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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): ocids-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

Telephone

+44 1642455340

Country

United Kingdom

NUTS code

UK - United Kingdom

Internet address(es)

Main address

<http://www.uk-cpi.com>

Buyer's address

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

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

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

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

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.

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