CSIR-Central Drug Research Institute Lucknow

15-11-22

File Ref: CDRI/2022 Consultant

Corrigendum

It is informed that tender for Regulatory Affairs Consultant with Tender ID-2022 _CSIR_135389_1 dated 15-11-22 is being changed in bid submission date to Dec.14, 2022 in place of Nov.21,2022.

Nasreem Ahmed Siddiqi

Head,BD

Government eProcurement System

Government eProcurement System

Published Corrigendum Details

Date : 15-Nov-2022 10:42 AM

Print

Organisation Chain :	Council of Scientific and Industrial Research||CDRI-Lucknow - CSIR||Purchase-CDRI - CSIR
Tender ID :	2022_CSIR_135389_1
Tender Ref No :	CDRI/2022/Consultant
Tender Title :	Regulatory Affairs Consultants with experience in small molecules, biologicals, phytopharmaceuticals development
Corrigendum Type :	Date

Corrigendum:1

Corrigendum Title	Corrigendum Description	Published Date	Document Name	Doc Size(in KB)
Corrigendum Tender	Corrigendum tender in Date	15-Nov-2022 10:41 AM	Corrigendum.pdf	110.93

Critical Dates

Publish Date	15-Nov-2022 12:00 PM	**Bid Opening Date**	15-Dec-2022 02:00 PM
Document Download/Sale Start Date	15-Nov-2022 12:15 PM	**Document Download/Sale End Date**	14-Dec-2022 01:30 PM
Clarification Start Date	NA	**Clarification End Date**	NA
Bid Submission Start Date	15-Nov-2022 01:00 PM	**Bid Submission End Date**	14-Dec-2022 01:30 PM

Details Before Corrigendum

Critical Dates

Publish Date	15-Nov-2022 12:00 PM	**Bid Opening Date**	22-Nov-2022 02:00 PM
Document Download/Sale Start Date	15-Nov-2022 12:15 PM	**Document Download/Sale End Date**	21-Nov-2022 01:30 PM
Clarification Start Date	NA	**Clarification End Date**	NA
Bid Submission Start Date	15-Nov-2022 01:00 PM	**Bid Submission End Date**	21-Nov-2022 01:30 PM

Government eProcurement System

Government eProcurement System

Tender Details

Date : 15-Nov-2022 09:59 AM

Print

Basic Details

Organisation Chain	Council of Scientific and Industrial Research||CDRI-Lucknow - CSIR||Purchase-CDRI - CSIR		
Tender Reference Number	CDRI/2022/Consultant		
Tender ID	2022_CSIR_135389_1		
Tender Type	Open Tender	**Form of contract**	EOI
Tender Category	Services	**No. of Covers**	1
General Technical Evaluation Allowed	No	**ItemWise Technical Evaluation Allowed**	No
Payment Mode	Not Applicable	**Is Multi Currency Allowed For BOQ**	No
Is Multi Currency Allowed For Fee	No	**Allow Two Stage Bidding**	No

Cover Details, No. Of Covers - 1

Cover No	Cover	Document Type	Description
1	Fee/PreQual/Technical/Finance	.pdf	Credential of firm
		.pdf	Technical bid as per specification

Tender Fee Details, [Total Fee in ₹ * - 0.00]

Tender Fee in ₹	0.00		
Fee Payable To	Nil	**Fee Payable At**	Nil
Tender Fee Exemption Allowed	No		

EMD Fee Details

EMD Amount in ₹	0.00	**EMD through BG/ST or EMD Exemption Allowed**	No
EMD Fee Type	fixed	**EMD Percentage**	NA
EMD Payable To	Nil	**EMD Payable At**	Nil

Click to view modification history

Work /Item(s)

Title	Regulatory Affairs Consultants with experience in small molecules, biologicals, phytopharmaceuticals development				
Work Description	for EOI of Regulatory Affairs Consultants with experience in small molecules, biologicals, phytopharmaceuticals development				
Pre Qualification Details	Please refer Tender documents.				
Independent External Monitor/Remarks	NA				
Show Tender Value in Public Domain	No				
Tender Value in ₹	1	**Product Category**	Consultancy	**Sub category**	NA
Contract Type	Tender	**Bid Validity(Days)**	105	**Period Of Work(Days)**	90
Location	CSIR-CDRI	**Pincode**	226031	**Pre Bid Meeting Place**	NA
Pre Bid Meeting Address	NA	**Pre Bid Meeting Date**	NA	**Bid Opening Place**	CSIR-CDRI

Should Allow NDA Tender	No	**Allow Preferential Bidder**	No

Critical Dates

Publish Date	15-Nov-2022 12:00 PM	**Bid Opening Date**	22-Nov-2022 02:00 PM
Document Download / Sale Start Date	15-Nov-2022 12:15 PM	**Document Download / Sale End Date**	21-Nov-2022 01:30 PM
Clarification Start Date	NA	**Clarification End Date**	NA
Bid Submission Start Date	15-Nov-2022 01:00 PM	**Bid Submission End Date**	21-Nov-2022 01:30 PM

Tender Documents

NIT Document

S.No	Document Name	Description	Document Size (in KB)
1	Tendernotice_1.pdf	NIT for EOI of Regulatory Affairs Consultants with experience in small molecules, biologicals, phytopharmaceuticals development	423.63

Work Item Documents

S.No	Document Type	Document Name	Description	Document Size (in KB)
1	Other Document	EOIdoc.pdf	EOI of Regulatory Affairs Consultants with experience in small molecules, biologicals, phytopharmaceuticals development	634.13

Auto Extension Corrigendum Properties for Tender

Iteration	No. of bids required for bid opening a tender	Tender gets extended to No. of days
1.	2	7

Bid Openers List

S.No	Bid Opener Login Id	Bid Opener Name	Certificate Name
1.	bs.eproc@csir.res.in	Brahma Singh	BRAHMA SINGH
2.	jp.eproc@csir.res.in	Jai Prakash	JAI PRAKASH
3.	maheshk.eproc@csir.res.in	Mahesh Kumar	MAHESH KUMAR
4.	anilkumar.eproc@csir.res.in	Anil Kumar	ANIL KUMAR

GeMARPTS Details

GeMARPTS ID	18KL0KKDJ9F7
Description	Regulatory Afairs Consultant
Report Initiated On	14-Nov-2022
Valid Until	14-Dec-2022

Tender Properties

Auto Tendering Process allowed	No	**Show Technical bid status**	Yes
Show Finance bid status	Yes	**Show Bids Details**	Yes
BoQ Comparative Chart model	NIL	BoQ Compartive chart decimal places	2

BoQ Comparative Chart Rank Type	NIL	Form Based BoQ	No

Tender Inviting Authority	
Name	THE STORES AND PURCHASE OFFICER
Address	Sector 10 Jankipuram Extension Sitapur Road Lucknow

Tender Creator Details	
Created By	Mahesh Kumar
Designation	Astt. SO
Created Date	15-Nov-2022 09:53 AM

FAX: 91-522-2772550 EPABX: 91-(522)-2772450/2772550 Ext. 4982, 4776 & 4401, Website: http://www.cdri.res.in

सीएसआईआर-केन्द्रीय औषधि अनुसंधान संस्थान
CSIR-CENTRAL DRUG RESEARCH INSTITUTE
(वैज्ञानिक तथा औद्योगिक अनुसंधान परिषद्)
(COUNCIL OF SCIENTIFIC & INDUSTRIAL RESEARCH)
जानकीपुरम विस्तार सीतापुर रोड़, लखनऊ/Jankipuram Extension, Sitapur Road, Lucknow- 226 031
(उत्तर प्रदेश/UTTAR PRADESH)भारत/India

File Ref : CDRI/2022/Consultant

Date: 15/11/2022

NOTICE INVITING TENDER (NIT)

Online Bids are invited on behalf of **Director, CSIR-CDRI**, Lucknow in **Single Bid System** only in **Indian currency** format for procurement of the following equipment.

क्रमांक Sl. No.	सामग्री विवरण Description of items	मात्रा Period	बोली प्रनाली Single / Double Bid	बोली प्रतिभूति Bid Security (EMD)
1.	**Regulatory Affairs Consultants with experience in small molecules, biologicals, phytopharmaceuticals development** (Specification and details as per tender document)	One year	**EOI**	शून्य Rs. Nil

CRITICAL DATE SHEET

Tender Ref. No.	CDRI/2022/Consultant
Bid Submission Start Date and Time	15/11/2022
Bid Submission End Date and Time	21/11/2022 upto13.30 hrs.
Date and Time for Opening of Bids	22/11/2022 from14.00 hrs. Onwards
Address for Communication	Stores & Purchase Officer CSIR –CENTRAL Drug Research Institute (CDRI) Sector 10 Jankipuram Extension Sitapur Road, Lucknow 226031, UTTAR PRADESH Phone: 0522-2772793, +91 9451306359 (M) E-mail: spo@cdri.res.in

EOI shall be submitted only using this **online** web portal **https://etenders.gov.in** only and bids in hard copy by mail / hand shall not be considered.

Sd/-
[N.S. Prasad]
Stores & Purchase Officer

CSIR – Central Drug Research Institute, Lucknow

Call for Expressions of Interest

for Regulatory Affairs Consultants with experience in small molecules, biologicals, phytopharmaceuticals development

CSIR-Central Drug Research Institute, Lucknow, a premier Institute under Council of Scientific and Industrial Research (CSIR), is involved in multidisciplinary biomedical research to develop drugs of relevance for India. To date, CDRI has discovered and developed 13 new drugs including Centchroman, an oral contraceptive and α-β Arteether for cerebral malaria & chloroquine resistant malaria.

CDRI's areas of interest are Infectious diseases, Ageing and Neurological disorders, Metabolic disorders, Cancer and Reproductive health. The Institute has a rich pipeline of drugs & technologies, including synthetic compounds, phytopharmaceuticals, formulations and diagnostics. CDRI intends to develop these for national and international markets. Please visit https://cdri.res.in/ for more details.

In order to ensure the streamlined development of its compounds in compliance with global regulatory standards, CDRI is looking for motivated pharmaceutical regulatory affairs professionals with experience in the development of synthetic small molecules or phytopharmaceuticals for India, USA or European markets.

We invite interested individuals with the requisite experience to submit an Expression of Interest (EoI) for their empanelment as Regulatory Affairs Consultants.

Eligibility Criteria

Indian nationals with a Master's degree or Ph.D. in Pharmaceutical Sciences / Medical Sciences/Biochemistry/Microbiology/Chemistry/Biotechnology or any other relevant area in Life Sciences or Medicine

Excellent oral and written communication skills

Post Graduate Diploma in Drug Regulatory Affairs (PGDDRA) preferred

Certified Regulatory Affairs Professionals preferred

List of clients served during last five years along with relevant supporting documents (e.g. projects handled).

Experience

Must have experience of more than 15 years' experience working with preclinical stage NCEs, fixed dose combinations, repurposed drugs, biological, phytopharmaceuticals for preclinical and clinical development.

Must have experience in interacting with Regulators

Must have a proven track record of preparing and submitting Regulatory dossiers as per CDSCO, US FDA or EMA etc.

Scope of work

1. Review Target Product Profiles and available data on ongoing projects to advise on Regulatory strategies for preclinical and clinical development
2. Provide inputs on gaps in the data package, if any
3. Identify and advise on the relevant guidance documents and/or consensus standards

4. Advise teams on requirements for IND filing,
5. clinical development (Phase I, II & III), marketing approval, export and labeling
6. Communicate with regulatory agencies regarding pre-submission strategies
7. Review data or technical reports that will be incorporated into regulatory submissions
8. Prepare and review regulatory submissions
9. Follow up on submissions and prepare responses to queries from the Regulator
10. Provide analyses of Regulatory strategies adopted by competitors
11. Track and monitor Regulatory milestones achieved by competitor products
12. Provide updates on changes in the Regulatory guidance for products of interest to CDRI
13. Review product promotional materials, labeling, batch records, specification sheets or test methods for compliance with applicable regulations and policies.

Place of work

Selected consultant can work remotely. Travel expenses shall be reimbursed for visit to CSIR-CDRI.

Period of Hiring

Engagement may be for the period of **12 Months** with about 60 hours work, extendable as per need.

Application procedure

Interested eligible candidates may submit a cover letter summarizing their professional experience and their motivations for wanting to work with CDRI along with their CV and photocopies of certificates of credentials client served along with relevant supporting documents within 30 days from the date of notification.

Applicants also need to mention the expected consultancy fee / charge either on monthly basis or hourly basis or work package basis.

Selection

Candidates meeting the selection criteria will be called for a personal discussion.

Naseem Ahmad Siddiqui
Head, BDG