



CDSA –THSTI

Ministry of Science & Technology, Government of India, Third Floor, THSTI Building, NCR Biotech Science Cluster, 3rd Milestone, Faridabad–Gurgaon Expressway, Faridabad- 121001 (Haryana)

GOOD CLINICAL PRACTICE PROFESSIONAL CERTIFICATION SCHEME (GCPPCS) APPLICATION FORM PROVISIONAL APPROVAL OF TRAINING INSTITUTES (TI)s

To apply for CDSA-THSTI Provisional Approval under the Good Clinical Practice Professional Certification Scheme (GCPPCS) please complete this application form and send it to CDSA-THSTI at the address mentioned above. CDSA-THSTI also accepts the application through mail with scanned copy of application accompanied by:

1. Documents as listed in Part V of application
2. Application Fee (with applicable taxes) in favor of CDSA-THSTI

Before completing this application form and submitting application, the relevant documents available at <http://thsti.res.in/cdsa/GCPPCS/> for the GCPPCS should be carefully studied. If any clarification is needed, please contact CDSA-THSTI at gcppcs.cdsa@thsti.res.in

Please fill in the application form by providing the information at the relevant space provided.

If additional space is required for providing information to any item, the information may be annexed as a separate sheet

PART-I GENERAL INFORMATION OF TI(s)

1.	Name of the Institution			
1.a	Year of establishment	DD/MM/YYYY		
2.	Address of main office			
		City		
		Country	State	
3.	Contact details	Country code – State code (if any)-Number		
		Mobile Country code -		
		*E-mail		
		Web		



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4.	Ownership details			
5.	Legal Registration details	<i>Registration (Regn.) as Pvt. Ltd/Public etc.</i>		
		<i>Regn. No.</i>		
		<i>Date of Regn.</i>		
		<i>Regn. Authority</i>		
6.	Address of registered office and Place of Registration			
7.	Chief Executive Officer (Authorized Representative)	<i>Name</i>		
		<i>Designation</i>		
8.	Primary Contact Person	<i>Name</i>		
		<i>Designation</i>		
		<i>Phone</i>		
		<i>Mobile</i>		
		<i>E-mail</i>		
9.	Branch office location(s)			
		<i>Mention above all Branch Office locations and annex details as per format.</i>		
10.	Training center(s) locations			
11.	Details of courses offered	<i>Name of course</i>	<i>No. of qualified candidates</i>	<i>Year</i>



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12.	List of other courses offered	Name of Course	No. of Qualified Candidates	Year
13.	Details of activities carried out by the Institutions			
14.	Is the Institution certified by any Certification Body (CB), If yes, please provide ? 1. Name of the Certification Body 2. Accreditation status 3. Scope of certification			
15.	Is the training Institution used for any other activity , if yes, please provide details			

PART–II PERSONNEL INFORMATION

1.	Personnel for Training under GCPPCS	Managerial Staff	Trainers/Technical Expert separate	Support Staff	Total

2. Training / Technical staff details

	Name	Educational Qualification	Experience	Designation	Years of experience	Office Phone	Mobile	Email ID	Nature of employment
2.1									
2.2									

3. Non-Technical/ Non-Training Staff

	Name	Educational qualification	Experience	Designation	Years of experience	Office phone	Mobile	Email ID	Nature of employment
3.1									



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PART – III INFRASTRUCTURE AND FACILITIES DETAILS

1	Ownership Details – Land / Infrastructure (Own / rented / lease).				
2.	The total area of land				
3.	Total built-up area				
4.	Room for Quality Manager				
5.	Room for Teaching staff	No.		Area	
	Number of class room(s)	No.		Area	
	Number of practical room(s)	No.		Area	
	Library and details of facilities in the library (Digital resources, no. of books and journals, etc)				
	Drinking water and food canteen facility				
	Washroom				
	Store-room				
	Canteen				
	Medical emergency				
	Using solar power				
6.	Facilities for online training				
	Can Institution conduct online training, if yes please mention the platform				
	Can Institution undertake an online assessment , If yes please mention the suitable platform				

PART–IV OTHER INFORMATION

1	Related organization(s), if any, and their activities	
2.	Major clients	



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3.	Financial performance (for last 3 financial years)	<i>Financial year</i>	<i>Total income</i>	<i>Total expenses</i>	<i>Net profit/loss</i>

PART-V ANNEXED INFORMATION

1.	Organization registration certificate	Annex – 1
2.	Memorandum/ Articles of Association (copy only)	Annex - 2
3.	Master list of documents relating to Provisional Approval of Institute for GCPPCS (with the issue and /or revision status)	Annex – 3
4.	Quality Manual in accordance with the scheme requirement	Annex – 4
5.	Documentation relating to Provision Approval of Institution for GCPPCS (Procedures, Competence criteria, Formats, Checklists, etc.)	Annex – 5
6.	Branch office(s) to be covered under recognition (list as per format Table –A)	Annex – 6
7.	List of Managerial Personnel & Trainers (list as per format Table – B)	Annex – 7
8.	Application fee – Amount , Cheque / DD No., Date :	Annex – 8
9.	Documentation Review – cum – Office Assessment Report for provisional Approval of Training Institution	Annex – 9
10.	Other Documents (annex list)	Annex – 10



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PART–VI DECLARATION

I, the authorized representative on behalf of our Institution, agree to the following Terms & Conditions of CDSA-THSTI as well as Rules and Procedures for Recognition of CDSA-THSTI under the Provisional Approval for the GCPPCS Training Institutions, and declare the following:

1. All statements, information and documents provided along with this application are correct to the best of our knowledge and belief.
2. CDSA-THSTI criteria, requirements, procedures and documents have been read, understood and implemented.
3. Have adequate resources to undertake GCP training work under the Provisional Approval for Training Institution for GCPPCS, undergo assessment as well as maintain conditions for approval.
4. Shall pay all necessary fees (including any applicable taxes) along with late fee, if applicable, to CDSA-THSTI.
5. Shall ensure that the operations, staff and procedures of our Institutions will always continue to comply with the CDSA-THSTI GCPPCS requirements and procedures.
6. Shall always maintain impartiality and integrity in operations.
7. Shall always provide, or give access to, all documents, records, information and facilities during the entire assessment process to enable a thorough assessment of our Institutions and also later during the period of approval.
8. Shall take adequate and prompt corrective and/or preventive action(s) as may be necessary on the issues raised by CDSA-THSTI.
9. Shall immediately notify CDSA-THSTI of any significant changes in organizational status - structure, operations, facilities, main policies, procedures, staff, or competence, which are likely to affect our approval.
10. Shall undertake routine assessments, surveillances, witnesses and reassessments as scheduled by CDSA-THSTI and also the verification or surprise visits as decided by CDSA-THSTI.
11. Any fee and charges payable by our Institute and which remains unpaid shall be recovered from our Institute with late payment charges as appropriate and decided by CDSA-THSTI.
12. If our Institute at any time is found not complying with the above declaration or the requirements of CDSA-THSTI as applicable or is found misrepresenting or misusing approval or carrying out malpractices or bringing CDSA-THSTI into disrepute, any action against our Institute may be taken including suspension or withdrawal of recognition or any other action as deemed appropriate by CDSA-THSTI.
13. If any information given along with this application is later found to be false, CDSA-THSTI may decide to cancel your application.

Signature with company -seal	
Name	
Designation	
E-mail	
Date	
Place	