union Funds**

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

## **II.2) Description**

### **II.2.1) Title**

Process and Product Microbiology (Glasgow Area)

Lot No

5

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

- 71620000 - Analysis services

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

NUTS codes

- UKM83 - Inverclyde, East Renfrewshire and Renfrewshire

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

Our facility in Glasgow will require Microbiology testing to support the GMP manufacturing of oligonucleotide therapies.

The following analysis is required, all under Ph.Eur:

- Endotoxin (Process product oligonucleotide)
- Bioburden (Process product oligonucleotide)

#### **II.2.5) Award criteria**

Quality criterion - Name: GMP Questionnaire / Weighting: 5

Quality criterion - Name: Technical Specification / Weighting: 20

Quality criterion - Name: Turnaround timescales (Lead Time) / Weighting: 20

Quality criterion - Name: Qualification and Experience / Weighting: 20

Quality criterion - Name: Order Processing, Account Management & Customer Service / Weighting: 5

Price - Weighting: 30

#### **II.2.7) Duration of the contract, framework agreement or dynamic purchasing system**

Duration in months

48

This contract is subject to renewal

Yes

Description of renewals

48 months with 1 additional 12 months period extension options

at the discretion of the Authority.

#### **II.2.10) Information about variants**

Variants will be accepted: Yes

### **II.2.11) Information about options**

Options: No

### **II.2.13) Information about European Union Funds**

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

## **II.2) Description**

### **II.2.1) Title**

Oligonucleotides

Lot No

6

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

- 71620000 - Analysis services

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

NUTS codes

- UKM83 - Inverclyde, East Renfrewshire and Renfrewshire

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

The facility at MMIC will manufacture both single and double stranded novel oligonucleotides for early phase clinical trials. The drug substance (API) may be a lyophilised powder or solution API and the finished drug product may be a solid or liquid formulation.

The requirements for oligonucleotides analysis include:

- Chemical analysis for oligonucleotide drug substance and drug product (release and stability analysis)
- Method development, verification and phase appropriate validation (as required)

### **II.2.5) Award criteria**

Quality criterion - Name: GMP Questionnaire / Weighting: 5

Quality criterion - Name: Technical Specification / Weighting: 20

Quality criterion - Name: Turnaround timescales (Lead Time) / Weighting: 20

Quality criterion - Name: Qualification and Experience / Weighting: 20

Quality criterion - Name: Order Processing, Account Management & Customer Service / Weighting: 5

Price - Weighting: 30

### **II.2.7) Duration of the contract, framework agreement or dynamic purchasing system**

Duration in months

48

This contract is subject to renewal

Yes

Description of renewals

48 months with 1 additional 12 months period extension options

at the discretion of the Authority.

### **II.2.10) Information about variants**

Variants will be accepted: Yes

### **II.2.11) Information about options**

Options: No

### **II.2.13) Information about European Union Funds**

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

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## **Section III. Legal, economic, financial and technical information**

### **III.1) Conditions for participation**

#### **III.1.2) Economic and financial standing**

Selection criteria as stated in the procurement documents

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## **Section IV. Procedure**

### **IV.1) Description**

#### **IV.1.1) Type of procedure**

Open procedure

#### **IV.1.3) Information about a framework agreement or a dynamic purchasing system**

The procurement involves the establishment of a framework agreement

Framework agreement with several operators

Envisaged maximum number of participants to the framework agreement: 3

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

The procurement is covered by the Government Procurement Agreement: Yes

### **IV.2) Administrative information**

#### **IV.2.2) Time limit for receipt of tenders or requests to participate**

Date

12 September 2024

Local time

12:00pm

#### **IV.2.4) Languages in which tenders or requests to participate may be submitted**

English

#### **IV.2.7) Conditions for opening of tenders**

Date

12 September 2024

Local time

12:00pm

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### **Section VI. Complementary information**

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

This is a recurrent procurement: No

#### **VI.2) Information about electronic workflows**

Electronic ordering will be used

Electronic invoicing will be accepted

Electronic payment will be used

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

NOTE: To register your interest in this notice and obtain any additional information please visit the Public Contracts Scotland Web Site at

[https://www.publiccontractsscotland.gov.uk/Search/Search\\_Switch.aspx?ID=774949](https://www.publiccontractsscotland.gov.uk/Search/Search_Switch.aspx?ID=774949).

A sub-contract clause has been included in this contract. For more information see:

<http://www.publiccontractsscotland.gov.uk/info/InfoCentre.aspx?ID=2363>

Community benefits are included in this requirement. For more information see:

<https://www.gov.scot/policies/public-sector-procurement/community-benefits-in-procurement/>

A summary of the expected community benefits has been provided as follows:

Through research and development

(SC Ref:774949)

## **VI.4) Procedures for review**

### **VI.4.1) Review body**

Glasgow Sheriff & Justice of the Peace Court

Sheriff Clerk's Office, 1 Carlton Place

Glasgow

G5 9DA

Country

United Kingdom