



## 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)**

#### **Documentation Review-cum-Office Assessment Report for Provisional Approval of Training Institutions (TI to fill 1,2,3 & 4 and Col 3 of the checklist, AT to fill the rest)**

*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**

1.	Name of the Training Institution (TI)	
2.	Approval applied for	
3.	TI's Documentation (TI to provide master list)	
4.	Brief Information about the TI (to be filled by TI)	
5.	Summary of Observations (by Assessment team)	
6.	Recommendations (by assessment team)	



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(1) Clause	(2) Description	(3) QM/Procedure no. /Document no. /Format no with clause no., Where a particular requirement is addressed ( TI to provide details)	(4) Compliance Y/N	(5) At Review Comments
<b>SECTION 1 : GOVERNANCE OF THE INSTITUTION</b>				
<b>1.1 General</b>	The management committee of the Institution shall establish and maintain a documented training management system and continually improve its effectiveness in accordance with the requirements of these criteria.			
<b>1.2 Leadership</b>	The management Committee of the institution shall establish and maintain a documented training management system and continually improve its effectiveness in accordance with the requirements of these criteria .			
<b>1.3 Responsibility and authority</b>	The institution shall define and document the responsibility and authority for all personnel to carry out the GCP Professionals training programme(s).			



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<b>1.4 Infrastructure</b>	The institution shall have trainers with appropriate educational qualifications, experience and training, adequate and appropriate support staff and facilities to conduct training programmes. The institution shall provide conditions to facilitate learning environment which shall include offices ,safe classrooms, clinics ,laboratories ,common spaces and other facilities viz adequate illumination ,adequate ventilation ,housekeeping and cleanliness ,safeguard against excessive weather conditions like dust ,cold, heat and rain and controlling noise and distractions.			
<b>1.5 Control of Documents</b>	The institution shall establish a documented procedure for preparing, reviewing and approving internal documents and controlling external documents, including the relevant regulations. It shall ensure that relevant documents are available to all concerned within the institution and to the interested parties.			
<b>1.6 Control of records</b>	The Institution shall identify and maintain records to provide evidence of conformity to the scheme criteria. A documented procedure shall be established to define the control of records providing for identification, indexing, storage, retention time			



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	and disposal. Besides, the institution shall also identify and maintain records based on the applicable statutory and regulatory requirements. There shall be a procedure for retention of records related to the trainees from the time of application to the current status of the candidates.			
<b>1.7 Financial resources</b>	The Institution shall provide financial resources, which shall be capable of sustaining a sound training programme consistent with its mission and objectives for long-term stability.			
<b>1.8 Compliance to Statutory and regulatory requirements</b>	The Institution shall identify and comply with any applicable statutory and regulatory requirements on the services provided.			
<b>SECTION 2 : LEARNING SERVICES REQUIREMENTS</b>				
<b>2.1 Communication</b>	The Institution shall notify the trainees through appropriate means about the syllabus, fees and the commitment required of the trainees to complete the training.			
<b>2.2 Admission Procedure</b>	There shall be a policy and procedure for admission of trainees including policy on concessions, which shall be made available to the candidates .The Institution shall provide information on Institution's policies and programmes, the responsibility of the trainees during the training, conduct / discipline, attendance norms, and financial			



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	obligation on part of trainees, assessment /qualifying criteria etc. The information shall be publicly available.			
<b>2.3 Provision of learning services</b>	The Institutions shall communicate to the trainees the responsibilities of the Institution. Information Technology (IT) shall ensure the availability and accessibility of training material.			
<b>2.4 Curriculum Planning</b>	The Institution shall ensure that the syllabus of their training programmes corresponds as a minimum with the Minimum Standard of Competence (MSC) developed by CDSA-THSTI all aspects of the MSC are covered. It shall also ensure that the total time to be devoted to lectures ,practical ,experiments etc. shall not be less than that prescribed by the Scheme and relevant regulatory bodies if any.			
<b>2.5 Development of Training Programmes</b>	Once the Subjects , topics and specific modules have been decided ,the Institution shall develop training material ,exercises ,case studies and plan for project work ,if any, as per the Scheme criteria .It will develop a course time table and delivery of the curriculum.			
<b>2.6 Competence Of Trainers</b>	The trainer(s) shall have the competence as per the Scheme MSC criteria for GCP professionals to train and evaluate in all the domains and as per the requirements of MSC .  The Institution shall review the performance of the trainers/annually			



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	and take adequate measures to upgrade their competence.			
<b>2.7 Continuous Evaluation</b>	The Institution shall analyse trainee performance regularly by monitoring the trainee assessment procedures to ensure adequacy and accuracy. It shall review the results of every batch of training.			
<b>2.8 Trainee Development</b>	The institution shall have a module on soft skill in the training programme to encourage trainees to develop necessary soft skills and attitudes to enable them to get suitable placements as GCP Professionals.			
<b>2.9 Training Methodology</b>	To make the transfer of knowledge and skills effective, appropriate MSC topic – specific training methodology shall be adopted. A typical cycle of explaining , demonstrate , imitate ,feedback, practice, evaluate ,problem – solving related inputs shall be followed. Where necessary , use of case studies ,experimental learning shall be resorted to. The training methods shall include both knowledge –based (to facilitate understanding of concepts) and skill based sessions (application of knowledge and skills in practical activities).			
<b>2.10 Duration</b>	Training shall be a minimum of the duration specified in the scheme criteria .			
<b>2.11 Results</b>	The Institution shall review the feedback and results of every			



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	training and take appropriate corrective actions.			
<b>2.12 Feedback</b>	The Institution shall obtain feedback from the trainees and take necessary corrective actions.			
<b>SECTION 3 : PERFORMANCE MEASUREMENT AND IMPROVEMENT</b>				
<b>3.1 General</b>	The Institution shall periodically monitor and measure the effectiveness of the training and support processes as required in the respective clauses of the standard. <b>Note :</b> The Institution may identify suitable indicators to monitor and measure the performance .			
<b>3.2 Continual Improvement</b>	The Institution shall regularly assess the effectiveness of training. It shall implement suitable corrective and preventive actions at various levels. The Institution's management shall ensure effective management , collection ,validation and analysis of data to monitor the Institution's performance as well as the satisfaction of interested parties. Where possible, Institution shall collect / share data from /with other Institutions and benchmark with its data to improve upon in deficient areas.			
<b>3.3 Management Review</b>	The management shall review the following at least annually for effectiveness and conformity: <ul style="list-style-type: none"> <li>• Actions outstanding from previous management review meetings</li> </ul>			



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	<ul style="list-style-type: none"> <li>• Actions resulting from any external audits ,</li> <li>• Administrative procedures</li> <li>• Curriculum design and presentation</li> <li>• Performance of trainers and future training</li> <li>• Complaints and appeals</li> <li>• Analysis of trainee results and feedback.</li> </ul>			
<b>3.4 Corrective actions</b>	There shall be established procedures for the identification and management of non- conformities in its operations. There shall be necessary corrections and corrective actions to eliminate the causes of non- conformities to prevent a recurrence.			
<b>3.5 Complaints and Appeals</b>	The Institution shall have a procedure for handling complaints and appeals from the interested parties.			
<b>3.5.1 Complaint</b>	Expression of dissatisfaction, other than appeal by any person or organization to the TI relating to the activities of GCP Professional training .			
<b>3.5.2 Appeal</b>	Expression of dissatisfaction, other than by appeal by any person or organization to the TI relating to the activities of GCP professionals training.			





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<b>Name of TI's representative</b>		<b>Date :</b>
<b>Name(s) of assessor(s) :</b>		
<b>1.</b>		<b>Date :</b>
<b>2.</b>		<b>Date :</b>