

Good Clinical Practice Professional Certification Scheme (GCPPCS)

CRITERIA FOR PROVISIONAL APPROVAL OF GCP TRAINING INSTITUTIONS

0. INTRODUCTION

The criteria for the Provisional Approval of the Training Institutions (TI) has been developed to provide guidance to the TI by providing training to the GCP professionals under the GCPPCS. The provisional approval document would be followed by full-fledged final criteria document following international best practices for the GCP professional training institutions.

This document provides a framework for the effective management and delivery of the competence-based relevant training aimed at the overall development of the trainees to be a competent GCP professional. The provisional approval is a process of establishing the competence of TIs in delivering the requisite elements of relevant training so that the trainees can carry out the task as GCP professionals effectively. This process focuses on learning, self-development and encourages the TIs to pursue excellence; assist the professional programme of these institutions towards a high level of performance, integrity and quality that earns them the confidence of the stakeholders and community they serve, thus serving the purpose of upholding high standards of quality and expectations of the various stakeholders of the system.

Salient objectives

- To assess institutions and their programme for meeting defined quality standards.
- To foster excellence in the TIs and building effectiveness in delivering competency-based training.
- To establish a framework for continuous improvement and provide the opportunity to benchmark with other institutions.
- To facilitate developing professional competence of the GCP professionals.
- To provide a basis for determining eligibility for assistance and investment of public funds by government/regulatory agencies.

Any TI seeking provisional approval can align its operations to the norms laid down hereinafter and create the necessary facilities to become eligible with on the following dimensions:

- a) top management commitment and effective institution management;
- b) infrastructure and support facilities;
- c) design, development and effective delivery of the training process;
- d) performance evaluation and improvement.

1.0 SCOPE

This provisional criterion specifies requirements for the Provisional Approval of a TI:

1.1 Need to demonstrate its ability to consistently provide competence-based GCP training that meets interested party requirements and facilitates the overall development of trainees.

1.2 Aims to enhance interested party satisfaction through the effective application of process approach for continual improvement of the system.

All requirements are generic and non-prescriptive, intended to apply to all institutions, regardless of type, size and nature of training service provided. It provides the framework to plan, establish, operate, monitor and improve GCP professionals training service. Institutions may determine the extent of prescriptions by which they shall be governed by:

- applicable statutory/ regulatory requirements.
- the policies and objectives.
- resources required for effective implementation of the criteria.

2.0 GLOSSARY

For these criteria, the following terms have specific meanings as defined here:

2.1

appeals

request made by a participant/trainee to an appellate authority to review a decision already taken

2.2

competence

ability to apply knowledge and skills to achieve intended results

2.3

complain

expression of dissatisfaction, other than appeal by any individual or organization to a training institution, relating to activities of that body or a certified person, where a response is expected

2.4

conformity

fulfilment of requirement

2.5

continual improvement

recurring activity to enhance performance

2.6

corrective action

action to eliminate the cause of non-conformity

2.7

document

the document is an instruction or procedure format for information and its supporting medium. Example: procedure, drawing, report, standard

2.8

documented information

information required to be controlled and maintained by an organization and the medium on which it is contained

Note 1 to entry: Documented information can be in any format and media, and from any source.

Note 2 to entry: documented information can refer to:

- the management system including related process
- information created in order for the organization to operate
- evidence of results achieved

2.9

effectiveness

the extent to which planned activities are realized and planned results achieved

1	2.10
2	interested party
3	person or organization that can affect, be affected by or perceive itself to be affected by a decision or
4	activity
5	2.11
6	management system
7	system to establish policy and objectives and to achieve those objectives
8	2.12
9	monitoring
10	determining the status of a system, a processor an activity
11	<i>Note 1 to entry:</i> to determine the status, there may be a need to check, supervise or critically observe
12	2.13
13	non-conformity
14	non-fulfilment of requirement
15	2.14
16	objective
17	result to be achieved
18	2.15
19	performance
20	measurable result
21	<i>Note 1 to entry:</i> performance can relate either to quantitative or qualitative findings
22	<i>Note 2 to entry:</i> performance can relate to the management activities, processes, products, systems
23	and organizations
24	2.16
25	process
26	set of interrelated or interacting activities which transforms inputs into outputs
27	2.17
28	quality
29	- quality is the degree of excellence and distinguishing nature of attributes of training
30	programme
31	- quality is the ongoing process of building and sustaining relationships by assessing,
32	anticipating and fulfilling stated and implied needs
33	- quality is the customers' perception of the value of the suppliers' work output
34	2.18
35	record
36	record is a document stating results achieved or providing evidence of activities performed
37	2.19
38	requirement
39	need or expectation that is stated, generally implied or obligatory
40	2.20
41	scheme owner
42	the organization responsible for developing and maintaining a certification scheme
43	2.21
44	training
45	the act or process of imparting or acquiring knowledge, skill or judgment
46	2.22
47	training institution
48	an organization that provides training services to potential GCP Professionals
49	2.23
50	training process
51	the process resulting in providing of educational / training service

2.24

training service

service concerned with training

3.0 CRITERIA

3.1 GOVERNANCE OF THE INSTITUTION

3.1.1 General

The Management Committee of the TI shall establish and maintain a documented training management system and continually improve its effectiveness in accordance with the requirements of these criteria.

3.1.2 Leadership

The Management Committee shall establish and follow methods to determine the needs and expectations concerning effective delivery of curriculum and varied development of the trainees.

3.1.3 Responsibility and authority

The TI shall define and document the responsibility and authority for all personnel to carry out the GCP professionals training programme(s).

3. 1.4 Infrastructure

The TI shall have trainers with appropriate educational qualifications, experience and training, adequate and appropriate support staff and facilities to conduct training programme.

The TI 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.

3.1.5 Control of documents

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.

3. 1.6 Control of records

The TI 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 and disposal. Besides, the TI 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.

3. 1.7 Financial resources

The TI shall provide financial resources which shall be capable of sustaining a sound training programme consistent with its mission and objectives for long term stability.

3. 1.8 Compliance to statutory and regulatory requirements

The training institution shall identify and comply with any applicable statutory and regulatory requirements on the services provided.

3.2 LEARNING SERVICES REQUIREMENTS

3. 2.1 Communication

The training institution shall notify the trainees through appropriate means about the syllabus, fees and the commitment required of the trainees to complete the training.

3.2.2 Admission procedure

There shall be a policy and procedure for admission of trainees including policy on concessions which shall be made available to the candidates. The TI shall provide information on its policies and programme, the responsibility of the trainees during the training, conduct/discipline, attendance norms, and financial obligation on part of trainees, assessment /qualifying criteria etc. The information shall be publicly available.

3. 2.3 Provision of learning services

The TI shall communicate to the trainees the responsibilities of the TI. Information Technology (IT) shall ensure the availability and accessibility of training material.

3. 2.4 Curriculum planning

The TI shall ensure that the syllabus of their training programme corresponds as a minimum with the Minimum Standard of Competence (MSC) developed by CDSA-THSTI and all aspects of the MSC are covered. It shall also ensure that the total time to be devoted to the training. It shall not be less than that prescribed by the Scheme and relevant regulatory bodies, if any.

3. 2.5 Development of training programme

Once the subjects, topics and specific modules have been decided, the TI 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.

3.2.6 Competence of trainers

The trainer(s) shall have the competence criteria:

- a)** Post-graduate degree in medical sciences/ nursing /pharmaceuticals/ biological sciences/ biostatistics/ clinical data management;
- b)** 5 years of work experience in clinical research after receiving a post-graduate degree;
- c)** GCP trained;
- d)** The team of personnel (evaluators or trainers or question paper setters) to have overall collective competence for all 6 domains.

The Institution shall review the performance of the trainer/s annually and take adequate measures to upgrade their competence.

3.2.7 Continuous evaluation

The TI shall analyze trainee performance regularly by monitoring the trainee assessment procedures to ensure adequacy and accuracy. It shall review the results of every batch of training.

3.2.8 Trainee development

The TI 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.

3.2.9 Training methodology

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, experiential 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).

3. 2.10 Duration

Training shall be a minimum of the duration specified in the scheme criteria.

3.2.11 Results

The TI shall review the feedback and results of every training and take appropriate corrective actions.

3.2.12 Feedback

The TI shall obtain feedback from the trainees and take necessary corrective action.

3.3 PERFORMANCE MEASUREMENT AND IMPROVEMENT

3. 3.1 General

The TI shall periodically monitor and measure the effectiveness of the training and support processes as required in the respective clauses of the standard.

Note: The TI may identify suitable indicators to monitor and measure its performance.

3. 3.2 Continual improvement

The TI shall regularly assess the effectiveness of training.

It shall implement suitable corrective and preventive actions at various levels.

The TI's management shall ensure effective management, collection, validation and analysis of data to monitor the TI'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.

3.3.3 Management review

The management shall review the following at least annually for effectiveness and conformity:

- a) actions outstanding from previous management review meetings;
- b) actions resulting from any external audits;
- c) administrative procedures;
- d) curriculum design and presentation;
- e) performance of trainers and future training;
- f) complaints and appeals;
- g) analysis of trainee results and feedback.

3.3.4 Corrective actions

There shall be established procedures for the identification and management of nonconformities in its operations. There shall be necessary corrections and corrective actions to eliminate the causes of non-conformities to prevent a recurrence.

3.5 Complaints and appeals

The TI shall have a procedure for handling complaints and appeals from the interested parties.

3.5.1 Complaint

Expression of dissatisfaction, other than an appeal by any person or organization to the TI relating to the activities of GCP professional training.

3.5.2 Appeal

Request by for reconsideration of any adverse decision related to the GCP professional training.

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