

Good Clinical Practice Professional Certification Scheme (GCPPCS)

CERTIFICATION PROCESS

0. INTRODUCTION

Clinical Developmental Services Agency (CDSA), an extramural unit of Translational Health Sciences and Technology Institute (THSTI) (jointly referred as CDSA-THSTI) is under the Department of Biotechnology, (DBT), Ministry of Science & Technology, Government of India. CDSA was created to facilitate the development of affordable healthcare products for public health diseases.

CDSA-THSTI has taken the initiative to develop a Certification Scheme for the GCP professionals as per International Standards of Personnel Certification ISO/IEC 17024:2012 leading to the promotion of quality clinical research conducted in India. CDSA-THSTI as the Scheme Owner aims for promoting uniformity in its implementation among the Personnel Certification Bodies (PrCB) for the GCP professionals seeking certification thereby developing an eco-system for certification of the GCP professionals.

The objective of this document is to define the process of certification of Good Clinical Practice professionals under the Good Clinical Practice Professionals Certification Scheme (GCPPCS) of Clinical Developmental Services Agency and Translational Health Sciences and Technology Institute (CDSA-THSTI).

1. SCOPE

This document explains the process of certification under the Good Clinical Practice Professionals Certification Scheme (GCPPCS) [hereinafter referred to as the Scheme] and the requirements that should be followed to obtain and maintain the certification for the GCP professionals.

EXCLUSION: The Scheme has prescribed assessment criteria for assessing GCP professional's competence - knowledge and skill in the conduct of clinical research involving humans. This assessment does NOT test on any Ministry of Health & Family Welfare, local or other government or private institutional policy.

2. DESCRIPTION OF CERTIFICATION PROCESS

2.1 Registration of Application

2.1.1 The applicant GCP professional shall apply to any of the approved Personnel Certification Bodies (PrCB) in the prescribed application form.

2.1.2 The approved PrCB shall respond to all enquiries received from prospective applicants for certification as GCP professional with complete information on the certification process, appropriate to the certification Scheme (including fee structure), a list of documents containing the requirements for certification, the applicant's obligations and rights, and the duties of a certified person which includes a code of conduct, within 7 days of receipt of the query.

2.1.3 The applicant GCP professional shall declare whether he/she has been an applicant under this Scheme by any other PrCB and if yes, shall provide details of the status of application/certification, scope and period of certification.

2.1.4 The applicant GCP professional shall, along with the application, declare any pending judicial proceedings relating to his conduct, and/or any pending proceedings by any regulatory body, concerning to GCP related activities and application from such an applicant shall not be entertained.

2.1.5 All applications for certification shall be reviewed for the completeness, adequacy and deficiencies observed, if any, shall be informed to the applicant within 7 days of receipt of application. Records of application review shall be maintained.

2.1.6 All applications found complete, shall be registered within 7 days of receipt of application/additional information, in order of receipt with a unique identification number, acknowledged and records maintained. Registration shall be done if found complete.

2.1.7 Applications from applicants found to be violating the terms and conditions of the Scheme while their application is being processed, shall not be processed any further and rejected after due notice of 15 days.

2.1.8 Applications from applicants who have misused the earlier certification or whose earlier certification was cancelled/application rejected or whose earlier application was rejected because of violation of terms & conditions shall not be registered within one year of cancellation of the certificate/rejection of the application.

2.1.9 Requests for certification from ex-applicants shall be processed like a fresh applicant and the entire procedure for grant of certification be adhered to subject to Cl 3.1.7 and 3.1.8.

2.1.10 The PrCB shall reject or close all applications under the following conditions:

- a) If deficiencies observed in the application are not completed within one month;
- b) If the applicant does not take the assessment within 3 months of registration of application;
- c) Misuse of the certification mark, if any;
- d) Evidence of malpractice;
- e) Voluntary withdrawal of the application.

2.1.11 In the event of closure/rejection of an Application, the PrCB may act as per its policy.

2.2 Competence Assessment Process

The criteria for assessment shall be as per the requirements listed in the Minimum Standard of Competence in the specific domain for which the GCP professional undertakes the assessment. The assessment to be either online or face to face.

2.3 Assessment Method

2.3.1 The assessment by standardized MCQs for testing the knowledge and case study based MCQs to test skill in the 6 domains of competence for the Basic level.

2.3.2 There will be no negative marking for the Basic level assessment.

2.3.3 The overall pass percentage for the successful candidates shall be 70%.

2.3.4 The assessment method to be based on ISO 17024.

2.4 Assessment team

The team shall comprises of minimum 2 examiners.

2.5 Examiner competence

2.5.1The examiners to have –

i). Post-graduate degree in medical sciences/ nursing /pharmaceuticals/ biological sciences/ biostatistics/ clinical data management.

ii). 5 years of work experience in clinical research after receiving post-graduate degree.

iii). GCP trained.

iv). The team of personnel (examiners and question paper setters) to have overall collective competence for all 6 domains.

2.5.2 The examiners shall record their results on the structured assessment sheet for each candidate.

2.6 Assessment Process

2.6.1 The assessment of the candidates shall be conducted within 3 months of registration of the application.

2.6.2 The PrCB shall schedule the assessments as and when the number of candidates is optimum as a minimum. The PrCB at its discretion may assess with less number of candidates. The PrCB shall ensure that the certification process is completed within 15 days from the date of the actual assessment, where applicable.

2.6.3 The PrCB shall inform all applicants who meet the eligibility criteria of the dates of assessment, including those appearing for a re-assessment and the means of assessment at least 15 days before the assessment. The PrCB shall make publicly available through its website the dates for the assessment and the names of the candidates.

2.6.4 The names of the candidates shall be communicated well in advance to the examiners for identification of conflict of interest if any. Any conflicts identified concerning the candidates shall be eliminated, minimized or managed by the PrCB.

2.6.5 The PrCB shall inform the candidates at the time of assessment, the names of the team of examiners for identification of conflict of interest if any. If the candidate has any conflict of interest and voluntarily decides not to undergo the assessment, the PrCB shall provide them with the option for another assessment or reimburse the applicable application fee.

2.6.7 The names of the candidates shall be communicated well in advance to the examination centre (if any) where the assessment is planned to be carried for identification of conflict of interest. Any conflicts identified concerning the candidates shall be suitably eliminated, minimized or managed by the PrCB.

2.6.8 The PrCB shall inform the candidates of the name of the assessment centre where the assessment is being planned for identification of conflict of interest if any. If the applicant candidate has any conflict of interest and voluntarily decides not to undertake the assessment, the PrCB shall provide them with the option for another assessment or reimburse the applicable application fee.

2.6.9 The decision of the examiners shall be communicated to the candidate by the PrCB. The PrCB shall maintain an updated register of applicants, candidates and certified GCP professionals with the scope of certification and their status of certification.

The Scheme Owner to receive quarterly data from the PrCB and updation on CDSA website.

2.6.10 The PrCB shall ensure that the assessment and certification process is such that they are fair, valid and reliable across assessment centres, across time zones and examiners.

2.7 Decision on Certification

2.7.1 The PrCB shall decide on certification, by a competent person(s) independent of assessment(s), based on the information gathered during the certification process and shall ensure the following:

- a) The assessment result of the candidate is not below the minimum score specified;
- b) Availability of necessary documentation as proof of the means of assessment chosen to assess the candidate;
- c) Any other requirements prescribed by the Scheme Owner.

The candidate should obtain at least 70% to be awarded Certificate.

2.7.2 There shall be no conditional grant of certification by the PrCB. The decision to certify the person shall be taken by an independent person who has neither been involved in assessing the candidate nor in the training of the candidate.

2.7.3 When candidates fail to meet the acceptance criteria for assessment, the PrCB shall inform them. The candidate may take another assessment with the same or another PrCB but would have to declare their previous performance while reapplying.

The PrCB may verify the information provided by contacting the PrCB mentioned in the application.

2.7.4 If a certified GCP professional relocates to a different place /state, he/she shall be required to inform the PrCB of the change in the location who in turn shall inform the certified GCP professional of the procedure to be followed for the continuance of the validity of the certificate.

2.7.5 The effective date of certification shall not be before the date of the decision to grant the certification to the GCP professional.

2.7.6 The validity of the GCP professional certificate will be for 5 years.

2.7.7 The applicants for GCP professional to have a code of conduct for being certified as GCP professional.

2.7.8 If any transition takes place for the Standard or Regulatory requirement, the MSC for GCPPCS would have to be aligned, the Scheme Owner to inform the approved PrCBs of the transitions, the transition policy and the time for completing the process of transition.

3. CERTIFICATE

3.1 The PrCB shall provide a certification document to the certified GCP professional. The certificates shall contain, as a minimum, the following information:

- a)** the name of the certified person;
- b)** a unique identification;
- c)** the name of the certification body;
- d)** a reference to the certification scheme, standard or other relevant documents, including issue date, if relevant;
- e)** the scope of the certification including, if applicable, validity conditions and limitations;
- f)** the effective date of certification and date of expiry.

3.2 The certificate format shall be as approved by the Scheme Owner.

The effective date on a certification document shall not be before the date of the certification/recertification decision.

The formal certification documentation shall include the signature of the individual(s) of the PrCB assigned such responsibility where permitted by law, other methods, including electronic signature, are acceptable.

4. SURVEILLANCE

4.1 Surveillance to be conducted in the third year of certification.

4.2 For the certified GCP professional who has been working consistently in the field of GCP after being certified, for them there will be no surveillance assessment on the production of evidence that the professional has been productively employed in GCP work.

4.3 For those who are unable to provide any evidence of working in the field of GCP and wish to continue with their certified status, they will have to undergo retest as surveillance.

5. RECERTIFICATION

5.1 Recertification after 5 years.

5.2 The recertification will be through the same assessment process as in initial certification for all certified professionals.

5.3 The PrCB shall send the Renewal notice to the certified GCP professional atleast 6 months before the expiry of the certificate validity period to the registered email id and/or to the registered address.

5.4 The certified GCP professional shall apply for renewal in the prescribed format along with a fee if any prescribed at least 4 months before the expiry of certification.

5.5 The PrCB shall review the performance of the certified GCP professional seeking recertification (renewal of the Certificate), with concerning compliance to certification criteria during the entire certification cycle, before a decision on the renewal of the certificate.

5.6 The performance of the certified GCP professional shall be reviewed based on the recertification assessment:

- a)** The surveillance assessment report(s);
- b)** Corrective actions are taken on any feedback given during surveillance;
- c)** Any suspension of the certificate during the previous validity period;
- d)** Complaints received if any;
- e)** Feedback on his professional services to be obtained by the PrCB;
- f)** Feedback reports from institution employed in, if applicable, to be obtained by the PrCB;
- g)** Adverse information, if any.

5.7 Recertification of the certified GCP professional shall be based on their satisfactory performance during the previous certification period and shall be done before expiry of the certification.

5.8 The PrCB shall not recertify GCP professional with conditions for compliance to be verified subsequently. There shall be no conditional certification of GCP professional.

5.9 The PrCB shall not recertify any certified GCP professional whose certification is under suspension.

5.10 When the performance of the certified GCP professional is not satisfactory, the PrCB shall withhold the recertification of the GCP professional clearly stating the reasons and give time for effecting corrective actions. The verification and decision on recertification shall be taken within 6 months of the expiry date.

5.11 The PrCB shall verify corrective actions.

5.12 The recertification shall be effected from the date of the expiry of the previous certificate and the intervening period shall be treated a period of suspension. The certified GCP professional shall not claim certification during this period.

5.13 In case the certified GCP professional does not complete satisfactorily actions within 3 months, a show-cause notice of 15 days shall be served with a chance to respond / personal hearing for any adverse decision. After the 15 days, the certificate shall stand expired from the date of expiry of previous validity.

5.14 When a certificate is not renewed it expires at the end of the validity period.

6. CHANGE OF LEVEL OF CERTIFICATION

6.1 Change to a higher level of certification, if prescribed, on application by a GCP professional shall be done after ascertaining the competence through the prescribed means of assessment for that level of certification.

6.2 The candidate shall be issued a fresh certificate as in initial certification instead of the current certificate after taking back the lower level certificate.

7. SUSPENSION OF CERTIFICATION

7.1 The PrCB shall issue instructions to the certified person for suspension of certification, with due notice of 15 days after giving chance to respond and personal hearing, if desired by the professional, when:

- a)** The surveillance audit shows unsatisfactory performance;
- b)** Any serious complaint/feedback which is found to be valid;
- c)** Any administrative requirement like payment of a fee or timely provision of information;
- d)** Any violation of terms and conditions of certification.

7.2 On receipt of instructions for suspension of certification, the certified GCP professional shall with immediate effect remove any reference to certification in all of his communication.

7.3 The certified GCP professional shall be advised to undertake a root cause analysis and identify and initiate necessary corrective actions for resolving the same.

7.4 Suspension shall not exceed six months and provided it is still within the validity period of the certificate. The certified GCP professional's inability to resolve issues relating to suspension within this period shall lead to cancellation of certification.

8. CANCELLATION OF CERTIFICATION

8.1 PrCB shall cancel the certificate when:

- a)** Certified GCP professional contravenes the terms and conditions of certification and provisions of this certification scheme like claiming or displaying the scope of certification other than that granted, or any fraudulent behaviour is established;
- b)** The corrective actions taken are not ensuring compliance, or the proposed plan for corrective actions will take a considerable time beyond 3 months for implementation;
- c)** Any administrative requirement like payment of a fee or timely provision of information.

8.2 PrCB shall cancel the certificate at the request of the certified GCP professional if the certified GCP professional is no longer interested.

8.3 In the event of cancellation the PrCB shall advise the certified GCP professional to return the certificate issued by the PrCB.

8.4 Any suspension or cancellation of certification to be publicly available on the Scheme Owner's and Certification Body website.

9. FEE

9.1 A fee may be charged to the person seeking certification without any discrimination.

9.2 The fee structure shall be publicly accessible and also be provided on request.

9.3 The PrCB shall notify and obtain consent to its fee structure from the candidate before granting of certification. As and when the fee changes, the same shall be communicated to all including applicants and obtain their consent.

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