

GUJARAT TECHNOLOGICAL UNIVERSITY

(Established Under Gujarat Act No.: 20 of 2007)



E -Tender Notice No:20/2023-24

**Including Technical & Financial Bid –
(Financial bid to be filled online only)**

**“E - Tender for purchase of “e – CTD Software”
pro version & advance version”**

Gujarat Technological University

Nr.Vishwakarma Government Engineering College, Nr.Visat Three Roads, Visat -

Gandhinagar Highway, Chandkheda, Ahmedabad – 382424 - Gujarat

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E-Tender Notice no: - 20/2023-24

“E-Tender for PROCUREMENT OF e-CTD Software” pro version & advance version

Name of Software	Quantity	Estimated Cost	EMD*	Tender Fees*	Service period
“e CTD Software”	10 license	₹ 10,00,000 For 5 Years	3% of the estimated Cost	₹ 1770 (including 18% GST) (non-refundable)	Five Years

* In form of DD in favour of Gujarat Technological University payable at Ahmedabad only should be attached along with the tender document.

- The Gujarat Technological University invites **Online Tender for PROCUREMENT OF e-CTD Software” pro version & advance version for GTU- Graduate School of Pharmacy** under two bid systems. Interested parties/firms who wish to participate in online tenders can download the tender documents from the n-procure website (www.gtu.nprocure.com) or GTU website www.gtu.ac.in under tender option. Bidders have to submit price bid in electronics format only through n-procure website till the last date & time prescribed for submission. **Price bid of Tender in physical form will not be accepted in any case.**
- EMD, Tender Fee, and other essential documents for the tender should be submitted through **Reg. A.D./Speed Post/courier only** to Gujarat Technological University, Nr. Vishwakarma Government Engineering College, Nr. Visat Three Roads, Visat – Gandhinagar Highway, Chandkheda, Ahmedabad – 382424. Gujarat. India on or before Dt.03/02/2024, 6:00 PM.
- Tender Documents received late / incomplete without requisite papers and Demand Draft for tender fee and EMD shall be summarily rejected. The GUJARAT TECHNOLOGICAL UNIVERSITY reserves the right to accept or reject any tender, without assigning any reasons.

Tender release (online)	: 05/01/2024 (4:00 PM)
Last Date of Submission of Tender(online)	: 29/01/2024 (06:00 PM)
Last Date of Submission of Tender (Physical)	: 03/02/2024 (06:00 PM)
Date of Opening of Tender (Technical Bid only)	Will be intimated to Bidders
Date of Opening of Commercial Bid	Will be intimated to Bidders
Tender shall be valid up to	: 180 Days

GENERAL CONDITIONS

- 1) Online tender is invited from the reputed and experienced supplier for the SUPPLY AND INSTALLATION OF “eCTD Software: pro version & advance version” at M. Pharm Laboratories at Gujarat Technological University, Gandhinagar Campus. Interested parties who wish to participate in online tenders can download the tender documents from the n-procure website. Bidders have to submit price bid in electronics format only on n-procure website till the last date & time for submission. Price Bid of tender in physical form will not be accepted in any case. **The specifications of software is shown in (Annexure – I).**
- 2) The manufacturers/authorised distributor/authorised dealer for supply and installation of “e CTD Software” pro version & advance version software may submit their offer as per the specifications mentioned in tender form. Complete tender form duly filled along with all details with non-refundable tender form fee DD of ₹ 1770/- in favour of ‘Gujarat Technological University payable at Ahmedabad’, and EMD (in the form of DD, payable at Ahmedabad) as per terms and condition.
- 3) EMD, Tender Fee, and other essential documents must be submitted on or before the last date and time mentioned above in the office of the Gujarat Technological University, Chandkheda, Ahmedabad. Gujarat Technological University reserves all the rights to reschedule, cancel or reject the tender without assigning any reasons thereof. For more details visit us at websites: www.gtu.ac.in
- 4) The tenderer should invariably submit the tender in sealed covers which will contain followings,
 - a. E.M.D. and Tender Fee Cover
 - b. Technical Bid Cover in physical bound duly signed form at University office. (Each Page should be duly signed and serially numbered including attachments.)

Tenderer has to submit commercial bid online only. Physical Commercial Bid will not be accepted. The sealed envelope duly superscripted with the name of tender with the contact details shall be submitted in a larger envelope must reach on/before **03/02/2024** through **Reg. A.D./Speed Post/courier only** to “Gujarat Technological University, Chandkheda Campus, Nr. Sabarmati-Koba Highway, Nr. Visat Three Roads, Chandkheda, Ahmedabad, 382424, Gujarat, India.” Offers sent through Fax/e-mail/Cable/Telegram/**in person** will NOT be accepted.
- 5) Tenderer should provide the following documents in **physical (hard/spiral)** bound with superscription “**Documents for purchase of <Name of Software(s) as per Tender Notice No. ...>**”
 - a. Valid Certificate of Authorized Manufacturers/ Authorized Reseller or Dealer of overseas companies/ Authorized Dealers of manufactures.
 - b. User list of related item and total experience in this field.
 - c. GST Registration No.
 - d. PAN card of Agency/Company
 - e. Undertaking by tenderer as per (Annexure – III).
 - f. The turnover of the bidding firms for any one of the last 2 financial years should be at least 100% of the estimated total cost of the items. The bidder should submit the certificate from

Chartered Accountant regarding the same. [As per Annexure 4].

g. Technical documents/specification of all mentioned items.

h. **Compliance sheet as per format in Annexure - VIII with given specification (must be signed by an authorized person)** along with necessary proofs for compliance. The technical specifications of Software(s) and accessories mentioned in the compliance sheet will be considered for technical verifications. If specifications are not matched with tender specifications, the bidder will be disqualified. **Thus, the bidder is advised to thoroughly study technical specifications along with other conditions and submit the compliance sheet accordingly.**

- 6) Tenderer should furnish complete details of the latest technology available with full documentation & descriptive literature and point out any special features of their system.
- 7) Tenderer shall furnish details of the Back-up engineering and system support that will be made available to Gujarat Technological University by the Manufacturers/ Authorized Reseller/ Authorized Dealers of Manufactures/ Authorized Suppliers.
- 8) **The Prices quoted must be firm and on FOR, GTU Gandhinagar Campus, K-6 Circle, E-4 Electronic estate, GIDC, Sector 26, Gandhinagar – 382028. Gujarat, India. No any other taxes/ charges etc. will be paid other than the quoted price.** Different components of the price for insurance, freight insurance, installation and commissioning at the destination site must be included in the final price but excluding GST (if any) and shown separately.
- 9) The delivery and installation of Software(s) by supplier should be completed within 30 days from date of Purchase Order.
- 10) Prices should be as per latest catalogue and shown separately for each item, its accessories, critical spares, components, etc.
- 11) **The lowest price (L1) will be considered in Indian rupees quoted for 5 years in commercial bid.**
- 12) All the tender documents must be duly stamped & signed by an authorized person. If the Indian Agent/ Representative submits a tender, then he/she will have to produce a certificate of such authority for making quotation on manufacturer's behalf.
- 13) On acceptance of the rates as per the approved tender and after completing official necessary formalities, the tenderer will be informed about the acceptance of his tender.
- 14) The undersigned also reserves the right to accept or reject the supplies in full or in part which do not strictly stick up to the specifications or to accept the material/articles supplied with slight variations in specifications or with a condition that the rates accepted shall be reduced at such rates as the competent authority of the University & Vendor by mutual understanding, looking to the variations and that such rates shall be binding on the tenderer. The vendor should provide additional items/materials/etc at free of cost if needed as an installation requirement at the actual site until complete installation of Software(s).
- 15) University reserves the right to accept or reject - higher version of specification etc. items under the same terms and conditions quoted by tenderer in tender form.
- 16) As soon as the tenderer submit the tender online and physically in the office of the undersigned, it shall be binding on him/her and he/she shall not be able to withdraw or amend the offer.

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- 17) The University may arrange for a Technical Discussion meeting of the bidders preferably with the experts and/or of Advisory Committee Members of Gujarat Technological University, where specifications offered by bidders will be analysed and clarifications, if required. The exact date and time will be communicated to the bidders by Gujarat Technological University.
 - 18) Orders for Software(s) will be dispatched to the successful party in two copies and the party has to return one copy duly stamped and signed as a token of the acceptance of the order. In case the order confirmation is not received within a time period of one week, it shall be presumed that the vendor has not accepted the order and will be liable to be cancelled. In such cases EMD will be forfeited and legal actions may be taken.
 - 20) Supplier shall be required for imparting training to our technical team and faculty on operation and use of software, its accessories and software for the intended applications and troubleshooting repair and maintenance etc. at GTU.
 - 21) Late, delayed, incomplete, conditional tenders and amendments & additions to tender after opening will not be accepted.
 - 22) Technical Bid Cover should contain
 - a. Tender document in original duly signed with stamp along with attested copies of GST and /or CST Registration Certificate, Latest Income Tax return (F.Y 2022-23, 2021-22 & 2020-21) other certificate documents as per checklist.
 - b. Tenderer should also furnish the details of the constitution of their firm, names and addresses of the Partners/ Proprietors/Directors and also the details of sister concerns if any. Also specify details or documents requested in Tender Enquiry.
 - c. Details of Tenderer in prescribed Format (Annex-IV).
 - d. No Pending Cases Declaration on a valid Stamp Paper (Annex-VI)
 - e. Tender Fee and Earnest money deposit (EMD) must be submitted in the form of a demand draft drawn on any nationalized bank payable at Ahmedabad to the Gujarat Technological University, Ahmedabad tender without separate EMD will not be considered.
 - f. Tenders should be submitted in an Envelope, titled as “The Technical BID”. This Envelope should be packed, sealed and be super-scribed as “TENDER FOR PROCUREMENT OF - NAME OF SOFTWARE(S)”

23) Security Deposit

- a. Security Deposit: Within 10 days of receipt of the acceptance letter, the service provider shall submit Security Deposit of 5 % (Five Percentage) of the Estimated Tender Value in the form of demand draft drawn on any nationalized bank payable at Ahmedabad to the Gujarat Technological University as Non-interest Bearing Security Deposit (SD) for the due performance of the contract This is applicable to a successful service provider. The Security Deposit shall be denominated in Indian Rupees. The SD will be returned after successful completion of work. . If the tenderer fails to comply with the above requirements within the said period the earnest money already deposited by tenderer shall be liable for forfeiture and the university shall purchase the services required at the risk and cost of the successful tenderer.
- b. EMD will be returned back to the successful bidder only after it furnishes Security Deposit.

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- c. The GTU shall forfeit the security Deposit submitted by the bidder, if the service provider abandons the contract or without reasonable excuse has failed to commence the work or has suspended the work, or in case the service provider does not execute the work in accordance with the terms and conditions of the contract or is persistently neglecting to carry out his obligations under the contract. The GTU also shall have the right to recover from the security deposit any amount that may be found due and payable by the service provider or recoverable by GTU from the service provider, under any head viz. Penalty, Fine, Liquidated damages, Deposits, etc.
- 24) **VALIDITY OF TENDER:** Tenderers are requested to note that their offer must be valid for acceptance minimum for a period of 180 days from the date of opening of tender. Offer with less validity period will be rejected.
- 25) **Technical Literature/Descriptive Catalogue/Pamphlets:** The vendors should submit their offer along with relevant Technical Literature/Descriptive Catalogue/Pamphlets along with their technical bid. In the absence of the above details of items offered may not be considered. The preference will be given to the party decided by the university authority without mentioning any reason. The decision of the university authority will be considered as final.
- 26) **Payment Terms:**
- a) The 100% payment will be paid after satisfactory installation/commissioning and training at GSP Gandhinagar Campus, K-6 Circle, E-4 Electronic estate, GIDC, Sector 26, Gandhinagar – 382028. Gujarat. India.
 - b) Fund transfer will be made through RTGS/online transfer only and not by any other mode.
 - c) Price of the offered item can be quoted in Indian currency only.
- 27) **Opening of Tender**
- You are at liberty to be present or authorize your representative to be present at the opening of the tender at the time and date specified in the schedule.
- 28) **Installation and Maintenance:**
- a. The tenderer shall be responsible for installation of the software at destination site and for making it fully operational. The DQ, IQ, PQ, OQ will be provided and wherever mentioned in technical specifications, the equipment must be complying with the CFR-21 (relevant parts) & other regulatory requirements. The tenderer must provide complete details regarding space and all infrastructure needed for installation of the software which Gujarat Technological University should arrange before its arrival.
 - b. The supplier should submit the complete documentation of installation and maintenance manuals of the Software(s).
- 29) **Penalty in case of the default.**
- a. The offer of the vendors should include the cost of installation. In case of delay on the part of the vendor, penalty of 0.5% per week of delay of the total order value will be deducted from the supplier's bill subject to maximum of 5% without prejudice to other terms & conditions of the order. The tenderer shall be responsible for installation of the software at destination site and for making it fully operational. The University reserves its right to get the work done by any other Supplier at the cost & risk of the Supplier under such circumstances.
 - b. For not maintaining quality of Software(s) and spare parts during Warranty and AMC period,

the University shall deduct penalty. The penalty charges will be decided by the University. If purchased from another vendor, cost of purchase will be recovered.

- c. In case of a refusal to execute the work by the successful bidder after acceptance, the Security Deposit shall be forfeited and legal action may be taken.

30) Services/Guarantee/Warranty:

- a. The successful bidder shall ensure to provide the cloud-based services without any interruption. In the events of downtime of the server or preventive maintenance, the vendor shall inform the institute in advance. In case of a breakdown of the server or any other software-related issues leading to interruption of services, the vendor shall ensure the restoration of the same as soon as possible. If reported downtime or breakdown is not rectified within 7 days during the service period, the vendor should extend the services of software (s) by the time period equal to delay in the rectification of the problem.

31) TERMINATION FOR DEFAULT

- a. If any dispute arises about the interpretation of any condition, the decision of the GTU shall be final. For settlement of dispute if any, jurisdiction of court shall be Ahmedabad.
- b. In case of dispute between GTU and the service provider both shall make every effort to resolve amicably by direct informal negotiation for any disagreement or dispute arising between them under or in connection with the contract.

32) 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 this contract in whole or in part if, the supplier fails to deliver any or all the goods/items within the time period(s) specified in the tender/work order/agreement., or any extension thereof granted by the purchaser or the supplier fails to perform any other obligations under the Contract.

Annexure–I

(Technical Specification)

The Tenderer have to quote the specific software to the technical specification as below.

A product to create and import the valid e-CTD package in an efficient and user friendly manner. With its help, it should be easy to compile, publish, manage and reviewed electronic submissions.

No. of users: Minimum 10

Software Type: Online mode (Cloud Based) or Hardware Based

Time duration: Minimum for 5 years

Technical Specifications:

Preferably 21 CFR part 11 compliant tool

Preferably supports different agencies like:

USFDA: United State Food & Drug Administration

EU: European Union

CA: Canadian Regulatory Agency

TGA: Therapeutic Goods Administration, Australia

MCC: Medicine Control Council, South Africa

JP: Japan Regulatory Agency

GCC: Gulf Cooperation Council

SA: South Africa

to create e-CTD submissions

Valid Submissions created by other tools can be imported into the application and it should have inbuilt import option

Drag and Drop feature to add documents

PDF property manager: System internally manage the PDF properties like PDF Version 1.4 as per ICH specification

Automatic File naming conventions based on the ICH guidelines

Comprehensive Study Tagging File (STF) creation and easy Life Cycle Management (LCM)

Consolidated View

Submission history management

Backbone XML validation

User Friendly

Annexure - II

CHECK LIST FOR TENDERER TO BE SUBMITTED ALONGWITH TENDER

The following documents are attached as Annexure with the tender:		Yes / No.	Page No
1.	Give the Page No. to entire set of Tender and documents enclosed with it in Physical (hard/spiral) form and sign on each page of tender document.		
2.	Whether EMD and Tender Fee in form of Demand Draft are placed in separate cover?		
3.	Whether copy of GST Registration / Provisional Registration (if Applicable) & PAN No. is attached?		
4.	Whether Undertaking of tenderer is attached? (as per Annexure - III)		
5.	Whether details of tenderer is attached? (as per Annexure - IV)		
6.	Whether copy of self-declaration regarding non-default in any statutory obligation / liability is attached? (as per Annexure - VI)		
7.	Whether copy of Income-Tax return of last three year (F.Y 2022-23,2021-22 & 2020-21) is attached ?		
8.	The turnover of the bidding firms for any one of the last 2 financial years should be at least 100% of the estimated total cost of the items. The bidder should submit the certificate from Chartered Accountant regarding the same. [As per Annexure-VII].		
9.	Whether the compliance sheet is attached ? (as per Annexure - VIII)		
10.	Whether all annexure as per tender are attached?		
11.	Whether the existing user (at least 3) list with contact details is attached?		
12.	Valid Authorization certificate from Manufactures		
13.	Delivery period declaration on letter head		
14.	Any Other details		

N.B. All photocopies of documents must be self-attested by authorized person in sequence.

DECLARATION

We solemnly declare that we have attached all the documents mentioned here above and mentioned in the tender. We also understand that non-compliance of any documents will be treated as non -respective tender and we will lose our claim to participate in the tender enquiry automatically and our tender will be liable to rejected.

Signature of Authorized Person :

Name of the Authorized Person:

Seal of the Company :

Annexure - III

I / We _____

(Name of the Tenderer)

Proprietor / Partner / Director hereby undertake to supply tender requirements to your Tender Enquiry specification and abide all terms and conditions of the tender enquiry as well as invitation to tender and instructions to tenderers.

Place:

Signature:

Date:

Name:

Designation:

Stamp of the firm

Annexure – IV
Details of Tenderer

1. Name of the Vendor :
2. Registered Office :
3. Working Place of the vendor :
4. Year of Establishment :
5. Type of Firm (Proprietorship, Partnership, Pvt. Ltd. or Ltd. Co.) etc :
6. Name, Address and Telephone (O):
Number of Responsible person (R):
Phone with STD code (M):
7. E-mail address :
8. Details of Tender Fee & E.M.D.
D.D. No.
Date
Name of Bank
9. Factory Act Registration No/Shop
Establishment Registration
Number. (Enclose certified copy
of Registration)
10. Permanent Account No. & GST
Certificate (Enclose Certified
PAN CARD & GST) copy

Note: For above details, attach separate sheet if required

Place:

Date:

Seal and Signature of Authorized person

Annexure - V

Commercial Bid

(To be submitted online only)

Sr. No.	Name of Software	Quantity	Service Period	Price
1	"e CTD Software	10 Users	5 Years	To be submitted on line only
1	"e CTD Software	10 Users	10 Years	To be submitted on line only

Note: -

- Rates must be inclusive of freight, insurance, transportation, supply, installation, maintenance, training, labour charges & etc. but excluding GST to the Gujarat Technological University, Gandhinagar campus.
- The L1 will be considered in Indian rupees quoted for 5 years.

Annexure – VI

(ON RS.300/- STAMP PAPER DULY NOTARISED)

Undertaking by the Bidder

I, (Name of Bidder/ Authorized person), Aged aboutyears, working at..... (Postal Address) do hereby swear this affidavit that, I am the proprietor/Partner of/Director of (Name of company/ firm) Registered at (Regd. Address)

I do hereby swear that, the tender documents submitted for the work of (name of the work) are true, correct and complete. I/My agency am/is not blacklisted by any organization in India from participating in any project/s, either individually or as member of a consortium. There have been no criminal proceedings / conviction against the bidder at any point of time. In case the documents pertaining to the tender submitted by me are found to be incorrect or false, I shall be liable for action under the relevant provision of Indian Penal Code and other relevant laws.

I further undertake that if above declaration proves to be wrong/incorrect or misleading, tender/contract stands to be cancelled/terminated immediately.

If work is allocated to our company/firm than outmost care will be taken and if we fail in any part than GTU can demand for financial loss, impose penalty, forfeiture of Security Deposit and also can take legal action against our company/firm.

We are not involved in any litigation that may have an impact of affecting or compromising the delivery of services as required under this assignment. I/We am/are not a relative/blood relation of any key managerial person of GTU, Ahmedabad. We are not a firm in which any key personnel of GTU, Ahmedabad or his/her relative is a partner. I/We am/are not a partner in a firm in which any key managerial person of GTU, Ahmedabad or his/her relative is a partner.

We further confirm that we are aware that our Gujarat Technological Universities bid with reference(Tender number with subject) would be liable for rejection or any appropriate action as GTU may deem fit, in case any material misrepresentation is made or discovered with regard to the requirements of tender mentioned above during stage of short-listing/selection process.

Signature:

Name:

Business Address:

Place:

Date:

Annexure – VII

Date: DD/MM/YYYY

(On the Letter Head of CA)

Turnover Certificate

This is to certify that M/s _____ (PAN: _____) registered at _____ has achieved following total turnover & turnover purely related to during the financial year 2022-23, 2021-22 & 2020-21.

Sr. No.	Financial Year	Total Turnover (In Rs.)	Turnover related to(In Rs.)
1	2022-23		
2	2021-22		
3	2020-21		

This certificate has been issued on the basis of documents and records provided to us.

Place:-

Date:- DD/MM/YYYY

Seal and Signature of CA with stamp.

UDIN:

Annexure – VIII
Compliance Sheet

Software Name:

Name of Bidder:

Name of Manufacturer:

Model Name and Number (with version, if any):

Se. No.	Parameter	Tender Specifications	Quoted Model Specifications	Remarks by bidder	Verification*
1					
2					

* Not to be filled by bidder

(N.B.: Bidder should also mention specifications of accessories, if any.)