Central Drugs Standard Control Organization
Directorate General of Health Services
Ministry of Health & Family Welfare
Government of India

NOTICE INVITING EXPRESSION OF INTEREST FOR

Selection of Software Services Provider (SSP) for Digital Transformation of Central Drugs Standard Control Organization, IPC & NIB

(Digital Drugs Regulatory System)

EoI IT-13011(17)/1/2023-CDSCO

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION

Ministry of Health and Family Welfare

Government of India

November 2023

FDA Bhawan, Kotla Road, New Delhi-110002

Invitation of EoI for Selection of Software Services Provider (SSP) for Digital Transformation of Central Drugs Standard Control Organization, IPC & NIB (Digital Drugs Regulatory System)

Central Drugs Standard Control Organization (CDSCO) is the National Drugs Regulatory Authority of the Government of India and is responsible for laying down the standards for Drugs, approval for Clinical Trials and New Drugs, control over the quality of imported Drugs, coordination of activities of State Drugs Control Organizations, enforcement of the Drugs and Cosmetics Act, granting and renewal of licenses for specified critical categories of Drugs such as blood and blood products, Vaccine and Sera, r-DNA products.

The regulatory landscape is continuously evolving, striving for alignment with global standards, while ensuring affordability and accessibility for its vast population. India's with its vast population and diverse health challenges, ensuring the availability of safe and effective medicines is not just a commercial imperative but also a significant public health concern.

To build a robust yet enabling digital regulatory ecosystem in India, CDSCO invites Expression of Interest from interested Software Services Provider for the Development and Maintenance of Digital Drugs Regulatory System (DDRS) of Central Drugs Standard Control Organization, IPC & NIB for an expected period of about 8 to 10 years.

The aim is to develop DDRS as a unified digital ecosystem. Once operational, all existing portals will be discontinued, and DDRS will serve as a Single Window, Single Sign On, and Unified Portal for all regulatory activities. This platform is envisioned to serve as a new approach to regulatory system in the form of India’s DPI for regulatory systems, thereby ensuring quality medicines for India and the world.

The system needs to be developed using a platform design approach, open-source technology stack, and open standards.

For overview of the existing system, scope, pre-qualification criteria, other terms and conditions and suggested response formats, please refer to specific sections of this EoI document.

Interested Service Providers who meet the pre-qualification criteria may furnish their Expression of Interest with all the necessary documents on or before 16:00 hours on Wednesday, 30th November 2023 at the email admn@cdsco.nic.in.

Schedule of events & bid details

S No	Particular	Timelines
1	Start date of issuance of EOI document	2nd November 2023
2	Last date for Submission of Queries (by email only)	15th November 2023
3	Pre-Bid Conference (In hybrid mode)	Date and Time: 22nd November 2023 at 3:00 P.M. Meeting link: https://cdscofda.webex.com/cdscofda/j.php?MTID=m8f94101f113eb8acfee63387705895d3 Address: Central Drugs Standard Control Organization, FDA Bhawan, Kotla Road, New Delhi-110002
4	Last date and time for EOI Submission	16:00 hrs on 30th November 2023

TABLE OF CONTENTS

1 INSTRUCTION TO THE BIDDERS 11
1.1 Conditions under which this EoI is issued 11
1.2 Compliant Proposals / Completeness of Response 11
1.3 Preparation and Submission of Proposal 11
1.4 Pre-bid Meeting 12
1.5 Responses to pre-bid queries and issue of corrigendum 12
1.6 Right to terminate the EOI process 13

2 INTRODUCTION 13
2.1 The Government of India Mission 13
2.2 Central Regulator: CDSCO 13
2.3 State Drugs Regulators 14
2.4 Central Drugs Laboratories 14
2.5 Indian Pharmacopeia Commission, Ghaziabad 15
2.6 National Institute Biological, Noida 16
2.7 State Drug Testing Laboratories 16

3 SCOPE OF WORK 18
3.1 Present IT Platforms of CDSCO, IPC Ghaziabad and NIB, Noida 18
3.2 The Status of the present IT Platforms of CDSCO 18
3.3 The proposal for Digital Transformation and Setting up of DDRS 19
3.4 Execution Strategy 24
3.5 Deliverables of the Software Service Provider 24

4 CDSCO'S RESPONSIBILITIES 26

5 SERVICE PROVIDER'S OBLIGATIONS 26

6 PRE-BID CONFERENCE 28

7 DEVIATIONS 28

8 DELIVERABLES 28

9 SERVICE LEVEL AGREEMENT 29

10 ACCEPTANCE, CERTIFICATION AND ROLL-OUT 31

11 PAYMENT TERMS AND MILESTONES 31

12 BID ELIGIBILITY, EVALUATION CRITERIA & EVALUATION PROCESS 32
12.1 Eligibility Criteria for Technical Evaluation 32
12.2 Bid Evaluation Committee 34

13 TECHNICAL & FINANCIAL EVALUATION 34
13.1 Technical Evaluation of Bids 34
13.2 Financial Evaluation of Bids 36

14 CONTRACT PERIOD 36

15 PURCHASE PREFERENCE POLICIES OF THE GOVERNMENT 36

16 MAKE IN INDIA ORDER 37

17 RIGHT TO VARY QUANTITIES AT THE TIME OF AWARD: 37

18 CONFLICT OF INTEREST 37

19 COPYRIGHT 37

20 CONFIDENTIALITY, COPYRIGHTS, AND INTELLECTUAL PROPERTY RIGHTS (IPRS) 37

21 ANNEXURE 1: ORGANIZATION CHART OF CDSCO 39

22 ANNEXURE 2: FUNCTIONS OF CDSCO AND ITS ORGANS 39

22.1 Functions of the CDSCO (HQ) 39

22.2 Broad Functional Activities and Duties of The Zonal and Sub-Zonal Offices of CDSCO 40

22.3 Functions of Port offices of CDSCO 41

22.4 Functions of Central Drugs Laboratories / Mini Laboratories 41

23 ANNEXURE 3: LICENSES / PERMITS ISSUED BY STATE AUTHORITIES 42

23.1 Various Licenses Issued by State Drug Controller Authorities 42

24 ANNEXURE 4: DETAILS OF PERMISSION/LICENSES HANDLED BY CDSCO/SUGAM 42

25 ANNEXURE 5: DETAILS OF PERMISSION/LICENSES HANDLED BY CDSCO/MD ONLINE 45

26 ANNEXURE-6: A DETAILED LIST OF SERVICES THAT CAN BE APPLIED ONLINE THROUGH ONDLS PORTAL 47

27 ANNEXURE 7: FUNCTIONS AT CDSCO WITHOUT COMPUTERIZATION (MANUAL OFFLINE) 49

28 ANNEXURE 8: OTHER CENTRAL GOVERNMENT AGENCIES THAT NEED TO BE INTEGRATED WITH CDSCO (ELECTRONIC) 53

29 ANNEXURE 9: INDEPENDENT PORTALS UNDER CDSCO THAT NEED TO BE INTEGRATED WITH CDSCO (ELECTRONIC) 54

30 ANNEXURE 10: DETAILS OF DELIVERABLES AND TERMS AND CONDITIONS FOR SOFTWARE SERVICE PROVIDER 55

30.1 Terms of Reference 55

30.2 SLA Deliverables 56

31 ANNEXURE 11: PRE-QUALIFICATION & TECHNICAL BID TEMPLATES 58

31.1 Form 1: Compliance Sheet for Pre-Qualification Proposal 59

31.2 Form 2: Particulars of the Bidder 60

31.3 Form 3: Compliance Sheet for Technical Proposal 61

31.4 Form 4: Letter of Proposal 63

31.5 Form 6: Project Citation Format 64

31.6 Form 6: Proposed Solution 65

31.7 Form 7: Proposed Work Plan 66

31.8 Form 8: Team Composition 66
31.9 Form 9: Curriculum Vitae (CV) of Key Personnel 67
31.10 Form 10: Deployment of Personnel 68
31.11 Form 11: Deviations 69
32 ANNEXURE 12: FINANCIAL PROPOSAL TEMPLATE 70
32.1 Form 1: Covering Letter 70
32.2 Form 2: Financial Proposal 72
32.2.1 Form 2A: Details of Financial Bid 72

List of Abbreviations

AERB	Atomic Energy Regulatory Board
BIS	Bureau of Indian Standards
BOQ	Bill of Quantities
BP	British Pharmacopoeia
CCPA	Central Consumer Protection Authority
CDAC	Centre for Development of Advanced Computing
CDEC	Custom Duty Exemption Certificate
CDL	Central Drugs Laboratory
CDSCO	Central Drugs Standard Control Organization
CDTL	Central Drugs Testing Laboratory
Cert-In	Computer Emergency Response Team
ChP	Chinese Pharmacopoeia
CIOMS	Council for International Organizations of Medical Sciences
CLA	Central Licensing Authority
CLAA	Central Licensing Authority
CMSS	Central Medical Services Society
COPP	Certificate of Pharmaceutical Product
CRF	Case Registration Form
CSP	Cloud Service Provider
CTRI	Clinical Trials Registry - India
DAHD	Department of Animal Husbandry and Dairying
DB	Database
DBT	Department of Biotechnology
DCC	Drugs Consultative Committee
DDRS	Digital Drugs Regulatory System
DGFT	Directorate General of Foreign Trade
DI	Drug Inspector

DoCA	Department of Consumer Affairs
DoP	Department of Pharmaceuticals
DPIIT	Department of Promotion of Industry & Internal Trade
DSC	Digital Signature Certificate
DTAB	Drugs Technical Advisory Board
EoDB	Ease of Doing Business
ER	Entity Relationship
FDC	Fixed Dose Combination
GCT	Global Clinical Trials
GeM	Government e Marketplace
GMP	Good Manufacturing Practices
GST	Goods and Services Tax
HRMS	Human Resource Management System
HvPI	Haemo vigilance Programme of India
IB	Investigator Brochure
ICEGATE	Indian Customs Electronic Gateway
ICF	Informed Consent Form
ICMR	Indian Council of Medical Research
ICS	Import Clearance System
ICSR	Individual Case Safety Report
IMPD	Investigational Medicinal Product Dossier
IND	Investigational New Drugs
IPC	Indian Pharmacopoeia Commission
IPR	Intellectual Property Rights
IVD	In Vitro Diagnostics
IVR	Interactive voice response
JP	Japanese Pharmacopoeia
KPI	Key Performance Indicators

LA	Licensing Authority
LIMS	Laboratory Information Management System
MA	Marketing Authorisation
MDTL	Mini Drugs Testing Laboratory
MeitY	Ministry of Electronics and Information Technology
MIS	Management Information System
MoEFCC	Ministry of Environment, Forest and Climate Change
ND	New Drugs
NIB	National Institute of Biologicals
NIC	National Informatics Centre
NOC	No Objection Certificate
NSQ	Not of Standard Quality
O&M	Operational & Maintenance
ONDC	Open Network for Digital Commerce
ONDLS	Online National Drugs License System for State Authorities
OWASP	Open Source Foundation for Application Security
PhEur	European Pharmacopoeia
PvPI	Pharmacovigilance Programme of India
RCGM	Review Committee on Genetic Manipulation
rDNA	Recombinant DNA
RDTL	Regional Drugs Testing Laboratory
SDLC	Software Development Lifecycle
SLA	Service Level Agreement
SND	Subsequent New Drugs
SSP	Software Service Provider
STQC	Standardisation Testing and Quality Certification
TEC	Technical Evaluation Committee
TRS	Timeline Review System

UAT	User Acceptance Testing
UI	User Interface
USP	United States Pharmacopeia
UT	Union Territory
UX	User Experience
WHO	World Health Organization
XML	Extensible Markup Language

1 INSTRUCTION TO THE BIDDERS

1.1 CONDITIONS UNDER WHICH THIS EOI IS ISSUED

1. This EoI is not an offer and is issued with no commitment. CDSCO reserves the right to withdraw the EoI and change or vary any part thereof at any stage. CDSCO also reserves the right to disqualify any bidder, should it be so necessary at any stage.
2. CDSCO reserves the right to withdraw this EoI if CDSCO determines that such action is in the best interest of the Government of India.
3. Timing and sequence of events resulting from this EoI shall ultimately be determined by CDSCO.
4. No oral conversations or agreements with any official, agent, or employee of CDSCO shall affect or modify any terms of this EoI and any alleged oral agreement or arrangement made by a bidder with any department, agency, official or employee of CDSCO shall be superseded by the definitive agreement that results from this EoI process. Oral communications by CDSCO to bidders shall not be considered binding on CDSCO, nor shall any written materials provided by any person other than CDSCO.
5. Neither the bidder nor any of the bidder's representatives shall have any claims whatsoever against CDSCO or any of their respective officials, agents, or employees arising out of, or relating to this EoI or these procedures (other than those arising under a definitive service agreement with the bidder in accordance with the terms thereof).
6. Applicants who are found to canvass, influence or attempt to influence in any manner the qualification or selection process, including without limitation, by offering bribes or other illegal gratification, shall be disqualified from the process at any stage.
7. Each applicant shall submit only one Pre-qualification requirements proposal.

1.2 COMPLIANT PROPOSALS / COMPLETENESS OF RESPONSE

1. Bidders are advised to study all instructions, forms, terms, requirements and other information in the EOI documents carefully. Submission of the bid shall be deemed to have been done after careful study and examination of the EOI documents with full understanding of its implications.
2. The response to this EOI should be full and complete in all respects. Failure to furnish all information required by the EOI documents or submission of a proposal not substantially responsive to the EOI documents in every respect will be at the Bidder's risk and may result in rejection of its proposal.

1.3 PREPARATION AND SUBMISSION OF PROPOSAL

1. The Bidder is responsible for all costs incurred in connection with participation in this process, including, but not limited to, costs incurred in conduct of informative and other diligence activities, participation in meetings / discussions / presentations, preparation of proposal, in providing any additional information required by the Purchaser to facilitate the evaluation process, unless explicitly specified to the contrary.

2. Purchaser will in no case be responsible or liable for those costs, regardless of the conduct or outcome of the bidding process.
3. This EOI does not commit Purchaser to award a contract or to engage in negotiations. Further, no reimbursable cost may be incurred in anticipation of award or for preparing this EOI, unless explicitly specified to the contrary.
4. All materials submitted by the Bidders will become the property of Purchaser and may be returned completely at its sole discretion.
5. The entire proposal shall be strictly as per the formats specified in this EOI and any deviation may result in the rejection of the Bidder's EOI proposal.
6. The response to EOIs must be submitted through email at admn@cdsco.nic.in by the date and time mentioned in the section "Schedule of events & bid details". Any proposal submitted on after the above deadline will not be accepted and hence shall be automatically rejected. Purchaser shall not be responsible for any delay in the submission of the documents.
7. Language: The Proposal should be filled by the Bidder 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 Proposal, the English translation shall govern.

1.4 PRE-BID MEETING

1. Purchaser shall hold a pre-bid meeting with the prospective Bidders as per the schedule mentioned in the section "Schedule of events & bid details".
2. The Bidders will ensure that their queries with regard to the EOI, to be addressed by the Purchaser during the Pre-Bid meeting shall reach by email on or before the last date mentioned in the section "Schedule of events & bid details" to Mr Dileep Rajput at admn@cdsco.nic.in.

1.5 RESPONSES TO PRE-BID QUERIES AND ISSUE OF CORRIGENDUM

1. The Nodal Officer notified by the Purchaser will endeavour to provide timely response to all queries. However, Purchaser makes no representation or warranty as to the completeness or accuracy of any response made in good faith.
2. At any time prior to the last date for receipt of bids, Purchaser may, for any reason, whether at its own initiative or in response to a clarification requested by a prospective Bidder, modify the EOI document by issuing a corrigendum.
3. The corrigendum (if any) & clarifications to the queries from all Bidders will be posted on cdsco.gov.in and emailed to all participants of the pre-bid conference.
4. Any such corrigendum shall be deemed to be incorporated into this EOI.
5. In order to afford prospective Bidders reasonable time in which to take the corrigendum into account in preparation of their bids, Purchaser may, at its discretion, extend the last date for the receipt of EOI Bids

1.6 RIGHT TO TERMINATE THE EOI PROCESS

1. Purchaser may terminate the EOI process at any time without assigning any reason. Purchaser makes no commitments, expression or implied that this process will result in a business transaction with anyone.
2. This EOI does not constitute an offer by the Purchaser. The Bidder's participation in this process may result in Purchaser short listing the Bidder to submit a complete technical and financial response at a later date.

2 INTRODUCTION

2.1 THE GOVERNMENT OF INDIA MISSION

The Government of India is currently engaged in upgrading the quality of regulatory practices in the country. It brings a high degree of uniformity in these practices across the States. A good regulatory system should help build a science-based regulatory framework to support and promote Research and Development in the country. One of the main interventions of the Central Government to achieve its Public Health objectives is to ensure that drugs available in the country are safe, efficacious and conform to prescribed quality standards.

The drugs regulatory system protects public health by assuring the safety, efficacy and quality of human and veterinary drugs, biological products, medical devices, diagnostics and cosmetics. The drugs regulatory system is also responsible for advancing public health by keeping its systems contemporary and helping speed innovations that make pharmacotherapy safer and more effective. The regulatory system also helps consumers get accurate and adequate information concerning the appropriate use of medicines and related products.

2.2 CENTRAL REGULATOR: CDSCO

Central Drugs Standard Control Organization (CDSCO) is the National Drugs Regulatory Authority of the Government of India. It exercises regulatory control over the quality of drugs and cosmetics and notified medical devices in the country. It is responsible for laying down the standards for Drugs, approval for Clinical Trials and new drugs, control over the quality of imported Drugs, coordination of activities of State Drugs Control Organizations and providing expert advice with a view to bringing about uniformity in the enforcement of the Drugs and Cosmetics Act as well as granting and renewal of licenses for specified critical categories of Drugs such as blood and blood products, Vaccine and Sera, r-DNA products.

The organizational infrastructure of CDSCO includes a Headquarters in Delhi, Zonal and sub zonal Offices in Ahmedabad, Baddi, Bangalore, Kolkata, Hyderabad, Ghaziabad, Chennai, Mumbai, Goa, Guwahati, Indore, Jammu, Rishikesh, Varanasi, Visakhapatnam, Port Offices in Ahmedabad, Bangalore, Chennai, Delhi, Goa, Hazira, Hyderabad, Kochi, Kolkata, Krishnapatnam, Mumbai, Vishakapatnam, Tuticorin, Laboratories in CDL Kasauli, CDL Kolkata, CDTL Chennai, CDTL Hyderabad, CDTL Indore, CDTL Mumbai, RDTL Chandigarh, RDTL Guwahati, IPC Ghaziabad, NIB Noida, and Mini laboratories at MDTL Ahmedabad, MDTL Bangalore, MDTL IGI Airport Delhi, MDTL Mumbai Airport, MDTL Mumbai Seaport, MDTL RGI airport Hyderabad.

The major objectives of CDSCO are:

- To upgrade knowledge of regulators and to increase consumer awareness.

- To interact and cooperate with the State, Central Government, Union Territories, and non-governmental voluntary organizations to improve the quality of healthcare facilities.
- To inculcate a sense of dedication amongst regulators, assist them to improve their professional excellence and effectiveness, enabling them to serve and safeguard the interest of the consumers.
- To promote and advance, in the interest of the public, the art of science and pharmaceutical technology and to develop the highest standards for pharmaceutical and Medical Devices industry products with technology.
- To offer better services to the public.
- To foster a science-based, predictable and consistent regulatory framework to support and promote Research and Development in the country.
- As Per the provisions of the Drugs and Cosmetic Act and Medical Rules, 2017, The Licenses for Class A and B Products are issued by the State Licensing Authority. The Licenses for Class C and D class Products are granted by the Central Licensing Authority (CLAA).

A detailed organizational chart and functions of each office to meet the above-mentioned objectives are provided in **Annexures 1 and 2** for reference.

2.3 STATE DRUGS REGULATORS

Under the provisions of the Drugs & Cosmetics Act, 1940 and the Drugs & Cosmetics Rules, 1945, the manufacture, sale and distribution of drugs and cosmetics are regulated by the State Drugs Control Authorities appointed by the State Governments. Even the sale of imported drugs after having been permitted by the CDSCO is monitored and regulated by State Drug Control Departments. Accordingly, the Drugs Control Departments of the States / UTs play a vital role in implementing the provisions of the Drugs & Cosmetics Act, 1940 and the Drugs & Cosmetics Rules, 1945.

The key functions of State drugs regulators are listed below:

- Grant/renewal of Licenses for Manufacture, Sale and Distribution of Drugs, Cosmetics and Medical Devices
- Monitoring the quality of Drugs and Cosmetics by drawing samples from the market and evaluating their quality at their Drugs Testing Laboratories
- Investigations and prosecution in case of violations under the Drugs and Cosmetics Act and Rules.

A detailed list of various Licenses / Permits issued by State Authorities is enclosed in **Annexure 3.**

2.4 CENTRAL DRUGS LABORATORIES

Presently, there are eight Central Drugs Control Laboratories apart from IPC, Ghaziabad, and NIB Noida. Further, the Government of India is in the process of building new Government Laboratories for drugs and Medical Devices/IVDs and Cosmetics along with Mini Laboratories at the Port office in the future. The broad function of Central labs Laboratories is summarized below:

- Analytical quality control of imported and manufactured drugs.

- Analytical quality control of drugs and cosmetics samples drawn by DI as statuary samples and testing of market surveillance samples in the country.
- Test and analysis of new drugs referred by CDSCO, HQ.

The following are the various central Laboratories:

S. No.	Name of the Laboratory
1.	Central Drugs Testing Laboratory, Chennai
2.	Central Drugs Testing Laboratory, Mumbai
3.	Central Drugs Laboratory, Kolkata
4.	Central Drugs Testing Laboratory, Hyderabad, Andhra Pradesh
5.	Regional Drugs Testing Laboratory, Guwahati
6.	Regional Drugs Testing Laboratory, Chandigarh
7.	Central Drugs Laboratory, Kasauli, Himachal Pradesh
8.	Central Drugs Testing Laboratory, Indore
9.	Indian Pharmacopoeia Commission, Ghaziabad, (U.P.)
10.	National Institute of Biologicals, Noida (U.P.)

2.5 INDIAN PHARMACOPEIA COMMISSION, GHAZIABAD

The various functions of the Indian Pharmacopeia Commission are as follows:

- To develop comprehensive monographs for drugs to be included in the Indian Pharmacopoeia, including active pharmaceutical ingredients, pharmaceutical aids, dosage forms, and medical devices and to keep them updated by revision on a regular basis.
- To publish new editions and addenda of the Indian Pharmacopoeia at regular intervals.
- To develop monographs for herbal drugs, both raw drugs and extracts/formulations thereon.
- To accord priority to monographs of drugs included in the National Essential Medicines List and their dosage forms.
- To take note of the different levels of sophistication in analytical testing/ instrumentation while framing the monographs.
- To accelerate the preparation, certification, and distribution of IP Reference Substances, including the related substances, impurities, and degradation products.
- To collaborate with pharmacopoeias like the PhEur, BP, USP, JP, ChP and International Pharmacopoeia to harmonize with global standards.

- To review existing monographs periodically to delete obsolete ones and amend those requiring upgrading /revision.
- To organize educational programs and research activities to spread awareness on the need and scope of quality standards for drugs and related articles /materials.
- To publish the National Formulary of India for updating medical practitioners and other healthcare professionals.
- To act as a National Coordination Centre for the Pharmacovigilance Programme of India (PvPI).

2.6 NATIONAL INSTITUTE BIOLOGICAL, NOIDA

NIB's primary statutory function is Quality Control of Biological, e.g. Insulin, erythropoietin etc., blood products- e.g. Human Albumin, Human Normal Immunoglobulin, Human Coagulation factor VIII, IX etc.; HIV, HBV, HCV diagnostic kits; therapeutic monoclonal antibodies like Trastuzumab and Rituximab, etc.; Blood Grouping Reagents; Glucometers etc. in accordance with provisions of Drugs & Cosmetics Act 1940 and Rule 1945 and Medical Device Rules 2017 amended from time to time and relevant pharmacopoeia or International norms as applicable.

2.7 STATE DRUG TESTING LABORATORIES

The broad function of state testing Laboratories is to test and analyse the samples forwarded by the Drug Inspectors from the concerned state.

The following are the various state Laboratories:

S. No.	State	Name of the Laboratory
1	Jharkhand	State Drug Testing Laboratory
2	Madhya Pradesh	FDL Bhopal
3	Andhra Pradesh	Andhra Pradesh Drug Control Laboratory
4	Tripura	State Drug Testing Laboratory
5	Kerala	State Drug Testing Laboratory Kerala
6		Regional Drugs Testing Laboratory
7		Drug Testing Laboratory, Medical College Campus Mulamkunnathukavu
8		Drug Testing Laboratory Near Govt. Medical college Kummannoor
9	Jammu & Kashmir	Jammu & Kashmir Drug Testing Laboratory
10		Combined Food & Drug Testing Laboratory
11	Meghalaya	Drug Testing Laboratory

S. No.	State	Name of the Laboratory
12	Karnataka	Drug Testing Laboratory
13	West Bengal	State Drug Control Research Laboratory
14	Pondicherry	Drugs Testing Laboratory
15	Rajasthan	Drug Testing Laboratory Jaipur
16		Drug Testing Laboratory Udaipur
17		Drug Testing Laboratory Bikaner
18	Uttarakhand	State Food &Drug Testing Laboratory Utrakhand Rudrapur
19		State Food &Drug Testing Laboratory Dehradun
20	Assam	State Drug Testing Laboratory
21	Delhi	Drugs Testing Laboratory Govt. of NCT of Delhi
22	Tamil Nadu	State Drug Testing Laboratory Chennai
23		State Drug Testing Laboratory Madurai
24		State Drug Testing Laboratory Guindy
25	Uttar Pradesh	FDAL Lucknow
26		Regional Food & Drug Laboratory Agra
27		Regional Food & Drug Laboratory Meerut
28		Regional Food & Drug Laboratory Varanasi
29		Regional Food & Drug Laboratory Gorakhpur
30	Bihar	Bihar Drug Control Laboratory
31	Maharashtra	Food & Drugs Administrations Laboratory, Mumbai, Maharashtra State
32		Food and Drugs Administrations Laboratory (M.S.), Nagpur
33		Food and Drugs Administration Laboratory M.S. Aurangabad
34	Chhattisgarh	State Drug Testing Laboratory Chasttisgarh

3 SCOPE OF WORK

3.1 PRESENT IT PLATFORMS OF CDSCO, IPC GHAZIABAD AND NIB, NOIDA

CDSCO has undertaken a number of information technology initiatives in the past to enable its stakeholder's engagement with CDSCO through an informative website and a number of online platforms. The following is a summary of such initiatives:

1. WEBSITE serving as the gateway for information dissemination and access to online platforms (https://cdsco.gov.in)
2. SUGAM Online: An online licensing portal of the CDSCO was launched in January 2016 and facilitates applicants to file applications for various services, officers of CDSCO for processing these applications and grant of permission for quick delivery of services. (https://cdscoonline.gov.in) A detailed list of services that can be applied online through Sugam is enclosed in **Annexure 4.**
3. MD online: The application for Licenses for Manufacturing of Medical Devices, including In-Vitro Diagnostic Devices and their issuance, is handled Online at this portal. (https://cdscomdonline.gov.in) A detailed list of services that can be applied online through the CDSCO MD portal is enclosed in **Annexure 5.**
4. SUGAM LABS: This Laboratory information management system is envisaged for the CDTL, and CDTL carries out the required tests and analysis for the confirmation of active pharmaceutical ingredients, pharmaceutical excipients, pharmaceutical products, Cosmetics, Drugs, Medical Devices and Vaccine to meet quality specifications. (https://sugamlabs.gov.in)
5. ONDLS: ONDLS is the Online National Drugs License System for State Authorities. ONDLS is a single window platform for the online processing of various applications submitted by the applicants for issuance of manufacturing and sales licenses, including Blood Banks and other certificates like COPP, GMP, WHO-GMP, Market Standing certificate etc., and post-approval changes. (https://statedrugs.gov.in). A detailed list of services that can be applied online through the ONDLS portal is enclosed in **Annexure 6.** All States have to be onboarded on the portal**.** Detailed UAT, etc., shall be required to be done with the states. The different states may have different implementation requirements due to their existing workings. The state-wise portal customization will be required for the onboarding of States/UT. It shall also include Data porting and integration with State Single Window Systems. The States/UTs shall also be provided IT support for easy onboarding.
6. Currently, IPC is operating its E-Commerce website, www.ipc.gov.in, for disseminating updates related to activities carried out by IPC, Sales and distribution of IP reference standards and various publications by IPC.
7. NIB, Noida has its website https://www.nib.gov.in/ and Hemo Vigil and Donor Vigil web-based applications under the Haemovigilance Programme of India (HvPI).

3.2 THE STATUS OF THE PRESENT IT PLATFORMS OF CDSCO

All these platforms have been developed by CDAC over a period of time and are at various stages of implementation and usage. Though they have helped computerize online application facilities for business stakeholders and online processing tools for CDSCO officers and state government officers, these platforms have challenges. Few examples are listed below:

- They have been mostly developed and implemented in Silos over the years. They are hosted and operated from individual domain names and have minimal integration with each other. Hence, do not permit a Single Window experience to Applicants and officers of Central and State Governments.
- The performance of these platforms has been found to be slow and inconsistent during peak load demands by the users.
- These platforms have not been integrated with other Government of India identification platforms like Aadhaar, PAN, DigiLocker, ONDC, etc., leading to the absence or manual verification.
- The in-built checks and balances within the platform for licenses and permits are not found to be parameterized enough, leading to manual verification of electronic data submitted by the applicants at various stages in duplicating efforts many times among officers.
- The usage of these platforms by the State Government Agencies for issuance of permits/licenses is not uniformly operational across the country, with most of the state government agencies operating their platforms.
- The integration with these state government agencies for data aggregation is also not fully in place, so generating national-level data on Licenses, permits, etc., is a time-consuming exercise with substantial manual efforts.

3.3 THE PROPOSAL FOR DIGITAL TRANSFORMATION AND SETTING UP OF DDRS

The proposed DDRS is aimed at building trust and confidence in the quality of Drugs, Medical Devices, Cosmetics, etc., in the domestic and global market, transparency and accountability in the regulation of the quality, effective enforcement of quality, safety and efficacy at the field level, and ensuring compliance to Indian pharmacopoeia & standards.

The aim is to develop DDRS as a unified digital ecosystem. Once operational, all existing portals will be discontinued, and DDRS will serve as a Single Window, Single Sign On, and Unified Portal for all regulatory activities.

The system needs to be developed using a platform design approach with open-source technology stack, and open standards built on the models of other successful DPIs in India. The proposed DDRS should be modular and should take care of the following:

1. Creation of a unified portal for end-to-end management of all categories of products regulated by CLA and State Licensing Authorities. The end-to-end management would entail processes like registration, approval, post-approval changes, import/export related licenses/approvals, enforcement, inspection and other stages involved in the complete lifecycle of the following product categories:
    a. Biologicals (Vaccines, Blood products, rDNA, Stem cell and cell-based products, banking of umbilical cord blood cells, etc.),
    b. Drugs (Fixed dose combinations, Investigational New Drugs, New Drugs, Subsequent New Drugs, Large volume parenteral, etc.),
    c. Medical devices (In Vitro Diagnostics, devices, etc.),
    d. Cosmetics,
    e. Veterinary products,

f. Emerging therapies and AYUSH products,

g. Blood centres,

h. Testing laboratories,

i. Any other product category mandated by the act and relevant rules.

2. Design and develop a modular, flexible, and unified system that enables the integration with different stakeholders seamlessly:

   a. Other governmental departments, commissions, external agencies, etc. such as (but not limited to) BIS, GeM, AERB, MeitY, GST, DoP, Customs, Import/Export, RCGM, CCPA, GTAEC, Central Bureau of Narcotics, CTRI, DSIR, ICMR, DGFT, private laboratories, audit agencies, consultants, testing labs, ONDC, etc., for coordination, verification of documents, obtaining relevant regulatory permissions/certifications, dual-use NOC, compliance purposes, etc.

   b. Bringing activities online, which are currently performed in offline mode, such as certification for export permission, post-approval changes, periodic safety update reports, adverse event reporting, payment of compensation (as per rules), show-cause notice, etc. Examples of a few such activities are attached as **Annexure 7**. An exhaustive list has to be compiled in consultation with the stakeholders.

   c. Customization of portals for different stakeholders such as States/UTs, manufactures, labs, other external stakeholders, etc., based on their individual requirements and ensuring its proper integration on the unified portal. The non-exhaustive list of Government agencies is attached as **Annexures 8 and 9**.

   d. Laboratory Information Management System (LIMS) to generate data such as receipt, reports, chromatographs, data sheets, balance weight print, etc.

   e. International agencies for reporting and retrieving updated information (e.g., WHO, Global Clinical Trials, etc.).

3. Develop dynamic online registries for capturing and displaying real-time information in a sortable, searchable and filterable manner for:

   a. Product categories (mentioned in point 1 above) including category, quantity, and supply details (by the manufacturers, importers, etc.).

   b. All licensed entities and all permitted products that are under the jurisdiction of CLA and SLA.

   c. Manufacturers, marketeers, retailers, pharmacies, excipients, intermediaries, primary packing material, technical persons etc.

   d. Subject matter experts from various fields.

   e. NSQs, spurious, adulterated, misbranded products. Inspection reports by drug Inspectors, lab reports, all the alerts issued by CDCSO/ministry/SLAs, etc., should supplement this data.

   f. All vendors and stakeholders (including whole sellers, suppliers of the pharmaceuticals materials and supplies meant for pharma use, sourcing of API, etc.) with information on sales, stock movement, inventory, geo-tagging, etc.

   g. Methods of Analysis, specifications, etc. submitted by the manufacturers and making it available to relevant stakeholders (e.g. CDSCO, testing labs, etc.).

4. Systems to trace and track the entire value chain to gather information on all licensed products (including spurious and NSQ products), better inventory management and monitoring the corrective and/or punitive outcomes of vigilance/enforcement, which will allow:
    a. Capturing and tracking of products right from sourcing of raw materials, details on import or manufacturing, supply chain (sales and distribution), consumption (retailers and patients categorised by quantity, area, season, etc.), etc.
    b. Tracing and tracking of every step of the complete supply chain based on details (such as labels, batch number, invoice, etc.) mentioned on the product.
    c. Inter-state co-ordination for spurious and NSQ products to tackle the problem of movement of spurious drugs across state boundaries. The investigation and launch of prosecution in such matters should also be uploaded on the unified portal.
    d. Monitoring of the corrective, punitive outcomes of vigilance and enforcement through action taken reports, etc.
    e. Maintenance of stock inventory data to be used to manage emergency and pandemic situations better.
    f. Maintenance of stock register facility at labs, zonal offices, port offices, etc.
    g. Uploading of invoices for the complete supply and distribution chain (manufacturers, distributors, retailers, etc.).
5. Designing, development, implementation, and maintenance (for ten years), including user interfaces for the web (including information already listed in portals mentioned in section 2.1), mobile (applications for both Android and iOS with Geo-tagging facility), SMS, Chat-Bot, Voice, IVR, etc., with the following features:
    a. Monitoring and reporting
        i. Provisions to capture and generate reports (such as action taken reports, etc.) and undertakings by different stakeholders.
        ii. Provision to capture information from various stakeholders on a routine basis, based on pre-defined input and output data points (similar to ITR returns and GST filing)
        iii. Separate MIS dashboards for different stakeholders. Auto fetching of data with search and filter functionality and provisions to generate and download custom reports through MIS in multiple formats. System to allow stakeholders to send multiple custom reports at periodic intervals (for reporting purposes).
        iv. Ability to download complete history (for product data, license number, firm name, case data, etc.) for requirements such as authentication, validation, administrative requirements, presenting to court, etc.
        v. Timeline Review System (TRS) for monitoring timelines for individual applications to NOs, ROs, Labs, etc. This should also display the ageing of applications assigned based on standard timelines. In case of any delay, it should automatically send an alert to the concerned authorities.
        vi. Automated alert systems to inform relevant stakeholders on the status of applications, drug alerts, cosmetic alerts, renewal of applications,

pendency status, prescribing information, progress reports, recall of drugs, etc.

vii. Monitoring of all types of court cases for prosecution and convictions.

viii. Version history, historical data, and archived data to be made accessible to relevant stakeholders along with its timestamps.

ix. System to trace and track licensing, approval and post-approval notifications.

b. Inspection, assessment and auditing

i. Module for capturing data on trainings and certification (for online and offline trainings).

ii. Performance reports of officials, labs, LAs, etc., are to be automatically generated using pre-defined KPIs. A searchable, filterable, sortable database of such reports should be available to relevant authorities.

iii. Unique number generation for samples collected, reports, applications, certifications, licenses, uploaded documents, memos, guidelines, notices, etc., in a standard format. Auto-generation of QR codes for verification purposes at every stage.

iv. System to automatically assign inspectors (in a masked manner), schedule site inspections, generate inspection reports (including geo-tagging information, etc.), monitor compliances, etc. Provision to manually override should also be provided to the concerned authorities.

v. Random and automatic allocation of work assignments (which may include applications for licensing, approval, inspections, auditing, etc.) to NOs, ROs, etc.

vi. System to check/verify the authenticity of the products available in the market by entering information such as license number, batch number, QR code, etc.

vii. Auto addition of details such as the name of the user, timestamp, IP address, etc., for ensuring the validity and authenticity of the documents.

viii. Provision of appeal to be provided to the stakeholders regarding the grant of license, lab test reports, etc.

c. Integration

i. Preparing customized forms for exchanging information with different stakeholders based on their specific requirements.

ii. Payment gateway for enabling international and domestic payments. The payment gateway should be integrated with respective state treasuries, consolidated funds of India, etc.

iii. Ability to import data using multiple standard formats like CIOMS – E2B XML format, PvPI Individual Case Safety Report (ICSR), excel, CSV, PDF, etc.

iv. Provision to sign documents using authentication mechanisms like OTP, DSC, etc. using Aadhaar, PAN card, DigiLocker, etc.

v. Development of role-based user access levels for different stakeholders (e.g.., head of institution, division head, admin/account/finance department, etc.). User roles are to be discussed in consultation with stakeholders.

vi. Allow provision to upload standard templates for filling out lengthy application forms (e.g., JSON upload on the income tax filing portal).

vii. Generation of certificates and licenses with logos and details of respective Licensing Authorities (LAs), accrediting agencies, testing labs, etc.

viii. Linking of licenses, approvals, endorsement, retention, renewal, etc. defined for different product categories.

d. Miscellaneous

i. User guides, manuals, training videos, interactive charts on navigating the platform (web and mobile application, etc.), and approval process for different product categories.

ii. System to capture information on committees such as DCC, DTAB, SEC, ethics committee, etc. and other information such as GCT, BA/BE centres, PRO functions, correction slips, gazette notifications, etc.

iii. Communication platform for interface between SLAs, CLA, labs, manufacturers, etc.

iv. Technical person management system to be put in place to ensure that the same technical person cannot be associated with more than one manufacturer.

6. The system should be designed in a way that enables various analytics (in-house and third-party) to be performed and to assess the proper functioning of different aspects of the regulatory system, such as:

a. Algorithms for basic checks and balances for verification of documents such as duplication in batch number or name, etc.

b. Algorithms to scan the database to avoid duplicate licenses, etc.

c. Algorithms to measure employee performance, KPI outputs, etc.

d. Algorithms to detect whether states are undertaking specific sampling, targeted cases, etc.

e. Algorithms for identifying companies that are manufacturing drugs at risk, drug quality surveillance, etc.

f. Other use cases are to be discussed in consultations with the stakeholders.

7. The data migration required to transition from the existing systems to the new system should be planned as part of incremental delivery.

8. Any change resulting from the updation of acts, rules, or guidelines:

a. Any activity consequent to the updation of the Act and its relevant Rules.

b. Any activity concerning the allocation of the business rules for the CLA and State Licensing Authority pertaining to the regulation of drugs, cosmetics, and medical devices.

c. Any changes required for legal or statutory compliance.

9. Miscellaneous

a. Notice board for any advisories, policies, guidelines, notices, updates, etc., with archived section.

b. DDRS should be in compliance with the data security guidelines of the Government of India and global best practices, including frequent security audits and routine fixes.

c. UI/UX implementation is to be done keeping the end-user experience in mind.

d. Feedback, bug error reporting and correction tracking system.

e. Complaint redressal mechanism with a dedicated online ticket system.

DDRS shall aim at bringing all stakeholders, viz Central Government Regulators and Agencies, State Government Regulators and Agencies, Businesses (Manufacturers, Importers, Exporters, Distributors, Retailers, etc.) and integrate with key Central Government Platforms like AADHAAR, PAN, DigiLocker, GST, DGFT, Customs, etc., State Government Platforms and other support & services agencies like Private Laboratories, Audit Agencies, Consultants etc., together.

3.4 EXECUTION STRATEGY

DDRS is proposed to be executed through an outsourcing model using a custom bid methodology in GEM for hiring the following service providers:

1. Software Service Provider as SSP on a contract basis.
2. Hiring Cloud Service Provider (CSP) for hosting the proposed DDRS in a DevOps environment and available 24x7 to all stake holders, with the ability to scale up and down as per traffic/usage demands.

CDSCO shall set up a Project Management Committee comprising Senior officers of CDSCO from various departments with a named Project Director. This team shall finalize and put in place the following for the vendors:

1. The Service Level Agreements (SLA).
2. Project Execution plan including Project Deliverables, Milestones, Timelines, User Acceptance Testing and Go Live Plan.
3. Standard Operating Procedure for post-digitalization of the functions of CDSCO and state authorities and integration required with various State and Central Government Agencies.
4. Performance Metrics desired of DDRS in terms of user transaction load and experience, as well as MIS Output required from DDRS.

3.5 DELIVERABLES OF THE SOFTWARE SERVICE PROVIDER

The broad deliverables of the Software service provider shall include:

1. Design and develop a Unified Single Window DDRS Portal as a True Cloud Application, incorporating all the functionalities of the existing portal as well as the missing and new features as and when required,
2. Architecture & Technology Upgradation of selected existing systems into the latest technology in alignment with DDRS, ensuring true cloud applications, integrated into DDRS as a single integrated platform with single sign-on functionality,
3. Modifications, enhancements, and development of DDRS, APIs for integrations, etc., for smooth functioning of the portal,
4. Migrate data from existing platforms (including portals by states, labs, etc.) to the new proposed DDRS system,
5. Data Archival and Management Policy Implementation,

6. Services for Integrating with other Government Systems like Aadhaar, PAN, DGFT, Customs, etc.,
7. Deploy and Go Live in the Cloud Service Provider chosen by CDSCO,
8. Ensuring Compliance and Data Security standards as notified from time to time by the Government of India (by agencies like CERT-In, NIC, MHA, etc.) and open standards such as OWASP Compliance, etc. This will also include procurement and setting up certificates like SSL, etc.
9. Roll–out the features of the new DDRS in a phased and modular manner,
10. Extend Operational and Maintenance Support to the rolled-out modules, including troubleshooting, bug fixing, reporting, etc.
11. Setting up a dedicated team for Operations and Maintenance (O&M) support for the DDRS Platform.
12. Routine backups of code and data. Provision to auto backup code and data before every committing any change in the code.

The methodology of execution to be followed by the SSP shall be as follows:

1. **Project Management:** The Software vendor shall execute this as a Turnkey assignment with a project plan, milestones, timelines, etc., for the overall project and regular Scrum and Sprint meetings using modern project management techniques.
2. **Development Methodology:** The Software service provider shall follow an Agile development approach, co-creating the applications with the active involvement of CDSCO officers and concerned stakeholders. Action items from the meetings shall be recorded for future reference. Any changes or updates should be first tested on the testing server, and only after extensive testing it should be migrated to the production server.
3. **Prioritization:** Consolidated requirements for each project to be segregated based on the priority after discussion with user division instead of ad hoc requirements.
4. **Milestones and Timelines:** There is a need for timeline-based development, exhaustive testing, and monthly reporting of enhancements in the application for both development and O&M.
5. **Integration:** Open API integration approach to be formulated for end-to-end integration as there has been a rise in integration requests from various stakeholders such as departments/ministries, state nodal officers, testing labs, etc.
6. **Architecture upgradation:** The DDRS platform should be scalable, and the architecture of DDRS should consist of the latest technology stack. Routine upgradation of architecture and portal should be carried out to ensure stability, responsiveness, and security. Architecture should be designed so that it can be upscaled or downscaled automatically (with manual override permission) depending on the overall load on the DDRS portal.
7. **Technology and Framework:** Technology stack should be developed using a platform design approach, open-source technology stack, and open standards. The proposed Digital Drugs Regulatory System (DDRS) should be modular and may include End to end Java Framework, Microservices, Docker Containers, Angular, React, PostgreSQL, Open KM DMS, Dev Ops, Gitlab, MySQL, Postgres Databases, UI/UX for front-end design or any other technology as appropriate.

8. **Training:** Provisioning training as and when required for the stakeholders and regulators on an all-India basis.
9. The SSP team may be deployed either onsite or work remotely from the vendor premises as their performance shall be evaluated based on the following:
    a. Quarterly Deliverables.
    b. Monthly Milestone Deliverables for Proposed Modules of the New Unified Portal.
    c. SLA compliance regarding service ticket closure for maintenance, roll-out of new functionalities or enhancement of existing functionality and support activities.
10. CDSCO may request SSP to deploy members at specific stakeholder offices for conducting training sessions, onboarding, resolving any outstanding issues (pre and post onboarding), carrying out technical discussions, developing user manuals, etc.

The details of deliverables, terms and conditions for the Software Service Provider are attached as **Annexure 10.**

4 CDSCO'S RESPONSIBILITIES

The following are the responsibilities of CDSCO:

1. Nomination of a Nodal Officer who will oversee the project and be empowered to make decisions regarding the project.
2. Carry out project tasks that fall under the CDSCO responsibility within reasonable time limits, particularly in matters related to reviews, approvals, acceptance, etc.
3. Provide appropriate hardware and software stack for the deployment of the proposed solution.
4. Provide timely access to personnel, test data, clarifications, and decisions and resolve any issues necessary for the SSP to carry out their obligations under this contract (including the work plan).
5. Report technical issues to the SSP personnel for resolution.
6. Facilitate the SSP in implementing required changes and functionalities in the software.
7. Facilitate acceptance testing roll-out of the application, including any internal (organizational) issues that need to be addressed.
8. Office space for any training to be provided by CDSCO in case of physical stakeholder training or meetings.
9. For maintenance of servers, SSP is to be provided access to the cloud as per the provisions of the project.

5 SERVICE PROVIDER'S OBLIGATIONS

In order to manage the development projects in an effective manner, the following activities are to be performed:

1. Nominate a senior person in the capacity of Project Manager, who will serve as the single point of contact and shall attend all meetings related to the project.

Business Analysts are to be assigned to CDSCO so that day-to-day operational issues can be resolved on time and any requirement clarification can be provided.

2. Plan and execute the project through a suitably qualified technical team. As part of this requirement, submit a project plan and keep it updated at all times.
3. Coordinate with CDSCO to finalize a sprint. All activities shall be planned and managed to meet the sprint cycle.
4. Ensure that the application solution is consistent with applicable guidelines of the Government of India Guidelines for compliance with Quality requirements, etc.
5. Develop Test Plans (covering test cases and expected results), prepare test data, carry out necessary acceptance tests, including security certifications (as may be applicable) and report the test results, including satisfactory conformance to requirements. All tests should be correlated to the functional requirements. Test plans are to be shared with the CDSCO Nodal person for approval.
6. Create user/operation manuals along with backup and restoration procedures.
7. Managing the cloud operation related to the release and maintenance of applications, taking over the operations and participating in the transition of the solution to any other data centre by the SSP at the end of the operation period if hosted outside.
8. During the Operations and Maintenance, SSP shall provide necessary modifications to the solution in conformity with the requirements, fix software defects, enhance the software as per an agreed plan and provide such other technical support and hand-holding necessary for the smooth functioning of the overall solution covered under the scope of the project in conformity with the agreed performance criteria.
9. The SSP is also expected to perform routing upgrade and keep the applications compliant with the Industry Standards.
10. SSP shall ensure that no component (including software) is technologically obsolete or has reached the end of the support period.
11. SSP should be flexible in deploying team members at stations as and when directed by CDSCO headquarters.
12. SSP should make active efforts to remove any software defects and shortcomings that are part of the agreed requirements.
13. In the event of a major scope change involving significant time and effort over and above routine operations and maintenance, the SSP shall facilitate the assessment of the impact on technical matters and timelines. Further, the SSP agrees to implement these changes after obtaining approval from CDSCO.
14. Implement gaps of third-party audits and assessments, as and when required, as part of the entire audit and assessment / STQC Certification.
15. Submit periodic reports and support reviews as may be agreed and necessary.
16. At the end of the Operations and Support period, assist in the smooth transition of the assets, i.e., hardware stack, software stack, data, and operations, to the CDSCO or a designated agency(s). The activities shall be planned in such a way that there is no break in service delivery. The CDSCO shall be intimated of the commencement of the activities well before the operations and support period ends.
17. SSP will inform CDSCO before planning or performing maintenance work for which downtime will be required for any infrastructure or software upgrade.

Maintenance notice with expected restoration time shall also be displayed on the website.

18. Regular progress reporting and review with the concerned project coordinator will be an integral part of the responsibility of the Service Provider.
19. Service Provider must also ensure that the outgoing resource provides a suitable handholding (knowledge transfer) period to the new resource.
20. Sub-contracting by the contractor without the approval of CDSCO shall be considered a breach of contract.

6 PRE-BID CONFERENCE

A pre-bid conference will be conducted to clarify the queries of the service provider, for which the details will be sent through email. The clarification will be uploaded on the GeM portal for reference by the service providers. CDSCO shall not be responsible for ensuring they have received the bidders' queries. Any requests received for clarifications after the indicated date and time may not be entertained by CDSCO. Participation is not mandatory. However, suppose a bidder chooses not to (or fails to) participate in the Pre-bid conference or does not submit a written query. In that case, it shall be assumed that they have no issues regarding the techno-commercial conditions.

All the queries are to be submitted in the following format at email admn@cdsco.nic.in.

Company Name:			
S. No.	**EoI document reference(s) (section & page number(s))**	**Content of EoI requiring clarification(s)**	**Points of clarification**

7 DEVIATIONS

The bidder may provide deviation to the contents of the EOI document in the format prescribed in Form 12.

The Purchase Committee would evaluate and classify them as "material deviation" or "non material deviation". In case of material deviation, the committee may decide to "monetize" the value of the deviations, which will be added to the price bid submitted by the bidder OR declare the bid as nonresponsive.

The Bidders would be informed in writing on the committee's decision on the deviation, prior to the announcement of technical scores. The bidders would not be allowed to withdraw the deviations at this stage, the bidder would not be allowed that to withdraw the deviations submitted without the prior consent of the CDSCO.

In case of non-material deviations, the deviations would form a part of the proposal & contract.

8 DELIVERABLES

While executing the project, the SSP is supposed to meet the following mode of deliverable:

1. Detailed SPRINT plan along with periodical Project Status Reports.
2. Deployment of a good technical team capable of handling the requirements.
3. Manage the team effectively so that the timelines as agreed upon are met.
4. Place team members at the stakeholder's locations to facilitate interactions, comprehend requirements, and carry out digitization tasks as necessary.
5. Source and executable application Software code, including any third-party base software licenses. In the case of packaged software, the code related to customization should be provided.
6. Technical documentation and user manuals (as per agreed formats). This shall include Deployment architecture, database architecture, ER diagrams, process flow, and sequence diagrams.
7. Procedure Manuals related to installation, operation, administration (including backup and restoration) and other details.
8. Services as agreed upon, including (but not limited to) Implementation, Operation Support, Maintenance, Training, etc. for the agreed duration.
9. Approved changes to the solution, as may be necessary, including integration with any external applications as may be necessary as the solution evolves and matures.
10. All the third-party Software Applications mentioned in the EOI shall be installed and maintained by the SSP.

While executing the project, the project deliverables are to be classified as following for billing purposes:

1. Development deliverables
   - Simple Features delivered within an effort of 2 days, which include page layouts, UI / UX changes or content changes.
   - Medium features delivered within 15 days, including feature/enhancement.
   - Complex feature development with an effort of more than 15 days
2. Maintenance deliverables
   - Count of defects resolved with severity 1.
   - Count of defects resolved with severity 2.
   - Count of defects resolved with Severity 3
3. Severity levels applicable for maintenance projects are as follows:
   - Level 1: critical business functionality is impacted.
   - Level 2: Problems which affect the normal execution of the work, but workarounds are available for the work to be completed in the existing functionality.
   - Level 3: Problems that have minimal impact on the operation or system and are trivial in nature.

9 SERVICE LEVEL AGREEMENT

Given below is the chart describing SLAs along with performance criteria and penalties that need to be adhered to by the SSP for the duration of the project:

Sr. No.	Major Area	Parameter	Requirements (Working Hours)	Penalty/ Breach
1	SPRINT roll-out	Timelines for meeting (major) delivery milestones as per the SPRINT schedule	Pilot roll-out shall be operationalised as per SPRINT.	i. Delay of 1 working week: 1% of the monthly payment as a penalty. ii. Delay of 2 working weeks: 3% of the monthly payment as a penalty. iii. Delay of 3 working weeks: 7% of the monthly payment as a penalty. iv. Breach of contract beyond 4 working weeks of delay.
2	Response time for bug fixing (once it is in production mode)	Time taken to acknowledge reported problem	i. Within 4 working hours from the time the problem is reported.	i. No penalty
			ii. Between 4 to 8 working Hours	ii.0.01% of the value monthly payment
			iii. For every 4 working hours of further delay beyond 8 working hours of delay.	iii. 0.02% of the value of the monthly payment
3	Resolution Time (Only for Bug fixing)	Time taken by the SSP to fix the problem and release the same into the production system.	Severity Level 1: within working 24 hours. Severity Level 2: within a maximum of one working week. Severity Level 3: As mutually agreed.	Inability to resolve Severity level. 1 problem on more than two occasions in a quarter shall attract a penalty of 2.0% of monthly payment for each additional 24 hours of delay beyond the permissible limit.

Software Defect Categorization

1. **Severity level 1:** critical business functionality is impacted.

2. **Severity level 2:** Problems which affect the normal execution of the work, but workarounds are available for the work to be completed in the existing functionality.
3. **Severity level 3:** Problems that have minimal impact on the operation or system and are trivial in nature.

10 ACCEPTANCE, CERTIFICATION AND ROLL-OUT

As this project involves both the deployment and the roll-out of the solution, SSP will be responsible for the completion of all the development work and provide test cases and test results prior to the start of the acceptance testing. The CDSCO team will be involved in testing only to verify the implementation of the given requirements as per the SRS document. SSP will have to create a requirements traceability matrix for mapping requirements to test cases. If a design document is needed, it must be prepared and shared as part of the deliverable. In all cases, the SSP must create/update the operations/user manual at the end of the sprint.

The following points related to Acceptance, Certification and Roll out shall be considered:

- An acceptance test plan, along with test cases and expected results traced to the requirements, shall be provided before the deployment, and the same shall be accepted by the CDSCO.
- Test cases shall consist of functionality, usability and should include a minimal set of conditions to simulate a high level of concurrent access to the portal.
- Any observations/feedback from the CDSCO related to the test plan and test cases shall be duly factored in as relevant.
- The creation of the test data is the responsibility of the SSP.
- The errors identified during testing shall be duly rectified and resolved. A maximum of three rounds of testing shall be permitted within which the UAT should be completed.
- The pre-requisite for the solution to be accepted is that it should have ZERO Severity Level 1 defects.
- Updated User manual

11 PAYMENT TERMS AND MILESTONES

1. The payment to the firm would be made based on work assigned and work completed to the satisfaction of CDSCO.
2. The selected bidder shall submit a quarterly invoice listing the successful completion of services during the month as per tasks planned and assigned at the beginning of the month and during the month.
3. The SPOC at CDSCO for the project shall be responsible for the clearance of the deliverables and the invoice.
4. The payment shall be made within 45 days of submitting the invoice.
5. The payment to the service provider will be made as per the below mentioned payment schedule after satisfactory services by the selected bidder:

S No	Milestone	Billable Fee (as % of Contract Value)
1	Getting in-principal approval from CDSCO on design specifications document and wireframe	5%
2	Development of DDRS, user manual, training videos, and extensive testing of DDRS on test server	15%
3	Go-live of the core functions with required integrations in phases: • Go-live phase 1: Go-live of the Sugam equivalent • Go-live phase 2: Go-live of the Sugam Labs equivalent • Go-live phase 3: Go-live of Medical Devices online equivalent • Go-live phase 4: Go-live of ONDLS equivalent	20% (5% amount to be paid after every go-live)
4	Integration, onboarding, and training of stakeholders mentioned in Annexure 8	10%
5	Integration, onboarding and porting of data for CDSCO, IPC, NIB, central testing laboratories, states licensing authorities, and state testing laboratories.	10%
6	Maintenance cost	40% (to be paid post go-live in equal quarterly installments for the remaining contract period)

Note: - The selected bidder shall have the option to increase the project cost by up to 30% of the total project cost after the award of the contract in mutual consultation and agreement with CDSCO.

12 BID ELIGIBILITY, EVALUATION CRITERIA & EVALUATION PROCESS

12.1 ELIGIBILITY CRITERIA FOR TECHNICAL EVALUATION

The agencies which fulfil the following minimum eligibility criteria (along with the Qualification and Experience of the Entity) shall be eligible to apply:

- The bidding firm/agency/company should be a legal entity registered in India with valid PAN and GST with a minimum period of five years of existence as of

the date of the BID document. The following entities may be allowed to participate in the bid process:

  - Companies registered under Companies Act 2013
  - Partnership firms registered under Limited Liability Partnerships (registered under LLP Act, 2008)
  - Partnership firms registered under Indian Partnership Act, 1932

- Documents to be submitted:
  - Certificate of incorporation or any other registration certificate.
  - GST registration certificate
  - Copy of PAN card
- The bidding agency should have an annual turnover of Rs. 100 Crore or more each year during the last three financial years. Documents to be submitted include:
  - A CA certificate on Government Software services turnover over the last three financial years, including an annual audited account to verify the turnover.
- The bidding firm/ agency/ company/ trust must have successfully done/ completed similar work/ services in any government departments/ organizations in India during the past three (03) years with the following criteria. However, the bidder should have at least experience in "Project Management and Delivery for Integrated IT Solution/e-Governance Projects or equivalent":
  - Three similar works, each of value of at least 4.0 Crore Or
  - Two similar works, each of value of at least 6.0 Crore Or
  - One similar work of value 9 Crore or more.
  - Attach copies of supporting documents:
    - Completion Certificates from the client; OR
    - Work Order + Self Certificate of Completion (Certified by the Statutory Auditor); OR
    - Work Order + Phase Completion Certificate from the client
- Agencies that are debarred or blacklisted by any Govt. Departments or any other organization/ Society whatsoever are not eligible to participate in the bidding process. A Certificate is to be submitted along with the bid by the bidders to the effect that they are not debarred or blacklisted by any Govt., and neither any case is pending under investigation on charges of corruption, unfair trade practices, mishandling/ abusing participants/users. In the event of any false information or/and on revealing of any such fact later, even if work is awarded, it shall be withdrawn without prejudice to any other legal action that may be initiated against that agency or deemed appropriate by CDSCO.
- The company should be in profit in the three preceding financial years.
- The bidder should have a solvency certificate not older than 3 months for at least Rs.4.0 Crores.
- The bidder should have the following certificates:
  - ISO 9001:2015, ISO20000-1:2018 and CMMI-5

- The Bidder (Service Provider) must have at least 500 full time IT professionals on its payroll.
- The bidder should carefully read and submit all the relevant documents required for the technical and financial evaluation of the bids.

The bidders are required to meet all the above-mentioned criteria. Only those who meet all the pre-qualifying criteria shall be considered for subsequent evaluation.

12.2 BID EVALUATION COMMITTEE

1. The Bid Evaluation Committee constituted by the CDSCO shall evaluate the bids.
2. The decision of the Technical Evaluation Committee in the evaluation of the Technical and Financial bids shall be final. Technical Bid evaluation is to ensure that the proposed solution by the bidders meets the requirements as outlined in the BID Document.
3. A two-stage procedure shall be adopted in evaluating the proposals. A technical evaluation shall be carried out first, followed by the Price Bid evaluation. TEC will conduct a detailed evaluation of the Technical Bids it received to determine whether they are substantially responsive to the requirements set forth in the BID. TEC will examine the information supplied by the bidders and shall evaluate the same as per the evaluation criteria specified in this BID.
4. During the Scrutiny of the Technical bid by the TEC approved by the competent authority, necessary clarification, if any, required by the CDSCO shall be furnished by the bidder within the time given by the CDSCO for the same. CDSCO is at liberty to verify any or all the documents submitted by the bidders, even by referring to third parties. After the technical evaluation is completed, the Price bids will be opened. The Price Bids' opening date and time will be intimated to the technically qualified bidders.
5. In case the bid is floated on GeM, the process of technical evaluation as specified in GeM will be applicable.
6. Proposal Presentation: TEC may invite each bidder to make a presentation. Such a presentation would allow the bidders to present their proposed approach to the TEC and the key point in their proposal.
7. The technical evaluation of bids will be carried out to ensure compliance with the requirements mentioned in the BID.

13 TECHNICAL & FINANCIAL EVALUATION

13.1 TECHNICAL EVALUATION OF BIDS

Proposals submitted by the Service provider will be evaluated based on Quality and cost-based selection. The criteria for selection will be based on the evaluation criteria and the document submitted as part of the technical offering. No financial elements should be mentioned in the bid.

The evaluation will be a two-stage process in which the technical submission will be evaluated, and then the selected SP will be eligible for FE. The FE will decide the L1 vendor based on weightage in TE and FE. Eligibility of bidder will be based on proof of documents submitted as per criteria, past experience, financial capability, and resource availability, which should form the technical offer by fulfilling the requisite qualifying

requirement as mentioned above. Sub-contracting by the service provider will be considered a breach of contract.

The technical evaluation of bids will be carried out to ensure compliance with the requirements mentioned in the BID. A minimum of 60 marks should be scored in the technical proposal for the bid to be declared technically qualified.

Technical evaluation criteria will include the following parameters:

S No	Project	Maximum marks
1	Experience of working on similar projects involving design, development, and maintenance of websites/applications in the last 5 (Five) financial years with minimum value >>4.00 Crores each): • Full Life Cycle: Governance core development project including dynamic portal and dashboard Mobile and Chatbot application expertise. The mobile development should include both Android and iOS. • Project experience with Architecture enhancement • Integration with external portals Bidders must attach evidence supporting their claim with a specific description of project experience.	20 Marks
2	Overall Approach & Methodology	20 Marks
3	Project work break down structure: Qualitative assessment based on timelines, resource assignment, dependencies and milestones	10 Marks
4	System Functionality: Meeting the requirements of CDSCO in terms of how close the proposal is to the functional requirements for the solution as have been proposed for CDSCO. A copy of the compliance presentation should be submitted along with technical Bid covering: • Understanding of the Scope of work • Approach and methodology for implementation	30 Marks
5	Bidder's inclusion of MSMEs in project delivery through allotment of at least <10%> of contract value to the project	10 Marks
6	Resume of all key technical resources proposed for the assignment	10 Marks

To qualify for the Technical Bid Evaluation, the bidder must confirm all the requirements stated in the BID documents.

Financial bids of only those bidders will be opened who are technically qualified and whose technical bids comply with the requirements mentioned in the BID document.

The date and time of the presentation to the prospective bidders will be intimated later by email. The bidder must submit a copy of the presentation through email on the day of the presentation.

13.2 FINANCIAL EVALUATION OF BIDS

The cost indicated in the Financial Proposal on GeM shall be considered as the final price, and the service provider declared as deemed as final and reflecting the total cost of services ("Bid Price"). Omission, if any, in costing any item shall not entitle the agency to be compensated, and the liability to fulfil its obligations as per the Scope of Work within the total quoted price shall be that of the bidder.

a) Any conditionality included in the financial bid will lead to disqualification of the entire bid.

b) On financial evaluation, the shortlisted bidders will be given a total score, which will be determined as follows:

   a. 75% weightage will be given to the Technical Score.

   b. 25% weightage will be given to the Financial Score.

c) The successful bidders will have to enter into an agreement with CDSCO comprising various clauses agreed upon amicably between both parties. Suitable and mandatory changes will also be added to the agreement for the smooth execution of the contract.

14 CONTRACT PERIOD

Unless otherwise stipulated, the contract Period for which the Service shall be contracted shall be eight years unless terminated earlier as per the contract. In addition, at the option of CDSCO, the contract period may be extended another two years on the same terms and conditions. Notice of renewal shall be provided by digital means to the Service Provider no later than thirty (30) days before the contract ends. The PMU team deployed in CDSCO will evaluate the work on a monthly basis as per the Sprint provided. The 3-month overlapping time is also required for a suitable takeover.

15 PURCHASE PREFERENCE POLICIES OF THE GOVERNMENT

Unless otherwise stipulated in TIS/ AITB, CDSCO reserves its right to grant preferences to the following categories of eligible Bidders under various Government Policies/ Directives:

- Class I Local Suppliers under Public Procurement (Preference to Make in India) Order 2017" (MII) of the Department for Promotion of Industry and Internal Trade (DPIIT - Public Procurement Section) as revised from time to time.
- Bidders from Micro and/or Small Enterprises (MSEs) under the Public Procurement Policy for the Micro and Small Enterprises (MSEs) Order, 2012, as amended from time to time.
- Start-up Bidders under Ministry of Finance, Department of Expenditure, Public Procurement Division OM No F.20\212014-PPD dated 25.07.2016 and subsequent clarifications; and/or
- Any other category of Bidders, as per any Government Policies, announced from time to time, if so, provided in the TIS/ AITB.

16 MAKE IN INDIA ORDER

Orders issued by the Government of India regarding eligibility to participate and for purchase preference to "Local Suppliers" to encourage 'Make in India' and promote manufacturing and production of goods and services in India shall apply to this procurement.

17 RIGHT TO VARY QUANTITIES AT THE TIME OF AWARD:

At the time of contract award, CDSCO reserves the right to increase or decrease without any change in the bid's unit prices or other terms and conditions provided this increase/ decrease does not exceed 50 (fifty) per cent of the tendered quantity.

18 CONFLICT OF INTEREST

Any bidder having a conflict of interest which substantially affects fair competition shall not be eligible to bid in this tender. Bids found to have a conflict of interest shall be rejected as nonresponsive.

19 COPYRIGHT

The copyright in all documents and other materials containing data and information furnished to CDSCO by the Bidder herein shall remain vested in the Bidder, or, if they are furnished to CDSCO directly or through the Bidder by any third party, including suppliers of materials, the copyright in such materials shall remain vested in such third party.

20 CONFIDENTIALITY, COPYRIGHTS, AND INTELLECTUAL PROPERTY RIGHTS (IPRS)

1. "Confidential Information" shall mean (i) intellectual property information; (ii) technical or business information; (iii) proprietary or internal information related to the current, future and proposed products or services of the Parties, including samples, apparatuses, equipment, financial information, process/flow charts, business models, information related to procurement requirements, purchasing, manufacturing, customers, investors, management, employees, business and contractual relationships, business forecasts, sales and merchandising, marketing plans, information the Parties provide regarding third parties; (iv) information disclosed pursuant to this Agreement and (v) all such other information which by its nature or the circumstances of its disclosure is confidential.
2. The Parties agree that they shall hold in trust any Confidential Information received by either Party under this Agreement, and the strictest of confidence shall be maintained in respect of such Confidential Information. The Parties also agree:
    a. To maintain and use the Confidential Information only for the purposes of this Agreement and only as permitted herein.
    b. To only make copies as specifically authorized by the prior written consent of the other party and with the same confidential or proprietary notices as may be printed or displayed on the original.

c. To restrict access and disclosure of Confidential Information to such of their employees, agents, vendors, and contractors strictly on a "need to know" basis and in accordance with clause 4 of this Agreement.

d. To return the confidential information contained in a tangible form of the other party when demanded by it.

3. Confidential Information in oral form must be identified as confidential at the time of disclosure and confirmed as such in writing within 30 (thirty) days of such disclosure. Confidential Information does not include information which:

   a. The recipient knew or had in its possession, prior to disclosure, without limitation on its confidentiality.

   b. Is independently developed by the recipient without breach of this Agreement.

   c. Information in the public domain as a matter of law.

   d. Is received from a third party not subject to the obligation of confidentiality with respect to such information.

   e. Is released from confidentiality with the written consent of the other party.

   f. SSP and its agents shall exercise professionally reasonable care to maintain the required confidentiality and privacy with regard to CDSCO data, wherever applicable.

4. All hardware, equipment, and software, including source code, licenses, technical documents, and services obtained for the express purpose of this engagement shall be in favour of the CDSCO and shall be submitted to CDSCO on demand subject to the terms of this Agreement.

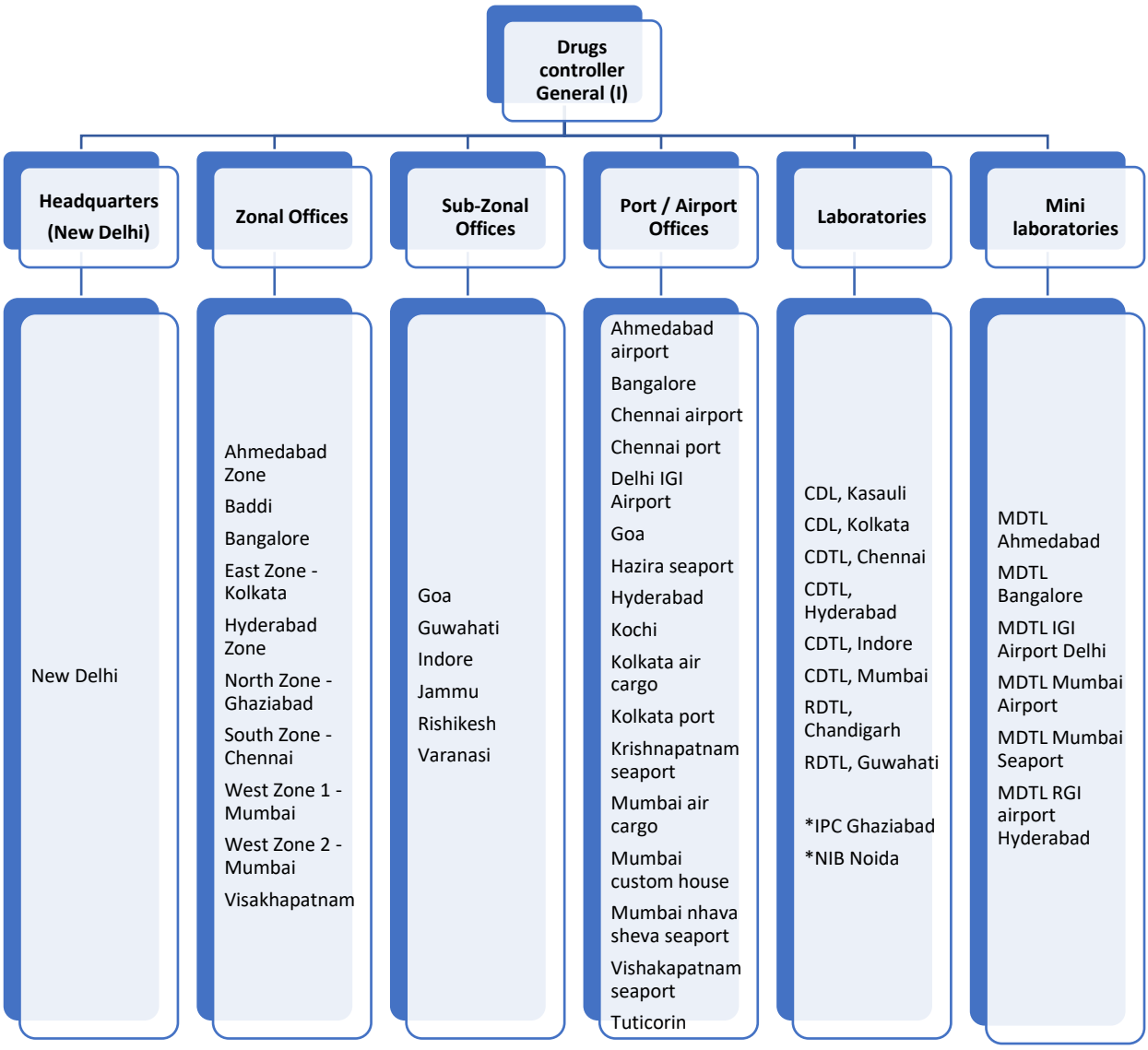
5. All records pertaining to this engagement shall be made available to the CDSCO and its authorized agents upon request for verification and/or audit on the basis of a written request.

6. CDSCO shall retain exclusive intellectual property rights to all artefacts to which CDSCO has sovereign rights or by virtue of a formalized agreement with another party. Nothing herein shall or will be construed or deemed to grant to the SSP any right, title, license, sub-license, proprietary right, or other claim against or interest in, to or under (whether by estoppels, by implication or otherwise) to the aforesaid CDSCO rights.

7. All proprietary information, correspondence, documentation, etc., exchanged among SSP and CDSCO in relation to managing and monitoring the implementation of the project and the performance shall be considered confidential and privileged by the parties and disclosed only to their respective Officers and members of committees on a need-to-know basis. SSP shall treat implementation as confidential and not use the same partially or totally for any purpose other than that of the agreement without the prior written approval of CDSCO.

8. **The Intellectual Property Rights in the Software and standard documentation, training materials, and related information and collaterals ("Standard Materials") shall remain vested with CDSCO.**

21 ANNEXURE 1: ORGANIZATION CHART OF CDSCO



22 ANNEXURE 2: FUNCTIONS OF CDSCO AND ITS ORGANS

22.1 FUNCTIONS OF THE CDSCO (HQ)

- Laying down standards of drugs, cosmetics, and medical devices.
- Laying down regulatory measures, amendments to Acts and Rules.
- To grant marketing authorization for new drugs.
- To regulate clinical trials in India.
- To approve licenses to manufacture certain categories of drugs as Central License Approving Authority, i.e., for Blood Banks, r-DNA drugs, Large Volume Parenteral and Vaccines and sera.
- To regulate the standards of imported drugs.
- Work relating to the Drugs Technical Advisory Board (DTAB) and Drugs Consultative Committee (DCC).

- Pharmacovigilance program of India.
- Coordinating activities of the State Drugs Control Organizations to achieve uniform administration of the Act and providing policy guidance.
- Guidance on technical matters\Participation in the WHO GMP certification scheme.
- Monitoring adverse drug reactions (ADR).
- Conducting training programs for regulatory officials and Government Analysts.

22.2 BROAD FUNCTIONAL ACTIVITIES AND DUTIES OF THE ZONAL AND SUB-ZONAL OFFICES OF CDSCO

- To participate in joint inspection for issuance/revalidation of Certificate of Pharmaceutical Products (COPPs) as per the WHO certification scheme.
- To participate in joint inspection for grant/renewal of Blood Bank, LVP, r-DNA, Medical Devices, Vaccines, and sera licenses.
- To participate in the inspection of Clinical Trial facilities as directed by the Drugs Controller General (India) from time to time.
- To carry out auditing/verification/post-certification of manufacturers pertaining to preferred bidders.
- To carry out surprise checks/raids/ jointly and independently on the basis of complaints received under the Whistle Blower scheme and also from other sources.
- To carry out joint inspection of Testing Laboratories for approval to carry out tests or analysis on drugs, cosmetics and raw materials, Medical Devices used in manufacturing drugs /cosmetics/Medical Devices for sale.
- Drawing drug samples for testing at central laboratories, carrying out investigations, and launching prosecutions in cases that do not conform to quality requirements.
- Deputation of drug samplers to various places of suspicion and collection of samples through them as surrogate patients from the sales premises by way of a survey to monitor the quality of drugs.
- To pursue court cases pending in different courts in the zone.
- Preparation of Monthly / Quarterly / Annual Reports.
- Renewal of licenses for blood banks.
- No objection certificates for grant of licence to manufacture drugs for examination, test or analysis as provided under Rule 89 of the Drugs and Cosmetics Rules.
- No objection certificates for grant of permission for manufacture for export only of unapproved / approved new drugs and banned drugs.
- Permit import of small quantities of drugs for personal use under Form 12B of

the Drugs and Cosmetics Rules.

- No objection certificates for grant of permission for import of dual-use items, not for medicinal use.
- Grant of license in Form-11.

22.3 FUNCTIONS OF PORT OFFICES OF CDSCO

- Scrutiny of Bills of entry with a view to ensuring that imported drugs comply with the provisions of Chapter III of the Drugs & Cosmetic Act and Rules thereunder and Drugs and Magic Remedies (Objectionable Advertisements) Act and Rules & Narcotic Drugs and Psychotropic Substances Act & Rules thereunder.
- To check the shipping bills for export for statistical data and keep control under the Narcotic Drugs and Psychotropic Substances Act & Rules and Drugs & Magic Remedies (Objectionable Advertisements) Act and the Rules there under.
- To ensure that no New Drug is imported into the country unless the Central Licensing Authority permits its import under Rules 122 A & 30-AA.
- To ensure that small quantities of drugs imported for clinical trials or for personal use are duly permitted under Test License (11 or 11-A) or Permit License as (12 B) as the case may be. Maintenance of Statistics regarding the import and export of drugs and cosmetics
- Coordination with Customs authorities.
- Coordination with States Drugs Controllers and Zonal Offices for post-import checks.
- Preparation of Monthly / Quarterly / Annual Reports
- To draw samples from import/export and re-import consignments.

22.4 FUNCTIONS OF CENTRAL DRUGS LABORATORIES / MINI LABORATORIES

The functions of Central and mini laboratories are summarized below.

- Analytical quality control of imported and manufactured drugs.
- Analytical quality control of drugs and cosmetics samples drawn by DI as statuary samples and testing of market surveillance samples in the country.
- Test and analysis of new drugs referred by CDSCO, HQ.

23 ANNEXURE 3: LICENSES / PERMITS ISSUED BY STATE AUTHORITIES

23.1 VARIOUS LICENSES ISSUED BY STATE DRUG CONTROLLER AUTHORITIES

MANUFACTURING OF DRUGS AND TESTING	FORM 24-25, 24F-25F, 27-28, 27B-28B, 27D-28D, 24B-25B, 25A-25A, 27A-28A, 27DA-28DA, FORM 30-29
BLOOD BANK & PRODUCT	FORM 27E-28E, 27C-28C, 27C-26G
MANUFACTURING OF COSMETICS AND TESTING	FORM COS5-COS8, COS6-COS9
WHOLESALE & RETAIL	FORM 19-20, 19-21, 19-20B, 19-21B, 19C-20G, 19C-20F, 19A-20A, 19A-21A
MEDICAL DEVICE LICENSE	FORM MD3-5, MD 4-6, MD-41-42

24 ANNEXURE 4: DETAILS OF PERMISSION/LICENSES HANDLED BY CDSCO/SUGAM

S. No.	Departments / Stakeholders	Divisions	Processes	Forms Available
1	CDSCO HQ	Import & Registration	Fresh Registration certificate (RC), Endorsement and re-registration	Form 40 / 41
			Post submission & Post Approval Changes (PAC)	Form 8 / 10
				Form 8A, 17 Cases of PAC
		Veterinary	Fresh Registration certificate (RC), Endorsement and re-registration	Form 40 / 41
			Post Submission	Form 8 / 10
		New Drugs/ SND/ FDC/IND	Permission to Market / Import / Conduct Clinical trials	Form CT-04/CT-18/CT-21
				Form CT-06/CT-19/20/CT-22/23

S. No.	Departments / Stakeholders	Divisions	Processes	Forms Available
				Form CT-10/CT-11, CT-12/CT-14, CT-13/CT-15, CT-16/CT-17
		Cosmetics Registration	Fresh RC, Endorsement, Re-registration	COS-1/ COS-2
			Application for Licence to Import Cosmetics	COS-4/COS-4A
				PAC
		Ethics Committee Registration	Ethics committee registration & re-registration	Form CT-01/CT-02 PAC
		Global Clinical Trials	Permission to conduct Clinical Trials	Form CT-04 / CT-06 PAC
			Import license for Test & Analysis	Form CT-16/CT-17
				11 Cases of PAC
		BA/BE	Permission to conduct BA/BE studies, Import license for Test & Analysis	Form CT-05/CT-07, PAC
				Form CT-16/CT-17
		Biological – New Drugs-Vaccines	Permission to Market / Import / Conduct Clinical trials	Form CT-04/CT-18/CT-21 and PAC
				Form CT-06/CT-19/20/CT-22/23
		SAE Reporting	Serious Adverse Events Reporting	24-Hour Reporting by Investigator
				14-Day Reporting by Investigator followed by Sponsor
				30-Day Reporting by Ethics Committee

S. No.	Departments / Stakeholders	Divisions	Processes	Forms Available
		International Cell	Written confirmation, BA/BE site approval and NOC	NOC
2	CDSCO Port Offices	Port Offices (7 Locations)	Permission to Import Drugs in small quantities for personal use	Form 12A/ 12B
3	CDSCO Zone	Zonal / Sub Zonal Offices (Test License and Form 12)	Import License for Test and Analysis for Drugs more than 4 years (Old Drugs), Dual purpose NOC	Form CT-10/CT-11, CT-12/CT-14, CT-13/CT-15, CT-16/CT-17PAC
4	Enforcement activities	Inspection	Joint inspection (Routine for cause inspection geotagging) Withdraw of drug sampler Statutory sample drawn by Drug sampler. Surveillance sample drawn by Drug sampler.	Currently Offline and proposed to be AI AI-based online site Inspection
		Issuing of show cause notice	Suspension/cancellation	Currently Offline
5	Drug alert system		Alert received from other drugs regulatory authorities of any country and Pharmacovigilance activity.	Current Offline
6	E grievance System		Raising and redressal of grievances system.	Current Offline

25 ANNEXURE 5: DETAILS OF PERMISSION/LICENSES HANDLED BY CDSCO/MD ONLINE

S. No.	Departments	Processes	Forms Available	Currently Offline / Online
1	State Licensing Authority	Application for Grant of License to Manufacture for Sale and Distribution of Class A or Class B Medical Device	Form MD-3/Form MD-5	Online
		Application for Grant of Loan License to Manufacture for Sale or for Distribution of Class A or Class B Medical Device	Form MD-4/Form MD-6,	Online
			Cases of PAC	Online
2	CDSCO Zone, CDSCO HQ	Application for Grant of License to Manufacture for Sale or for Distribution of Class C or Class D	Form MD-7/Form MD-9	Online
		Application for Grant of Loan License to Manufacture for Sale or for Distribution of Class C or Class D	Form MD-8/Form MD-10, Cases of PAC	Online
3	CDSCO HQ	Application for License to Manufacture Medical Device for Purpose of Clinical Investigation, Test, Evaluation, Examination, Demonstration or Training	Form MD-12/MD-13	Online
		Application for License to Import Medical Devices for the Purposes of Clinical Investigations, Tests, Evaluation, Demonstration or Training	Form MD-16/Form MD-17	Online
		Application for Grant of Permission to Conduct Clinical Investigation of an Investigational Medical Device	Form MD-22/Form MD-23	Online
		Application for Grant of Permission to Conduct Clinical Performance Evaluation of New in vitro Diagnostic Medical Device	Form MD-24/Form MD-25	Online
		Application for Grant of Permission to Import/Manufacture for Sale or for Distribution of Medical Device	Form MD-26/Form MD-27	Online

S. No.	Departments	Processes	Forms Available	Currently Offline / Online
		which does not have Predicate Medical Device		
		Application for Grant of Permission to Import or Manufacture for Sale or for Distribution of New In Vitro Diagnostic Medical Device	Form MD-28/Form MD-29	Online
		Application for issue of import License to import medical device	Form MD-14/Form MD-15, Cases of PAC	Online
		Application for Grant of Registration to Medical Device Testing Laboratory for carry out Test or Evaluation of a medical device on behalf of the manufacturer	Form MD-39/Form MD-40	Online
4	District Office	Sell, Stock, Exhibit or Offer for Sale or Distribute	Form MD-41/Form MD-42	Online
5	State Licensing Authority, CDSCO Zone, CDSCO HQ	Free Sale Certificate, Market Standing Certificate, Non-Conviction Certificate	FSC, MSC, NCC	Some states are online, and other states are offline
6	CDSCO Port Office, CDSCO HQ	Application for personal Licence	Form MD-20/Form MD-21	online
		Application for License to import investigational medical devices for the purposes of a government hospital or statutory medical institution for the treatment of patients	Form MD-18/Form MD-19	Online
7	Enforcement activities	Inspection: Joint inspection (Routine for cause inspection geotagging) Withdraw of drug sampler	Current Offline	Currently Offline and proposed to be AI-based online site Inspection

S. No.	Departments	Processes	Forms Available	Currently Offline / Online
		Statutory sample drawn by Drug sampler. Surveillance sample drawn by Drug sampler. Issuing of show cause notice: Suspension/cancellation.		
8	Drug alert system	Alert received from other drug regulatory authorities of any country and Pharmacovigilance activity.	Current Offline	offline
9	e-grievance System	Raising and redressal of grievances system.	Current Offline	offline

26 ANNEXURE-6: A DETAILED LIST OF SERVICES THAT CAN BE APPLIED ONLINE THROUGH ONDLS PORTAL

Details of Permissions / Licenses issued by State Authorities.

Authority	Process	Details of Permission/Licence	Application	Licence	NOC	Offline / Online
State/UT Authority	Sale Licence of drugs	Retail & Whole of different type drugs	8	8		Some states are online, and other states are offline.
	Manufacturing Licence of drugs	Non CLAA drugs	2	2		
		CLAA drugs	8	8		
		endorsement	2		2	
		Post approval change				
	Blood Bank Licence	Fresh Blood Bank	2			
		Endorsement component/facility	2			
		Renewal	2			

Authority	Process	Details of Permission/Licence	Application	Licence	NOC	Offline / Online
		Post approval change	6			
	COPP	Fresh Grant				
		Renewal				
		endorsement				
	Manufacturing for sale or for distribution of (Class A or Class B Medical Devices)	Fresh Grant	2	2		
		Renewal	2	2		
		endorsement	2	2		
		Post approval Change	15			
	Grant of Registration Certificate to sell, stock, exhibit, or offer for sale or distribute a medical device. Including In Vitro Diagnostic Medical Device	Fresh	1	1		
Enforcement activities	**Inspection**: Joint inspection (Routine for cause inspection geotagging) Withdraw of drug sample Statutory sample drawn by DI. Surveillance sample drawn by Drug sampler	Currently Offline and proposed to be an AI-based online site Inspection				
Issuing of show cause notice	Suspension/cancellation	**Currently Offline**				

Authority	Process	Details of Permission/Licence	Application	Licence	NOC	Offline / Online
Drugs alert system	Alert received from other drug regulatory authorities of any country and Pharmacovigilance activity.	**Currently Offline**				
e-grievance System	Raising and redressal of grievances system.	**Currently Offline**				

27 ANNEXURE 7: FUNCTIONS AT CDSCO WITHOUT COMPUTERIZATION (MANUAL OFFLINE)

Division	Detail of activities
FDC Division	Blank format of IPC NOC, CT NOC (Form CT 06), BE NOC (CT-07), Test and analysis (CT-11), License to Import New Drug or IND for CT, BABE or for examination, Test, and analysis (CT-17), Permission for import and market of FDC(CT-20), Permission for manufacturing of FDC (CT23). As per NDCT Rule 2019, these legal forms must be generated online via SUGAM Portal. Accordingly, it is requested to provide the same on the Sugam online portal for FDC Division.
GCT DIVISION	Since the implementation of SUGAM in 2017, the approval for Global Clinical Trial Approval/NOC, Test License, and Post Approval Changes have been issued online through SUGAM. However, for the application of Global Clinical Trial Approval/NOC approved before the implementation of SUGAM (Year 2017), i.e. Test License issue/renewal, Post Approval Changes Notifications (Protocol Amendment, Site Addition/deletion, IB/IMPD/ICF, CRF update, Clinical Trial Quarterly, Biannually, Annually status reports, Development Safety Update Report, Clinical Study Reports, Premature Closure/termination of the study report notification etc. which is currently received by physical mode and processed by physical files may be converted to online mode for SUGAM portal processing.
Medical Device Division	Online provisions are to be made for the following: a) Fulfilment of conditions stipulated in various licenses and permissions. b) Neutral Code and Special Code.

Division	Detail of activities
	c) Clarification of Applicant d) PAC for MD-13/17/23/27 e) PSUR / adverse reporting
Blood centre Division	Licensing of Blood Centre Division (Renewal/Grant/ Additional Products), Licensing of large volume parameters (Grant/ Additional Products)
Blood Products and cell-based products	Blood product: a) CT-04 (Application for grant of permission to conduct a clinical trial of a new drug or investigational new drug) b) NOC of Form 29 c) Post-approval change in blood product in respect of registration certificate. d) NOC for collection of plasma from the blood centres. Post-approval changes for clinical trial: a) Addition of clinical trial sites b) Deletion of clinical trial c) Change in the principal investigator. d) Amendment in clinical trial protocol ICF, CRF e) Ethics committee approvals f) Status report g) Or any other post-approval amendment which is implemented in GCT New drug (stem cell-section) a) CT-04 (Application for grant of permission to conduct clinical trial of new drug or investigational new drug) b) CT -04a (Information to initiate clinical trial of new drug or investigational new drug as part of discovery, research and manufacture in India) c) CT -10 (Application for grant of permission to manufacture new drug or investigational new drug for clinical trial or bioavailability or bioequivalence study or for examination, test and analysis) d) CT -12 (Application for grant of permission to manufacture formulation of unapproved active pharmaceutical ingredient for test or analysis or clinical trial or bioavailability or bioequivalence study) e) CT 13 (Application for grant of permission to manufacture unapproved active pharmaceutical ingredient for development of

Division	Detail of activities
	formulation for test or analysis or clinical trial or bioavailability or bioequivalence study) f) CT -16 (Application for grant of licence to import new drug or investigational new drug for clinical trial or bioavailability or bioequivalence study or for examination, test and analysis) g) CT -18 (Application for grant of permission to import new drug for sale or for distribution) h) CT -21 (Application for grant of permission to manufacture new drug formulation for sale or for distribution) i) CT 24 (Application for licence to import of unapproved new drug for treatment of patients of life threatening disease in a government hospital or government medical institution) j) CT -26(Application for grant of permission to manufacture unapproved new drug but under clinical trial for treatment of patients of life threatening disease in a government hospital or medical institution. Post approval changes for clinical trial: a) Addition of clinical trial sites b) Deletion of clinical trial c) Change in principal investigator. d) Amendment in clinical trial protocol ICF, CRF e) Ethics committee approvals f) Status report g) Or any other post approval amendment which is implemented in GCT Post approval change for MA: a) Change in manufacturing site (addition/deletion). b) Change in the name of the drug substance c) Change to a drug substance manufacturing facility d) Change in the drug substance manufacturing process, e) Changes to the cell bank f) Change in a facility involved in the manufacture of a drug substance g) Change in equipment used in drug substance manufacturing process h) Change in the specifications for the drug substance i) Change in the labelled storage conditions for the drug substance j) Change in the description or composition of the drug product k) Changes involving a drug product manufacturer/manufacturing facility

Division	Detail of activities
	l) Change in a facility involved in the manufacture of a drug product m) Change in equipment used in drug product manufacturing process n) Change in the controls (in-process tests and/or acceptance criteria) applied during the manufacturing process or on intermediates o) Change in the specifications for the excipient p) Change in the specifications for the excipient, involving the analytical procedures q) Change in the specifications for the drug product r) Change in the specifications for the drug product, involving the analytical procedures s) Changes affecting the quality control (QC) testing t) Change in the specifications for a primary container closure component u) Change in the specifications for a primary container closure component, involving analytical procedures v) Change in the re-test period (or shelf life) for the drug product w) Change in the labelled storage conditions for the drug product or the diluted or reconstituted product x) Change in the Efficacy parameter y) Change in the route of administration
Veterinary Drug	Applications for manufacturing/Import and marketing of New Drug (Form-44), Application for test license (Form-12), Application for NOC for Form-29, Applications for Post approval changes in Form-45, Form-45A, Form-46, Form-46A, Form-41, Form-10, Form-28D etc (Documents required as per Guidance for industry document for Veterinary Biologicals in India which is available in official site of CDSCO i.e. cdsco.gov.in)
Subsequent New Drug Division	Online provisions to be made for the following: a) Issuance of IPC NOC b) Issuance of SEC Letter c) Amendments of BA/BE Protocol, Clinical Trial protocol d) Any Post approval changes / Amendments of permissions for BA/BE Study, clinical trial & Marketing Authorization and Import License. e) Approval of Package Inserts & processing of approval of draft carton labels.
Misc. Activity	As and when it arises from the Government Regulatory Authorities

28 ANNEXURE 8: OTHER CENTRAL GOVERNMENT AGENCIES THAT NEED TO BE INTEGRATED WITH CDSCO (ELECTRONIC)

S No	GoI Ministry/Department	Activity
1	Customs	Custom Clearance and ICEGATE
2	Ministry of Environment, Forest, and Climate Change	Approval of Environmental Clearance and Genetic Engineered products
3	Department of Animal Husbandry and Dairying	Matters related to Veterinary drugs and vaccines
4	Atomic Energy Regulatory Board (AERB)	Medical diagnostic x-ray equipment for obtaining type approval
5	Bureau of Indian Standards	Applicants are to comply with the standards of BIS for cosmetics and medical devices. Pulling up relevant standards in a searchable and filterable manner.
6	Department of Consumer Affairs	The Essential Commodities Act, 1955
7	Indian Council of Medical Research	Testing of critical IVDs Approval from Gene Therapy Advisory and Evaluation Committee (GTAEC) Approval for R&D manufacturing site
8	National Institute of Biologicals (NIB)	CMDTL for IVD
9	DDG IH (Medical Grant Section)	Custom Duty Exemption Certificate
10	All State Licensing Authorities	For all CLAA products like Blood Centre, CoPP etc.
11	National Pharmaceutical Pricing Authority (NPPA) & Department of Pharmaceutical (DoP)	Availability and Pricing of drugs, Medical Devices and IVDs.
12	Central Consumer Protection Authority	Matters regarding false or misleading claims.
13	Department of BioTechnology	Approval from the review committee on genetic manipulation (RCGM)
14	Central Bureau of Narcotics	Provide consent on quotas for different drugs.

S No	GoI Ministry/Department	Activity
15	Central Medical Services Society	For enquiring about approval status needed for procurement of products.
16	Clinical Trials Registry – India	To verify the applications for clinical trials
17	Department of Scientific and Industrial Research	Approval for R&D manufacturing site
19	Director General of Foreign Trade	Concerns related to export of products.
20	Department of Revenue	Narcotics and psychotropic drugs, and GST integration
21	Legal Metrology Department	Integration of portal for regulations on BT Meter and Thermometer
22	Department of Health	Regulatory aspects namely quality, safety, Efficacy of Drugs/Medical Devices
24	Department for Promotion of Industry and Internal Trade (DPIIT)	Matters related to Patents, Compulsory License and matters related to export and import
25	Department of Commerce	Matters related to export and import
26	Department of Science & Technology	To support innovation, research and development.
27	Ministry of External Affairs	All international matters, MoU, International Organization
28	Pharmexcil	Matters related to export

29 ANNEXURE 9: INDEPENDENT PORTALS UNDER CDSCO THAT NEED TO BE INTEGRATED WITH CDSCO (ELECTRONIC)

S No	Portal Name	Information available
1	National Single Window Clearance System (NSWS)	Single platform for applying to all categories of licenses pertaining to various departments/agencies
2	Pharmatrac	Sales details of certain firms, AIOCD portal
3	iVEDIA (Pharmaexcil) / DAWA (DoC)	Track and Trace of Drugs for Export
4	ipindiaservices	Patent status details

S No	Portal Name	Information available
5	DGCI&S	Import and Export Data
6	ICEGATE	Customs Data
7	CBIC portal	Customs Data
8	Services.gst.gov.in	GST
9	Ministry of Corporate Affairs	Company incorporation details
10	State portals	Independent portals by different states.
11	NIB Portal	For facilitating testing of Biological samples
12	IPC Portal	Activities carried out by IPC, Sales and distribution of IP reference standards and various publications of IPC
13	ONDC	For getting information on consumption of products (including stock inventory details).
14	Aadhaar	For authentication and verification purposes
15	DigiLocker	For authentication and verification purposes

30 ANNEXURE 10: DETAILS OF DELIVERABLES AND TERMS AND CONDITIONS FOR SOFTWARE SERVICE PROVIDER

30.1 TERMS OF REFERENCE

The vendor shall deploy a team of resources with various skill sets to provide the following types of services:

- Software Development
- Software Maintenance, Enhancements and User Support

The help desk team shall be the first and primary contact point for external stakeholders regarding their enquiries. Their services include providing resolution to users' queries, ticket booking for bug fixing/database change management, data updation, coordination with other technical team members, etc.

Software Development & Maintenance Team Shall be responsible for software development, bug fixing, enhancements, technical discussions, data migration, software, versioning, impact analysis etc.

30.2 SLA DELIVERABLES

The following deliverables shall constitute this service:

1. SSP shall be responsible for the complete turnkey operation of the IT systems (software only) to ensure a minimum of 99.9% uptime availability of all the applications under this project.
2. SSP shall be responsible for all the development, implementation, testing, maintenance, support, feature enhancements, documentation, operations, and management of the application. The agency should carry out all the modifications/updation/additions/deletions in the applications.
3. Each application should follow the complete SDLC.
4. Proper Documentation with versioning of all the applications should be maintained, like System design, DB design, functionality document (process document), user manual, test case report, Impact Analysis Report, Change Document etc.
5. All application changes should be properly documented and reflected in respective documents.
6. Any change in the application should be done through a change request form. After completing the change, a request closure form should be filled out.
7. A log should be maintained for all the changes done in the application or database.
8. Proper coding standards should be followed in all applications.
9. Periodic code review should be done for improvement in source code.
10. Code and query optimization should be done to the extent possible.
11. Proper testing should be done for the changes done in the application or database. Testing should be done on exhaustive test cases. The team leader should review these test cases and maintain a test report.
12. Ensure proper backup of the application and database as per the approved backup policy.
13. In case of any eventuality, it has to be ensured that the downtime is minimum, and the system is restored with minimum data loss.
14. It should also be ensured that all security measures are undertaken to prevent application vulnerabilities/threats/hacking or data theft.
15. Bidder shall be responsible for maintaining the confidentiality of application, data and any other information and ensuring that information is not shared outside the CDSCO. The required confidentiality agreement shall be signed by the Agency as well as by each team member deployed at CDSCO. The agency should submit a copy of the Confidentiality Agreement to CDSCO.
16. The source code is to be handed over to CDSCO on a periodic basis along with the compiled version and executable.

17. Any software developed and data generated shall be the property of CDSCO. Software, Documents, Information, and other elements of the project shall have the copyrights of CDSCO unless some copyright material is used with due permission of any third party.
18. Proper versioning of source code should be maintained.
19. It should be ensured that uploading the modified application to the live servers is carried out carefully to avoid any wrong upload or accidental file replacement.
20. Security audit of the application should be done for the removal of any security flaws and for hosting provider requirements.
21. The team shall also be responsible for giving demos and presentations of applications as and when required.
22. Preventive maintenance shall be carried out on the database and functioning of the program to handle large volumes of traffic.
23. Bug-Fixing and End-User Problem Resolution
    - The end-user support would include all activities related to resolving the bugs/defects reported by application users. Every bug/defect should be logged and categorized on the severity levels. SSP shall identify the solution, take necessary approvals from CDSCO, and release the patch for User Acceptance Test (UAT) after fixing the defects. SSP shall document defects/bugs encountered as well as document the resolution of the same and ensure re-installations in the event of system crashes/failures.
24. Customer support should be provided for user problems and queries.
25. The new software applications developed as well as any enhancements carried out in the existing IT systems, shall comply with the necessary Internet Security guidelines from NIC/CERT-IN empanelled Internet Security Auditors.
26. Configuration Management and Version Control
    - As the application undergoes enhancements and modifications due to problem requests, defect fixes and change requests, keeping the source code under version control and the system under configuration management becomes increasingly important. SSP shall ensure that a copy of the production environment is backed up and stored in the repository before the new / modified components are copied to Production.
27. Release Management

    As part of the release management, SSP shall perform the following activities:
    - Group the related change requests, assess their development progress, and prepare a release schedule.
    - Prepare a detailed release plan for every release. This plan should include the release number and date of release. It should also contain details about the change request to be released.
    - Provide Helpdesk support for the resolution of technical queries by end users.

- Conduct Application training for the users in outstation locations as and when required.

28. User Support
    - Implementation support to users
    - End-user problem resolution
    - Training to users will be provided through the manpower deployed.
29. Administration Support
    - Latest source code, application deployment files, and configuration files for the entire solution
    - System/server configuration
    - Storage
    - Security
    - Database
    - Backup/restore etc.
30. Monthly Backup: Database and applications.
31. Quarterly updation: Technical Documents.
32. Reporting required from the Organization:
    - Weekly and monthly reports with project status and open issues
    - Weekly/fortnightly/monthly Performance Monitoring Reports for the Application
    - Updated system design documents, specifications
    - Updated user manuals, administration manuals, training manuals, etc.
    - Call Log / emails & Resolution Reports for Helpdesk
    - Software change logs, etc.
33. In addition to the above, SSP has to hand over the Source Code, Patches and releases (If any), Application Software, and All content used in the design of the Website, along with Technical Documents, user Manual, functional Manual, installation guide and any other if required for the creation of development environment and hosting.

31 ANNEXURE 11: PRE-QUALIFICATION & TECHNICAL BID TEMPLATES

The Bidders are expected to respond to the EOI using the forms given in this section and all documents supporting Pre-Qualification / Technical Evaluation Criteria.

Pre-Qualification Bid & Technical Proposal shall comprise of following Forms:

Forms to be used in Pre-Qualification Proposal

Form 1: Compliance Sheet for Pre-qualification Proposal

Form 2: Particulars of the Bidder

Forms to be used in Technical Proposal

Form 3: Compliance Sheet for Technical Proposal

Form 4: Letter of Proposal

Form 5: Project Citation Format

Form 6: Proposed Solution

Form 7: Proposed Work Plan

Form 8: Team Composition

Form 9: Curriculum Vitae (CV) of Key Personnel

Form 10: Deployment of Personnel

Form 11: Deviations

31.1 FORM 1: COMPLIANCE SHEET FOR PRE-QUALIFICATION PROPOSAL

S. No.	Basic Requirement	Required	Provided	Reference & Page Number
1.	Document Fee	Demand Draft	Yes / No	
2	Power of Attorney	Copy of Power of Attorney in the name of the Authorized signatory	Yes / No	
3	Particulars of the Bidders	As per Form 2	Yes / No	
3	Sales Turnover in Software Development	Extracts from the audited Balance sheet and Profit & Loss; OR Certificate from the statutory auditor	Yes / No	
4	Technical Capability	Completion Certificates from the client; OR Work Order + Self Certificate of Completion (Certified by the Statutory Auditor); OR Work Order + Phase Completion Certificate from the client	Yes / No	

S. No.	Basic Requirement	Required	Provided	Reference & Page Number
5	Certifications	Copy of certificates mentioned in your proposal	Yes / No	
6	Legal Entity	Copy of Certificate of Incorporation; and Copy of Service Tax Registration Certificate	Yes / No	
7	Manpower Strength	Self Certification by the authorized signatory	Yes / No	
8	Debarment	A self certified letter	Yes / No	

31.2 FORM 2: PARTICULARS OF THE BIDDER

S. No.	Information Sought	Details to be Furnished
1	Name and address of the bidding Company	
2	Incorporation status of the firm (public limited / private limited, etc.)	
3	Year of Establishment	
4	Date of registration	
5	ROC Reference No.	
6	Details of company registration	
7	Details of registration with appropriate authorities for service tax	
8	Name, Address, email, Phone nos. and Mobile Number of Contact Person	

31.3 FORM 3: COMPLIANCE SHEET FOR TECHNICAL PROPOSAL

S. No.	Specific Requirements	Documents Required	Compliance	Reference & Page Number
1.	Covering Letter for Technical Proposal	As per Form 4	Yes / No	
2.	Average turnover from Software Development and Implementation Services Work in last 3 years (Turnover in Rs Crores)	Extracts from the audited Balance sheet and Profit & Loss; OR Certificate from the statutory auditor; and Project citation (Form 5)	Yes / No	
3.	Experience in Bespoke Software Application, Development, and/or COTS implementation in India (last 5 years)	Completion Certificates from the client; OR Work Order + Self Certificate of Completion (Certified by the Statutory Auditor); OR Work Order + Phase Completion Certificate (for ongoing projects) from the client; and Project citation (Form 5)	Yes / No	
4.	Experience of Bespoke Software Application, Development, and/or COTS Implementation in similar department/domain globally (last 5 years)	Completion Certificates from the client; OR Work Order + Self Certificate of Completion (Certified by the Statutory Auditor); OR Work Order + Phase Completion Certificate (for ongoing projects) from the client ; and Project citation (Form 5)	Yes / No	
5.	Experience in Software Support and Maintenance Services in India (last 5 years)	Completion Certificates from the client; OR Work Order + Self Certificate of Completion (Certified by the Statutory Auditor); OR Work Order + Phase Completion Certificate (for ongoing projects)	Yes / No	

S. No.	Specific Requirements	Documents Required	Compliance	Reference & Page Number
		from the client; and Project citation (Form 5)		
6.	Solution Proposed, Approach & Methodology, Understanding and work Plan (As per the requirements specified in Technical evaluation)	A note and Forms 6 The note should highlight understanding of the CDSCO's requirements through providing justifications for: 1. Solution proposed and its components, 2. Scalability 3. Security 4. Ease of implementation 5. User base 6. Interoperability 7. Technologies used, 8. Challenges likely to be encountered 9. Learning on how to deal with the challenges 10. Client references Form 7	Yes / No	
7.	System Functionality: Meeting the requirements of CDSCO in terms of how close the proposal is to the functional requirements for the solution as have been proposed for CDSCO.	A note containing the Mapping as per information provided	Yes / No	
8.	Trainings proposed by the vendor and the amount of emphasis laid on Training the employees schedule details, locations, sessions and their description	A note on training containing 1. Training model 2. Approach 3. Deliverables	Yes / No	

S. No.	Specific Requirements	Documents Required	Compliance	Reference & Page Number
9.	Resume of all key technical resources proposed for the assignment	CV & a Note (Form 8, 9 and 10)	Yes / No	
10.	Tools and Assets As per requirement specified in Technical evaluation)	Tools and Assets which could be leveraged for the assignment A note and demonstration of the Tool/Assets	Yes / No	
11.	Deviations (if any)	Form 11	Yes / No	

31.4 FORM 4: LETTER OF PROPOSAL

<Location, Date>

To:

Sh. Dileep Rajput

Director (Admin),

Central Drugs Standard Control Organization,

Ministry of Health and Family Welfare,

Directorate General of Health Services,

Government of India FDA Bhavan, ITO, Kotla Road,

New Delhi -110002,

Tel: 011-23216376

Email id: admn@cdsco.nic.in

Subject: Submission of the Technical bid for the development and maintenance of Digital Drugs Regulatory System

Dear Sir/Madam,

We, the undersigned, offer to provide Systems Implementation solutions to the CDSCO for the development and maintenance of Digital Drugs Regulatory System with your EoI dated 2nd November 2023 and our Proposal. We are hereby submitting our Proposal, which includes this Technical bid and the Financial Bid.

We hereby declare that all the information and statements made in this Technical bid are true and accept that any misinterpretation contained in it may lead to our disqualification.

We undertake, if our Proposal is accepted, to initiate the Implementation services related to the assignment not later than the date indicated in Fact Sheet.

We agree to abide by all the terms and conditions of the EOI document. We would hold the terms of our bid valid for 90 days as stipulated in the EOI document.

We understand you are not bound to accept any Proposal you receive.

Yours sincerely,

Authorized Signature [In full and initials]:

Name and Title of Signatory:

Name of Firm:

Address:

Location:

Date:

31.5 FORM 6: PROJECT CITATION FORMAT

Relevant IT project experience (provide no more than 5 projects in the last 5 years)	
General Information	
Name of the project	
Client for which the project was executed	
Name and contact details of the client	
Project Details	
Description of the project	
Scope of services	
Service levels being offered/ Quality of service (QOS)	
Technologies used	
Outcomes of the project	
Other Details	
Total cost of the project	
Total cost of the services provided by the respondent	

Relevant IT project experience (provide no more than 5 projects in the last 5 years)	
Duration of the project (no. of months, start date, completion date, current status)	
Other Relevant Information	
Letter from the client to indicate the successful completion of the projects	
Copy of Work Order	

31.6 FORM 6: PROPOSED SOLUTION

Technical approach, methodology and work plan are key components of the Technical Proposal. You are suggested to present Approach and Methodology divided into the following sections:

1. Solution Proposed
2. Understanding of the project (how the solution proposed is relevant to the understanding)
3. Technical Approach and Methodology

S. No	Proposed Solution (Provide the Product Name or fill Custom Built, in case of a new development)	Version & Year of Release	OEM	Features & Functionalities	O&M Support (as required as per EOI)	Reference in the Submitted Proposal (Please provide page number/section number/ volume)

31.7 FORM 7: PROPOSED WORK PLAN

No	Activity	Calendar months							
		1	2	3	4	5	6	7	n
1									
2									
3									
4									
5									

1. Indicate all main activities of the assignment, including delivery of reports (e.g.: inception, interim, and final reports), and other benchmarks such as CDSCO approvals. For phased assignments indicate activities, delivery of reports, and benchmarks separately for each phase.
2. Duration of activities shall be indicated in the form of a gantt chart.
3. All activities should meet the 8/80 criteria i.e should at least take 8 hours and a maximum of 80 hours.

31.8 FORM 8: TEAM COMPOSITION

S. No.	Name of Staff with qualification and experience	Area of Expertise	Position assigned	Task Assigned	Time committed for the engagement

31.9 FORM 9: CURRICULUM VITAE (CV) OF KEY PERSONNEL

General Information	
Name of the person	
Current Designation / Job Title	
Current job responsibilities	
Proposed Role in the Project	
Proposed Responsibilities in the Project	
Academic Qualifications: • Degree • Academic institution graduated from • Year of graduation • Specialization (if any) • Key achievements and other relevant • information (if any)	
Professional Certifications (if any)	
Total number of years of experience	
Number of years with the current company	
Summary of the Professional / Domain Experience	
Number of complete life cycle implementations carried out	
The names of customers (Please provide the relevant names)	

Past assignment details (For each assignment provide details regarding name of organizations worked for, designation, responsibilities, tenure)
Prior Professional Experience covering:
• Organizations worked for in the past
  ○ Organization name
  ○ Duration and dates of entry and exit
  ○ Designation Location(s)	

General Information	
○ Key responsibilities • Prior project experience ○ Project name ○ Client ○ Key project features in brief ○ Location of the project ○ Designation ○ Role ○ Responsibilities and activities ○ Duration of the project Please provide only relevant projects.	
Proficient in languages (Against each language listed indicate if speak/read/write)	

31.10 FORM 10: DEPLOYMENT OF PERSONNEL

No	Name of Staff	Staff input in Months (Colour code as shown below)[3]													Total staff man months proposed
		1	2	3	4	5	6	7	8	9	10	11	12	n	Total
1															
2															
3															
N															
														Total	

1. The input should be indicated individually for Professional Staff
2. The input should be indicated by category for Support Staff
3. Months are counted from the start of the assignment.

	Full Time Input		Part Time Input		No Input

31.11 FORM 11: DEVIATIONS

<Location, Date>

To:

Sh. Dileep Rajput

Director (Admin),

Central Drugs Standard Control Organization,

Ministry of Health and Family Welfare,

Directorate General of Health Services,

Government of India FDA Bhavan, ITO, Kotla Road,

New Delhi -110002,

Tel: 011-23216376

Email id: admn@cdsco.nic.in

Subject: Deviations on the EoI for the development and maintenance of Digital Drugs Regulatory System

Dear Sir:

We declare that all the services shall be performed strictly in accordance with the Tender documents except for the variations and deviations, all of which have been detailed out exhaustively in the following statement, irrespective of whatever has been stated to the contrary anywhere else in our bid.

Further we agree that additional conditions, if any, found in the Tender documents, other than those stated in deviation schedule, shall not be given effect to.

A - On the Terms of Reference

No.	Deviation	Material	Non-Material	Impacted Deliverable(s)	Impacted Timeline(s)	Financial Impact
1.	<Deviation description>	<Yes / No>	<Yes / No>	<Name(s) of Deliverables to get affected by the Deviation>	<Effect on Timelines due to the Deviation>	<Value>
2.	<Deviation description>	<Yes / No>	<Yes / No>	<Name(s) of Deliverables to get affected by the Deviation>	<Effect on Timelines due to the Deviation>	<Value>
3.	<Deviation description>	<Yes / No>	<Yes / No>	<Name(s) of Deliverables to get affected by the Deviation>	<Effect on Timelines due to the Deviation>	<Value>

B – Any other areas

No.	Deviation	Material	Non-Material	Impacted Deliverable(s)	Impacted Timeline(s)	Financial Impact
1.	<Deviation description>	<Yes / No>	<Yes / No>	<Name(s) of Deliverables to get affected by the Deviation>	<Effect on Timelines due to the Deviation>	<Value>
2.	<Deviation description>	<Yes / No>	<Yes / No>	<Name(s) of Deliverables to get affected by the Deviation>	<Effect on Timelines due to the Deviation>	<Value>
3.	<Deviation description>	<Yes / No>	<Yes / No>	<Name(s) of Deliverables to get affected by the Deviation>	<Effect on Timelines due to the Deviation>	<Value>

Yours sincerely,

Authorized Signature:

Name and Title of Signatory:

Name of Firm:

Address:

32 ANNEXURE 12: FINANCIAL PROPOSAL TEMPLATE

32.1 FORM 1: COVERING LETTER

<Location, Date>

To:

Sh. Dileep Rajput

Director (Admin),

Central Drugs Standard Control Organization,

Ministry of Health and Family Welfare,

Directorate General of Health Services,

Government of India FDA Bhavan, ITO, Kotla Road,

New Delhi -110002,

Tel: 011-23216376

Email id: admn@cdsco.nic.in

Subject: Submission of the Financial bid for the development and maintenance of Digital Drugs Regulatory System

Dear Sir/Madam,

We, the undersigned, offer to provide the Implementation services for the development and maintenance of Digital Drugs Regulatory System in accordance with your EoI dated 2nd November 2023 and our Proposal (Technical and Financial Proposals). Our attached Financial Proposal is for the sum of <<Amount in words and figures>>. This amount is inclusive of the local taxes.

1. **PRICE AND VALIDITY**
   a. All the prices mentioned in our Tender are in accordance with the terms as specified in the EOI documents. All the prices and other terms and conditions of this Bid are valid for a period of 90 calendar days from the date of opening of the Bid.
   b. We hereby confirm that our prices include all taxes. However, all the taxes are quoted separately under relevant sections.
   c. We understand that the actual payment would be made as per the existing tax rates during the time of payment.

2. **UNIT RATES**
   We have indicated in the relevant forms enclosed, the unit rates for the purpose of on account of payment as well as for price adjustment in case of any increase to / decrease from the scope of work under the contract.

3. **TENDER PRICING**
   We further confirm that the prices stated in our bid are in accordance with your Instruction to Bidders included in Tender documents.
4. **QUALIFYING DATA**
   We confirm having submitted the information as required by you in your Instruction to Bidders. In case you require any other further information/documentary proof in this regard before evaluation of our Tender, we agree to furnish the same in time to your satisfaction.

5. **BID PRICE**
   We declare that our Bid Price is for the entire scope of the work as specified in the section 3. These prices are indicated Commercial Bid attached with our Tender as part of the Tender.

Our Financial Proposal shall be binding upon us subject to the modifications resulting from Contract negotiations, up to expiration of the validity period of the Proposal, i.e., [Date].

We understand you are not bound to accept any Proposal you receive.

We hereby declare that our Tender is made in good faith, without collusion or fraud and the information contained in the Tender is true and correct to the best of our knowledge and belief.

We understand that our Tender is binding on us and that you are not bound to accept a Tender you receive.

Yours sincerely,

Authorized Signature:

Name and Title of Signatory:

Name of Firm:

Address:

32.2 FORM 2: FINANCIAL PROPOSAL

S. No.	Item	Total Price	Taxes (wherever applicable)	Total cost (total price + taxes)
a)	Application Customization / Development and database creation cost (A)			
b)	Software Support and Maintenance Costs (Quarterly Expenses for remaining years of contract after "Go-Live") (B)			
c)	Support Manpower (C)			
d)	Data Digitization cost (D)			
e)	Training cost (E)			
f)	Software Licenses (F)			
g)	Others (Please specify) (G)			
Total Cost				
Total cost in figures:				

32.2.1 FORM 2A: DETAILS OF FINANCIAL BID

S. No.	Category	Component	No of components / units of service (X)	Rate (per unit) (Y)	Total Cost (=X*Y)
A: Application Development & Database Creation					
1.	Application and Portal Development				
Total A:					
B: Operations and Maintenance Costs (Quarterly Expenses for remaining years of contract after "Go-Live") (B)					
1.	Application Maintenance & Operational Expense including up gradation,				

S. No.	Category	Component	No of components / units of service (X)	Rate (per unit) (Y)	Total Cost (=X*Y)
	deployment of patches, fixes etc.				
2.					
3.					
	…				
Total B:					
C: Support Manpower					
1.	<Programmer>				
2.	<System Analyst>				
3.	<Database administrator>				
4.	<Project Manager>				
	…				
Total C:					
D: Data Digitization					
1.	Cost of digitization of data (data entry of the Master data and minimum historical transactional data entry)				
Total D:					
E: Training					
1.					
2.					
3.					
	…				
Total E:					
F: Licenses Costs (for the entire period)					

S. No.	Category	Component	No of components / units of service (X)	Rate (per unit) (Y)	Total Cost (=X*Y)
1.					
2.					
3.					
	…				
Total F:					
G: Other (please specify)					
1.					
2.					
3.					
	…				
Total G:					