



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**  
**PERSONNEL CERTIFICATION BODY (PrCB)s**

1. Documents as listed in Part IV of the application;
2. Application Fee (with applicable taxes) in favour of CDSA-THSTI

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

*Please provide information as per the format and in the space given and use the Extra Sheet as Annex if needed.*

## PART – I GENERAL INFORMATION

1.	Name of the Personnel Certification Body									
2.	Address of Regd. Office									
		City								
		State						PIN		
3.	Contact Details	Phone								
		Fax								
		E-mail								
		Web								
4.	Ownership Details									
5.	Legal Registration Details	Status								
		Regn. No.								

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		<i>Date of Regn.</i>		
		<i>Regn. Authority</i>		
		<i>Place of regn</i>		
6.	<b>Chief Executive</b>	<i>Name</i>		
		<i>Designation</i>		
7.	<b>Primary Contact Person</b>	<i>Name</i>		
		<i>Designation</i>		
		<i>Phone</i>		
		<i>Mobile</i>		
		<i>E-mail</i>		
8.	<b>Branch Office Location(s) with activities</b>			
		<i>Mention above all Branch Office locations of the Certification Body where GCPPCS is being operated and annex details as per the format in Table A.</i>		
9.	<b>Can Certification Body undertake online assessment, if needed? If Yes, please mention the platform for online assessment</b>			
10.	<b>Is certification body doing online evaluations, If yes, please provide details</b>			

**PART – II PERSONNEL INFORMATION**

11.	<b>Personnel for GCPPCS</b>	<i>Managerial Staff</i>	<i>No of Examiners</i>	<i>No. of Invigilators if used</i>	<i>Support Staff</i>	<i>Technical experts</i>	<i>Total</i>
	Location(s)						



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	Mention only numbers above and annex details of key Managerial Personnel, all examiners/ Invigilators & Technical Experts at the Main Office as well as Branch Office locations as per the format in Table B.							

12.	<b>Accreditation held as per ISO 17024</b> <i>Please specify Accreditation Body's name, Acc. No. and Validity Period</i>		
	<b>Any Other Accreditation</b> <i>Please specify Accreditation Body's name, Acc. No and validity period.</i>		
13.	<b>Other Approval(s) from Govt. or Regulatory Bodies, if any</b>		
14.	<b>Other activities within the same legal entity</b>		
15.	<b>Related Organization(s), if any, and their activities</b>		
16.	<b>Major Clients</b>		



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17.	<b>No. of Certificates issued to personnel as per ISO 17024, or any other certification</b>	ISO 17024 Certification				
		Any other Certification				
18.	<b>Financial Performance</b> (for last 3 financial years) Of the entity as a whole	<i>Financial Year</i>	<i>Total Income</i>	<i>Total Expenditure</i>	<i>Income from certification</i>	<i>Net Profit</i>

In case, PrCB is not making profits than CAB has to provide justification on its resources and sustenance.

### PART – IV ANNEXED INFORMATION

1.	Organization Registration Certificate & Memorandum / Articles of Association ( <i>copy only</i> )	<b>Annex – 1</b>
2.	Master List of Documents relating to Scheme ( <i>with issue and/or revision status</i> )	<b>Annex – 2</b>
3.	Quality Manual in accordance with Scheme requirements/ ISO/IEC 17024	<b>Annex – 3</b>
4.	Documentation relating to Scheme for (Procedures, Competence Criteria, Formats, Checklists etc.)	<b>Annex – 4</b>
5.	Branch Office(s) with activities to be covered under approval ( <i>list as per format in Table – A</i> )	<b>Annex – 5</b>
6.	List of Managerial Personnel, Examiners, Invigilators & Technical Experts ( <i>list as per format in Table – B</i> )	<b>Annex – 6</b>
7.	Application Fee - <i>Amount, Cheque / DD No., Date:</i>	<b>Annex – 7</b>
8.	Documentation Review-cum-Office Assessment Report for Provisional Approval of Personnel Certification Body	<b>Annex – 8</b>
9.	Other Documents (annex list)	<b>Annex – 9</b>

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**PART –V DECLARATION**

I, the authorized Representative on behalf of our Certification Body, agree to the following terms & conditions of CDSA – THSTI as well as Rules and Procedures for CDSA – THSTI Approval under the Good Clinical Practice Professional Certification Scheme (GCPPCS) and to 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 certification work under the Good Clinical Practice Professional Certification Scheme (GCPPCS), undergo assessment as well as maintain conditions for approval.
4. Shall pay all necessary fee and charges (including any applicable taxes) to CDSA-THSTI along with late fee if applicable.
5. Shall ensure that the operations, staff and procedures of our certification body will always continue to comply with the CDSA – THSTI Scheme requirements and procedures.
6. Shall always maintain impartiality and integrity in operations as well as in certification work.
7. Shall always provide and give access to, all documents, records, information and facilities during the entire assessment process to enable a thorough assessment of our certification body 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, mail policies, procedures, staff or competence, which are likely to affect our approval.
10. Shall undertake routine assessments, surveillances & reassessments as scheduled by CDSA-THSTI and also the verification or surprise visits as decided by CDSA-THSTI.
11. If our certification body at any time is found not complying with the above declaration or the requirements of CDSA-THSTI or ISO/IEC 17024 standard as applicable or is found misrepresenting or misusing approval or carrying out malpractices or bringing CDSA – THSTI into disrepute, any action against our certification body may be taken including suspension or withdrawal as deemed appropriate.
12. If any information given along with this application is later found to be false, CDSA –THSTI may decide to cancel our application or approval.
13. We shall obtain NABCB accreditation as per ISO/IEC 17024 for the scheme for Good Clinical Practice Professional Certification Scheme (GCPPCS) within 1 year of grant of Provisional approval.



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#### Authorized Representative

<i>Signature</i>	
<i>Name</i>	
<i>Designation</i>	
<i>E-mail</i>	
<i>Date</i>	
<i>Place</i>	

#### CERTIFICATION BODY BRANCH OFFICE LOCATION(S)

#### TABLE – A

S. No	Branch Office location with complete address	Phone, Fax & E-mail ; Local Contact Person (With Designation)	Activities Performed
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			



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#### CERTIFICATION BODY MANAGERIAL PERSONNEL, EXAMINERS, INVIGILATORS & TECHNICAL EXPERTS

#### TABLE –B

S. No	Name with Designation	Qualifications & Years of Relevant Experience	Location
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			