Good Clinical Practice Professional Certification Scheme (GCPPCS)

ASSESSMENT PROCESS FOR PROVISIONAL APPROVAL OF TRAINING INSTITUTIONS

0. INTRODUCTION

The **Good Clinical Practice Professional Certification Scheme (GCPPCS)**, hereinafter referred to as the **Scheme**, aims at providing a model for GCP professionals quality practice and performance and envisages that independent, competent Training Institutes (TI) shall deliver the requisite elements of relevant training as per the Scheme criteria.

1. SCOPE

This document defines the process for TIs to undertake assessments for approval to operate under the Scheme as per the prescribed criteria and approval by CDSA-THSTI.

For the process of assessments, the TIs shall need -

a) to demonstrate its ability to consistently provide competency in the required domains for the GCP professionals training that meets the Scheme requirements and facilitate the overall development of the trainees;

b) to enhance the trainee's satisfaction through effective application of process for continual improvement of the system;

c) all requirements of the training to be applied uniformly to all TIs, regardless of the type and size.

1.1 Authority

The Scheme Owner CDSA-THSTI shall be the sole authority for the coordination and getting the assessment of the TIs applying for provisional approval and finally for accreditation.

1.2 Initial assessment

1.2.1 Document review (DR)

On receipt of the TI application, supporting documents including training material and requisite fee, the GCPPCS Secretariat of CDSA-THSTI shall nominate an assessment team for document review.

After the DR the Secretariat shall inform the applicant TI about the observations if any. The TI shall be required to act upon the observation/s so that the points raised during the DR, if found satisfactorily answered or required action taken by the TI is evidenced, then the DR process can be closed to proceed to the next stage, which would be the Office Assessment (OA).

1.2.2 Office assessment (OA)

1.2.2.1 Following the DR, the Secretariat shall inform the applicant TI regarding the schedule for OA to verify compliance to the documented system. The OA team will verify the documents relating to the following:

a) the TI shall manage the process of training the GCP professionals as per the training process for the Scheme;
b) the TI shall maintain records to demonstrate that the training is effectively conducted;
c) the TI shall ensure the requirements of the Scheme are met with at any point in time;
d) the TI understand the conditions for maintaining the provisional approval relating to the assessment criteria relating to conformities and non-conformities;
e) the TI shall train the GCP professionals only under the Scheme and shall use the scheme and TI logo for the Scheme following the rules prescribed under the Scheme;
f) the TI shall have a process to handle appeals by the trainee/trained GCP professionals against any of its decisions;
g) the TI shall have a process to handle complaints from the users of the services of the certified GCP professionals or any other interested party.

In the case of TI is having multiple branches or centers from where the same training is delivered, the OA shall be carried out at a sample of such locations.

1.2.2.2 Witness assessment

a) following DR and OA, the conduct of two training programs of the TI shall be witnessed. The assessment team shall evaluate all aspects of the training program and activities of the trainers for conformity to the applicable Scheme criteria, and the applicant TI's procedures for effective delivery of the program;
b) the Scheme Owner reserves the right to demand witness of a specific trainer;
c) the applicant TI shall be informed of the non- conformities and concerns if any;
d) the applicant TI shall submit root cause analysis (RCA) and proposed corrections/corrective actions (CA) for the non-conformities and address the concerns indicating actions taken/proposed to be taken within30 days to the AT;
e) on acceptance of the RCA/CA, TI shall submit evidence of having implemented the actions within 30 days of acceptance;
f) an additional full or partial assessment of the training programme may be done to verify the compliance of corrective actions if any major non conformity (NC) is raised;
g) the decision on granting of Provisional Approval shall be taken depending on the Assessment Reports and actions taken to the satisfaction of the AT and when the applicant TI's conformance for the Scheme criteria and any other requirement/s is fully demonstrated;
h) once provisional approval is granted, the TI shall be informed by the Secretariat;
i) the annual fee in advance shall be paid by the TI on receipt of an invoice from the Scheme Owner;

j) a formal letter of Provisional Approval shall be issued by CDSA-THSTI on receipt of a fee;
k) subsequently, every year the provisionally approved TI shall have to undergo a surveillance assessment and follow stipulated procedures of the Scheme;
l) the Provisional Approval shall be valid for a period of 3 years from the date of approval.

1.3 Surveillance assessment

1.3.1 To assess the TI's continuing compliance to the Scheme criteria and any other requirement/s and the effective implementation of its documented system, CDSA-THSTI shall conduct an annual surveillance OA.

1.3.2 CDSA-THSTI reserves the right to carry out short notice assessment(s) as necessary for a specific TI in case of complaints/concerns raised against the delivery or administration of the program. Cost for the same shall be borne by the TI.

1.3.3 Surprise assessment may also be conducted at the office or the training programme.

1.4 Extension of scope

1.4.1 Any approved TI can request for extension of its scope to cover additional domains (if on offer) by making a written request to the CDSA-THSTI by paying the applicable scope extension fee.

1.4.2 The TI shall submit the updated documentation with changes highlighted for review.

1.5 Suspension or cancellation of approval

1.5.1 CDSA-THSTI may suspend or cancel the approval of a TI because of any of the following reasons but not be limited to:

a) non-compliance or violation of the Scheme criteria and any other requirement/s;
b) providing insufficient or incorrect information;
c) improper use of Scheme Logo / Certification Mark;
d) changes in the Certificate format without CDSA-THSTI's approval;
e) major changes in the training material without CDSA-THSTI's approval;
f) failure to report any major changes in the training program to CDSA-THSTI;
g) any other condition deemed appropriate by CDSA-THSTI;
h) non-payment of fees.

1.5.2 The TI shall be served a show-cause notice giving 15 days to respond and shall be provided with a personal hearing before taking a decision.

1.6 Expiry of registration

The provisional approval of a TI shall automatically expire at the end of its validity period unless formal approval to full criteria (to be notified) is obtained timely by the concerned TI.

1.7 Appeals

An appeal against the decision of the CDSA-THSTI can be made in writing to the chairperson of the steering committee. The appeal to be looked into by a 3 member panel, the members may be from the steering committee who were in any way not involved with the decision making against which the appeal is made and having no conflict of interest. The final decision on the appeal to be made by the chairperson, steering committee.

1.8 Schedule of fee

Under preparation.

1.9 Terms

1.9.1 The approval to a TI shall be granted for a period of 3 years, subject to satisfactory performance based on the surveillance report at least once a year.

1.9.2 The TI providing the training shall conduct the training on its own and shall not subcontract it in part or full.

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