



DELHI PHARMACEUTICAL SCIENCES AND RESEARCH UNIVERSITY

TENDER / BID DOCUMENT FOR

Supply of

“Electronic Common Technical Document (eCTD) Software”

For Drug Regulatory Affairs Department, DPSR University

Last date of Bid Submission : 24/09/2021 up to 11:00 AM

Opening of Technical Bid : 24/09/2021 at 02:30 PM

**Delhi Pharmaceutical Sciences & Research University
(Established Under Act 07 of 2008, Govt. of NCT of Delhi)**

The 1st Pharmacy University of India

Mehrauli-Badarpur Road, Pushp Vihar, Sector-3, New Delhi-110017, INDIA

Phone: 29553487, Fax: 91-11-29554503

Website: www.dpsru.edu.in (GSTIN: 07AAAGD0279H1ZM)

FACT-SHEET

S. No.	Particular	Details
1	Tender Reference No.	F.No. 10/1356/Store/DPSRU/2020
2	Tender ID on Delhi Govt. e-procurement web-portal	
3	Selection Method	Technical Evaluation with Least Cost based selection as per Tender Specification.
4	Availability of Tender / Bid Document	Tender/Bid Document can be downloaded from e-Procurement platform of Delhi Government i.e. https://govtprocurement.delhi.gov.in and can also be downloaded from website of this University i.e. http://dpsru.edu.in/tenders
5	Bid Security Declaration	Bidders must submit the Bid Security Declaration as per the format given in Annexure III
6	Performance Bank Guarantee (PBG)	3 % of the total cost of Work / Supply order in the form of FDR/Bank Guarantee in favour of Registrar, Delhi Pharmaceutical Sciences & Research University, payable at Delhi and issued from any of the Nationalized Scheduled Commercial Banks located in Delhi / NCR
7	Nodal Officer for correspondence and clarification	Purchase Officer, Admn. Block, Old Building Delhi Pharmaceutical Sciences and Research University, Mehrauli-Badarpur Road, PushpVihar Sector-3, New Delhi-110 017, INDIA e-mail: Tel. No.: 011-29553771, 29554649
8	Last date of bid submission	Bid must be submitted in Online on e-procurement platform of Delhi Government i.e. https://govtprocurement.delhi.gov.in on or before the 24/09/2021 up to 11:00 AM.
9	Opening of Technical Bid	24/09/2021 at 02:30 PM
10	Opening of Financial Bid	After Successful Clearance of Technical Evaluation

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F.NO. 10/1356/STORE/DPSRU/2020

Dated: 03/09/2021

E-PROCUREMENT

<https://govtprocurement.delhi.gov.in>.)

TENDER DOCUMENT

Online Bids/ Quotations are invited from the Reputed Manufacturers or Authorized Distributors/Dealers of Manufacturer for Supply & Installation of **“Electronic Common Technical Document (eCTD) Software”** for Drug Regulatory Affairs Department, DPSRU University as per the specification given in the **Annexure-I**. The bids must be uploaded on GNCT of Delhi E-procurement website i.e. <https://govtprocurement.delhi.gov.in>. on or before 24/09/2021 **up to 11.00 AM**. The tender document can be accessed on GNCTD E-Procurement website as well as on University Website <http://dpsru.edu.in/tenders>.

INSTRUCTIONS TO BIDDERS

1

Eligibility for Bidders:

1.1 The Bidder must be a Reputed Manufacturer or Authorized Distributor/Dealer of Manufacturer. If bidder is an authorized distributor/dealer of manufacturer, he must furnish legible copy of authorization certificate issued by the manufacturer.

1.1(i). Further, any bidder from a country which shares a land border with India will be eligible to bid in this tender only if the bidder is registered with the Competent Authority i.e. “Registration Committee” constituted by the Department for Promotion of Industry and Internal Trade, GOI. A certificate, as per Annexure-IV is required to be submitted by the bidder along with the bid documents.

1.2 The Bidder must be bearer of valid GST Registration. The Bidder must upload legible self-attested copy of GST Registration Certificate issued from

a Competent Authority

- 1.3 The Bidder must have Permanent Account Number (PAN). Self-attested copy of PAN must be furnished.
- 1.4 The Bidder must have average financial Turnover of Rs. 10.00 Lakhs during last 3 financial years (2018-19, 2019-2020 & 2020-21). The Bidder must upload Self attested scanned copy of Documentary proof indicating the annual Turnover for the last three financial years (2018-19, 2019-2020 & 2020-21) in the form GST paid acknowledgment or any other relevant document duly signed by the concerned Government officer indicating the annual turnover therein or Balance Sheet duly signed by Chartered Accountant or any other relevant document showing turnover duly signed by Chartered Accountant.
- 1.5 The Bidder should quote the specifications & makes/brands of the Software/items as per specifications mentioned in annexure-I of the Bidding Documents. If, there is any deviation in the specifications & brands/makes of the Equipment/machines, Bidder must mention the deviation in the deviation column of Annexure-I. Self-attested copy of duly filled Annexure-I must be uploaded.
- 1.6 The bid must be valid for 180 days from the last date of submission of bids. A Bid valid for a shorter period is liable to be rejected as non-responsive.
- 1.7 If, the Bidder is manufacturer, he must furnish the details of its organization, stating number of personnel employed, manufacturing facilities, after sales service facilities and quality control systems in the **Annexure-II**.

OR

If, the Bidder is Authorized Distributor / Dealer, he must furnish the details of its organization, stating no. of personnel employed, ties up for after sales-service facilities, whether he is authorized dealer or not for the items he is intending to supply, how he will provide after- sales- service etc. in the **Annexure-II**.

- 1.8 The Bidder must furnish details of their customers with full address, telephone no., etc. and details of similar supplies made, during the last two financial years, in the **Annexure-II**.
- 1.9 A self-certified undertaking by the authorized signatory of the bidder that "the bidder has not been blacklisted by any Central / State Government (Central/State Government and Public Sector) or under a declaration of ineligibility for corrupt or fraudulent practices" as on bid submission date

must be submitted.

1.10 In the event of the Software/ item(s) being imported product(s), Custom Duty Exemption Certificate (CDEC) will be issued by the University on the written request of the supplier; who, in turn, will furnish copies of relevant Customs Related Documents namely Airways Bill, Packing List, TR-6 challan etc. along with Bill/Invoice.

1.11 Bidder must agree to all Terms & Conditions of Bid Document and must furnish duly filled self-attested **Annexure-II** In token of acceptance.

1.12 Rates should be quoted on F.O.R basis. The University is entitled to Concessional GST, for which DSIR Certificate will be issued on written request of the vendor.

2 Technical Specifications

The detailed Technical specifications, quantity required are mentioned in **Annexure-I**.

3 Cost of Bidding

The Bidder shall bear all the costs associated with the preparation and submission of its Bid, and the Principal hereinafter referred to as "the purchaser", will in no case be responsible or liable for those costs, regardless of the conduct or outcome of the Bidding process.

The Bidder is expected to examine all instructions, forms, terms and conditions in the Bid documents. Failure to furnish all information required by the Bid documents or submission of a Bid not substantially responsive to the documents in every respect will be at the Bidder's risk and may result in the rejection of its Bid.

4 Documents to be submitted with the Bid:

I "TECHNICAL BID"

II "PRICE BID"

A complete price in Rupees in the prescribed Performa of BOQ must be filled & signed and submitted online along with bid document.

5 Bid Validity

Bids shall remain valid for 180 days from the last date of submission of bids. A Bid valid for a shorter period is liable to be rejected as non-responsive.

6 **Delivery Period**

08 (Eight) Weeks from the date of placing the supply order.

7. **Extension of validity of Bids**

In exceptional circumstances, the purchaser may solicit the Bidder's consent to an extension of the period of validity of 365 days. The request and the responses thereto shall be made in writing. A Bidder granting the request will not be required nor permitted to modify its Bid.

8. **Opening of Technical Bid by Purchaser**

- 8.1 The purchaser will open "Technical Bids" in the presence of Bidders' representatives only who choose to attend, at 02.30 PM on 24/09/2021 in the Registrar's Chamber.
- 8.2 The Bidders representatives, who are present, shall sign attendance register / sheet evidencing their attendance.
- 8.4 The Bidders name, modifications or, Tender withdrawals and the presence or absence of the Bid Security Declaration, registered with DGS&D/NSIC and such other details as the purchaser, at its discretion, may consider appropriate will be announced at the opening.

9. **Bid Rejection**

The Bid will be rejected under any one or more of the following cases: -

- i Non-production of original documents for verification, if required.
- ii Not meeting the Technical Specifications.
- iii If Bidder found indulging in malpractice of pooling of Bid.
- iv If bidder is not found eligible as per requisite criteria mentioned in the clause1.
- v If the quoted rates are not as per criteria.
- vi If a firm **quotes NIL** rates, the bid shall be treated as unresponsive and will not be considered.

10. **Opening / Downloading of Commercial Bid by Purchaser**

The Price Bids of the bidders, who qualifies in technical Bid evaluation, ***will be opened after the successful clearance of Technical Evaluation*** in the Registrar's Chambers, DPSRU Campus in the presence of Bidders' representatives who choose to attend.

The Bidders' representatives who are present shall sign attendance register / sheet evidencing their attendance.

In the event of the specified date of Bid opening being declared a holiday for the purchaser, the Bids shall be opened at the appointed time and location on the next working day.

11. Evaluation and Comparison of Bids

The purchaser will evaluate and compare the total Bid Price for each item, which have been determined to be substantially responsive as per the clause-1 (Each item-wise L-1Evaluation)

The purchaser's price evaluation of a Bid will be as per B.O.Q. No other charges will be paid or considered.

12. Purchaser's right to accept any Bid and to reject any or all Bids

The purchaser reserves the right to accept or reject any Bid, and to annul the Bid process and reject all Bids at any time prior to award of contract, without thereby incurring any liability to the affected Bidder or Bidders of any obligation to inform the affected Bidder or Bidders of the grounds for the purchaser's action.

13. Notification of contract and placement of supply order

Prior to the expiration of the period of Bid validity, the purchaser will notify the successful Bidders in writing that its Bid has been accepted.

The notification of award will constitute the formation of the contract.

Upon the successful Bidder's furnishing of Performance Security, the purchaser will promptly notify each unsuccessful Bidder and will discharge its Bid Security Declaration.

14. Signing of contract

At the same time as the purchaser notifies the successful Bidder that its Bid has been accepted, the purchaser will send the Bidder the Contract Form provided in the Bid documents, incorporating all agreements between the parties.

Within 7 days of receipt of the contract form, the successful Bidder shall sign and date the contract and return it to the purchaser.

15. Warranty

The supplier warrants that the goods supplied under this contract are new, unused and most recent. The supplier further warrants that the goods supplied under this contract shall have no defect arising from design or materials or workmanship or from any act or omission of the supplier that may develop under normal use of the supplied goods in the conditions at consignee place.

The warranty shall remain valid for a minimum period of **12 months**, or more, as given by the Original Equipment Manufacturer, after the goods or any portion thereof, as the case may be, have been delivered and commissioned to the final destination indicated in the contract.

The purchaser shall promptly notify the supplier in writing of any claims arising under this warranty.

Upon receipt of such notice, the supplier shall, with all reasonable speed, repair or replace the defective goods or parts thereof, without costs to the purchaser.

If the supplier, having been notified, fails to remedy the defect(s) within a reasonable period, the Purchaser may proceed to forfeit the Performance Bank Guarantee.

16. Performance Security

The successful Bidder must deposit a performance security, which will be the 3% (Three per cent) of the total value of contract. The performance security should be in the form of FDR or Bank Guarantee from a Nationalized Commercial bank in favour Registrar, Delhi Pharmaceutical Sciences & Research University, New Delhi-110 017. The Performance Security (Security Money) shall bear no interest. The Performance Security should valid for a period of 60 days beyond the completion of all contractual obligations by the supplier including warranty / guarantee period. The performance security will be forfeited in case the successful Bidder fails to supply as per the contract /supply order or fail to meet the obligations under warrant /guarantee period.

Failure of the successful Bidder will lead to suspension of the bidder from any future procurement of the University as per the Bid Security Declaration.

17. Inspection

The inspection of the Software/Goods shall be carried out to check whether the same are in conformity with the technical specifications attached to the contract.

The final inspection of the ordered goods shall be carried out by the Technical Expert Committees duly constituted by the Competent Authority of the University. If the firms fails to supply as per specification mentioned in

the supply order within stipulated time, its performance security will be forfeited.

18. Penalty for late deliveries

If the supplier fails to deliver any or all the software/goods or to perform the services within delivery period of 08 (Eight) Weeks the purchaser shall, without prejudice to its other remedies under the contract, deduct from the contract price, as penalty for late deliveries @ 0.5% per week for undelivered items.

Once the maximum deduction of 5% is reached, the purchaser will terminate the contract and forfeits the Performance Security for undelivered goods.

19. Payment

The Supplier's request for payment shall be made to the Registrar in writing, accompanied by an invoice describing with GST No. of University, as appropriate, the Goods delivered, rate and amount. Complete payment shall be made within 60 days by the purchaser after satisfactory completion of work (subject to approval of competent authority) or after submission of an invoice /bill or claim by the supplier; whichever is later

20. Purchaser right to vary quantities at the time of Award

The purchaser reserves the right at the time of award of contract to increase or decrease by up to 25% (Twenty Five Per cent) the quantity of goods specified in the schedule of requirement without any change in price or other terms & conditions.

21. Termination for Default

The purchaser may, without prejudice to any other remedy for breach of contract, by written notice of default sent to the supplier, terminate the contract in whole or in part:

- If the supplier fails to execute the supply order by the date specified in the order or within any extension thereof granted by the purchaser.
- If the supplier fails to perform any other obligation(s) under the contract.
- If the supplier, in the judgment of the purchaser has engaged in corrupt or fraudulent practices in executing the contract.

22. Force Majeure

Notwithstanding the provisions of clause 19 & 22 the supplier shall not be liable to forfeiture of its performance security, liquidated damages of termination for default, if and to the extent that, it's delay in performance or other failure to perform its obligations under the contract is the result of an

event of force majeure.

“Force Majeure” means an event beyond the control of the supplier and not involving the supplier’s fault or negligence and not foreseeable. Such events may include, but are not restricted to, acts of the purchaser either in its sovereign or contractual capacity, wars or revolution, fires, floods, epidemics, quarantine restrictions and freight embargoes.

If a force majeure situation arises, the supplier shall promptly notify the purchaser in writing of such conditions and the cause thereof. Unless otherwise directed by the purchaser in writing, the supplier shall continue to perform its obligations under the contract as far as is reasonably practical and shall seek all reasonable alternative means for performance not prevented by the force majeure event.

23. Resolution of disputes

The Purchaser and the supplier shall make every effort to resolve amicably by direct informal negotiation any disagreement or dispute arising between them under or in connection with the contract.

Any dispute is subject to the jurisdiction of Delhi courts only.

24. Site Inspection

Bidders are advised to inspect the site at DPSRU, Sector-3, Pushp Vihar, New Delhi-110017 and its surroundings where these Equipment/Machines are to be delivered & installed and satisfy them before submitting their tenders. A bidder shall be deemed to have full knowledge of the work whether he inspects it or not and no extra charges consequent on any misunderstanding or otherwise shall be allowed.

25. Language

The Proposal should be filled by the bidders in English language only. If any supporting documents submitted are in any language other than English, translation of the same in English language is to be duly attested by the Bidders. For purposes of interpretation of the documents, the English translation shall govern.

26. Special Instructions:

Supplier/ Bidder must ensure to upload the self-attested legible scanned copies of all the documents in support of the Eligibility of Bidder as mentioned in the Clauses 1.1 to 1.12.

ANNEXURE -I

S.No.	Nomenclature of the item/equipment	Quantity
1	Electronic Common Technical Document (eCTD) Software, 10+1 Users License (Technical specifications mentioned below)	1

Technical Specifications

S. No	User Requirement Specifications
1	21 CFR Part 11 Compliance
2	Regulatory Compliance Validation Tool- Inbuilt
3	ICH And Regional Recommended File Naming – Fully automated
4	Automatic Setting of Bookmarks, Hyperlinks To Inherit Zoom
5	Web-Based Solution
6	PDF In-Line Editing
7	Ectd Support To US-FDA, EMA, Health Canada, Swiss Medic, SAHPRA (MCC), TGA, JFDA, GCC/SFDA, Thai FDA, EAEU, China
8	Automatic NeES Creation From Existing Submission
9	Drag & Drop Option To Add Documents from Repositories
10	Support System (24x7)
11	Import Existing Templates (Cloning) (built-in)
12	Publishing eCTD in paper Format
13	Auto Conversion of word Documents to PDF
14	ECTD Viewer with complete Life Cycle Management (LCM) History
15	Visual Indicators for Leaf Operations (New, Replace, Append, Delete)
16	All Sequence view to view all sequences in one page
17	Multi-Tenant/ Single-Tenant Housing option
18	Regulatory Publishing/Submission services
19	Integrated with Regulatory Information Management System (RIM)
20	Integrated with Document Management System (DMS)
21	Integrated with Structured Product Labeling (SPL)
22	Filtering of Applications/Sequences
23	Re-ordering of Documents in A section
24	Fully Automated Re-Compile/Synchronization with checksum updates
25	Inheriting Attributes (DS, DP, Manuf, Excipient, Etc.) Fully Automated
26	Auto creation of Toc from Bookmarks or vice versa
27	Auto Correction of all PDF Properties
28	Creation of consolidated sequence with newly auto-Generated Index. Xml and Regional Xml files for Base-Line Submissions and Re-Use
29	Multi-Device And browser Compatibility
30	Simultaneous submissions to multiple agencies using custom templates with existing Documents
31	Module Templates compliant with latest ICH and Regional Specifications
32	Comprehensive STF Management with easier tagging of files
33	Multiple excipient sections can be created in a single Go, instead of adding them one at a time
34	Easy over writing of files by doing a simple drag and drop over existing file
35	Easy envelope creation for EU Submission with auto creation of all Country, Language and PIL sections
36	Option to create headers and footers in documents
37	Option to resize pages in PDFs as per agency specification
38	Display validation criteria version number based on regional guidelines in validation report
39	Regulatory body wise access to users and metadata creation based on regional/local guidelines
40	Module wise compilation for viewing only part of the submission
41	Latest view which also supports multiple DTD Versions (old , current) for all regulatory bodies
42	Option to create multiple envelopes for multiple countries and update the country nodes in module 1 for Gcc submissions
43	Re-use previous sequences

Annexure-II

BID FORM

Bid No.....

To

**The Registrar,
Delhi Pharmaceutical Science & Research University
Pushp Vihar, Sector-3,
New Delhi-110 017.**

Sir,

Having examined the Bid Documents, the receipt of which is hereby duly acknowledged, we, the undersigned, offer to supply in conformity with the said Bid documents in accordance with the schedule of prices attached herewith and made part of this Bid.

We undertake, if our Bid is accepted, to deliver the goods within the delivery period of 08 (Eight) Weeks, as specified in the Bid document.

If our Bid is accepted, we will submit the Performance Guarantee for an amount equal to 3% of the contract value.

We agreed to all Terms and conditions of **this Bid valid for a period of 180 days from the last date of submission of bids** and it shall remain binding upon us and may be accepted at any time before the expiration of that period.

Until a formal contract is prepared and executed, this Bid, together with your written acceptance thereof and your notification of award, shall constitute a binding contract between us.

We undertake that, in competing for (and, if the award is made to us, in executing) the above contract, we will strictly observe the laws against fraud and corruption in force in India namely "Prevention of Corruption Act 1988", if we find in Bid pooling or against law against fraud and corruption my / our firm may be black listed.

Further we certify that our organization is not blacklisted by any Govt. Department.

Dated _____

(Signature)

SEAL

Annexure-III

Bid Security Declaration Form (On Company's Letterhead)

Date: _____ Tender No. _____

To,

Registrar,
Delhi Pharmaceutical Sciences and Research University
Sector 3, Pushp vihar,
New Delhi 110017

I / We. The undersigned, declare that:

I/We understand that, according to your conditions, bids must be supported by a Bid Security Declaration.

I/We accept that I/We may be disqualified from bidding for any contract with you for a period of **three** years from the date of notification if I am /We are in a breach of any obligation under the bid conditions, because I/We

- have withdrawn / modified / amended, impairs or derogates from the tender, my / our Bid during the period of bid validity specified in the form of Bid; or
- having been notified of the acceptance of our Bid by the purchaser during the period of bid validity (i) fail or reuse to execute the contract, if required, or (ii) fail or refuse to furnish the Performance Security, in accordance with the Instructions to Bidders.

I/We understand this Bid Security Declaration shall cease to be valid if I am/we are not the successful Bidder, upon the earlier of (i) the receipt of your notification of the name of the successful Bidder; or (ii) thirty days after the expiration of the validity of my/our Bid.

Signature

Name:

Duly authorized to sign the bid for an on behalf of (insert complete name of Bidder)

Dated:

Corporate Seal

Annexure-IV

CERTIFICATE

(On Company's Letterhead)

I have read the clause regarding restrictions on procurement from a bidder of a country which shares a land border with India; I certify that this bidder:

- (i) is not from such a country
or
- (ii) has been registered with the Competent Authority. Evidence of valid registration by the Competent Authority is attached.

(Tick either of the options above)

I hereby certify that this bidder fulfills all requirements in this regard and is eligible to be considered.

Signature

CONTRACT FORM

THIS AGREEMENT made the _____ day of _____, 201__ between (Name of Purchaser & address) (hereinafter "the Purchaser") of the one part and (Name of Supplier & address) (hereinafter "the Supplier") of the other part

WHEREAS the purchaser is desirous that certain Goods and ancillary Services should be provided by the Supplier, viz, (Brief Description of Goods and Services) and has accepted a bid by the Supplier for the supply of those Goods and Services in the sum of (Contract Price in Words and Figures) (hereinafter "the Contract Price").

NOW THIS AGREEMENT WITNESSETH AS FOLLOWS:

In this Agreement words and expressions shall have the same meanings as are respectively assigned to them in the Conditions of Contract referred to.

2. The following documents shall be deemed to form and be read and construed as part of this Agreement, viz.:
- (a) The Bid Form and the Price Schedule submitted by the Bidder;
 - (b) The Schedule of Requirements;
 - (c) The Technical Specifications;
 - (d) The General Conditions of Contract;
 - (e) The Special Conditions of Contract; and
 - (f) The Purchaser's Notification of Award.

In consideration of the payments to be made by the Purchaser to the Supplier as hereinafter mentioned, the Supplier hereby covenants with the Purchaser to provide the Goods and Services and to remedy defects therein in conformity in all respects with the provisions of the Contract.

The Purchaser hereby covenants to pay the Supplier in consideration of the provision of the Goods and Services and the remedying of defects therein, the Contract Price or such other sum as may become payable under the provisions of the Contract at the times and in the manner prescribed by the Contract.

IN WITNESS whereof the parties hereto have caused this Agreement to be executed in accordance with their respective laws the day and year first above written.

Signed, Sealed and Delivered by the
Said _____ (For the Purchaser)
In the presence of: _____

Signed, Sealed and Delivered by the
Said _____ (For the Supplier)
In the presence of _____



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The following documents must submit along with technical bid otherwise the bid will be treated as non-responsive

Sr. No.	Particulars of the Documents	Page No/s
1.	Bid Security Declaration and Proof of PAN No	
2.	Proof of GST Registration Number and average financial Turnover of Rs. 10.00 Lakhs during the last 3 financial years	
3.	Undertaking of not being blacklisted as per Annexure-II and Certificate as per Annexure-IV	
4.	Brochure/Leaflets/Technical Information, including Make & Model, Imported/ Indian of the item(s)	
5.	Technical specifications, terms and conditions and delivery period etc. to be submitted on firm's letter head	
6.	Authorization Certificate from Original Equipment Manufacturer (OEM) or their Distributor to quote/sell the product, in case the Bidder is not the OEM	
7.	Purchase Orders (3 POs of 80% each or 5 POs of 60% each of estimated cost of items) of any Govt. Institution/ organization/PSU	

2015

DPSRU

उद्यमः कार्य साधक

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PRICE BID

S. No	Item Description	Qty.	Unit price (in Rs.)	GST %	Total Unit Price (in Rs.)	Total Amount (in Rs.)
1	Electronic Common Technical Document (eCTD) Software, 10+1 Users License (As per Technical specifications mentioned in the tender document)	01 No.				

Signature of the Authorized Signatory with Date