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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

Documentation Review-cum-Office Assessment Report for Provisional Approval of Personnel Certification Bodies (PrCB to fill items 1,2,3,& 4 and Col 3 of the checklist , AT to fill the rest)

Please fill in the prescribed 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 PrCB	
2.	Approval applied for	
3.	PrCB's Documentation (PrCB to provide master list)	
4.	Brief Information about the PrCB - (to be filled by PrCB)	
5.	Summary of Observations (by Assessment Team)	
6.	Recommendations (by Assessment Team)	

(1) Clause	(2) Description	(3) QM/Procedure no. /Document no. /Format no with clause no., Where a particular requirement is	(4) Compliance Y/N (by AT)	(5) At Review Comments



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		addressed (CB to provide details)		
SECTION 1: ADMINISTRATIVE REQUIREMENTS				
3.1 Legal entity	The PrCB shall be a legal entity in the economy in which it is located, or shall be a defined part of a legal entity, such that it can be held legally responsible for all its certification activities. A governmental certification body is deemed to be a legal entity based on its governmental status. A PrCB, that is part of an organization involved in functions other than certification, shall be separate and identifiable within that organization.			
3.2 Organizational Structure	The PrCB shall define and document the duties responsibilities and the reporting structure of its personnel and any committee and its place within the organization. When the PrCB is a defined part of a legal entity, the documentation of the organizational structure shall include the line of authority and the relationship to other parts within the same legal entity.			
3.3 Integrity	The PrCB and its personnel shall maintain integrity at all times. The PrCB shall implement adequate measures to ensure integrity.			
3.4 Impartiality				
3.4.1	The PrCB shall be impartial.			



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3.4.2	The PrCB shall be so structured and managed as to safeguard impartiality .			
3.4.3	The PrCB and its staff shall not engage in any activities that may conflict with their impartiality.			
3.4.4	The PrCB shall act impartially with its applicants, candidates and certified GCP Professionals.			
3.4.5	<p>The PrCB shall have a process to identify , analyze , evaluate ,monitor and document the threats to impartiality arising from its activities including any conflicts arising from its relationships on an ongoing basis.</p> <p>a) This shall include those threats that may arise from its activities or its relationships or the relationships of its personnel. Where there are any threats to impartiality , the PrCB shall document and demonstrate how it eliminates or minimizes such threats and document any residual risk. The demonstration shall cover all potential threats that are identified , whether they arise from within the PrCB or from the activities of other persons ,bodies or organizations.</p> <p>b) Top management shall review any residual risk to determine if it is within the level of acceptable risk. When a relationship poses an unacceptable threat to impartiality, then</p>			



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	certification shall not be provided. c) The risk assessment process shall include identification of and consultation with appropriate interested parties to advice on matters affecting impartiality including openness and public perception.			
3.4.6	The PrCB shall not impart education and /or training for GCP professionals within the same legal entity.			
3.4.7	The PrCB shall have a process to eliminate or minimize risk to impartiality if training/education of GCP professionals is carried out in a related body which is linked to the PrCB by common ownership etc.			
3.4.8	The PrCB shall have a process to ensure that the examiners and invigilators are free of any conflict of interest with the applicant(s) by means of being a teacher or trainer in the recent past .A separation of 2 years is considered acceptable for the purpose.			
3.5 Confidentiality	The PrCB shall ensure confidentiality of information unless required by law , obtained in the course of its certification activities by having a suitable system .Information gathered would not be used for any commercial or other purposes other than that to support certification of candidates .			



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3.6 Security	The PrCB shall develop and document policies and procedures to ensure security throughout the assessment and certification process.			
3.7 Liability and Financing :				
3.7.1	The PrCB shall be able to demonstrate that it has evaluated the risks arising from its certification activities and that it has adequate arrangements (e.g., insurance or reserves) to cover liabilities arising from its operations in each of its fields of activities and the geographic areas in which it operates.			
3.7.2	The PrCB shall evaluate its finances and sources of income and demonstrate that initially, and on an ongoing basis , commercial ,financial or other pressures do not compromise its impartiality.			
4 TECHNICAL REQUIREMENTS				
4.1 Personnel				
4.1.1	The PrCB shall have, as part of its organization , personnel , either employed or on contract ,having sufficient competence for managing process of certification of GCP Professionals.			
4.1.2	The PrCB shall have defined processes for selecting ,training ,and formally authorizing examiners and for selecting technical experts ,if needed ,used in this activity.			
4.2 Competence				



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4.2.1	<p>The competence for the examiners and question paper setters used by the PrCB shall be :</p> <ul style="list-style-type: none"> 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 (examiners or trainers or question paper setters) to have overall collective competence for all 6 domains. 			
4.2.2	<p>Personal records : The PrCBs shall maintain up-to-date personal records ,as per requirements of the Scheme document of each of its personnel involved in its certification activities.</p>			
4.3 Certification Process :				
4.3.1	<p>The PrCB shall manage the process of certifying GCP professionals as per the documented ‘ Certification Process ‘ prescribed under the scheme.</p>			
4.3.2	<p>The PrCB shall maintain records to demonstrate that the certification process is effectively implemented.</p>			
4.3.3	<p>The PrCB shall ensure that the requirements of the scheme are met with at any point in time.</p>			
4.3.4	<p>The PrCB shall certify GCP professionals only under the scheme and shall use the logo of the Scheme in the certificates issued to the certified GCP Professionals following the</p>			



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	rules prescribed under the scheme .			
4.3.5	The PrCB shall have written agreement with the certified GCP professionals on the use of the certificate issued to them.			
4.3.6	The PrCB shall have a process to handle appeals and shall be publicly available by the candidates against any of its decisions.			
4.3.7	The PrCB shall have a process to handle complaints from the GCP Professionals and shall be publically available from the users of the services of the certified GCP or any other stakeholder.			
4.4 Certification agreement				
4.4	The PrCBs shall have a legally enforceable agreement for the provision of certification activities to GCP Professionals. Besides, the PrCBs shall ensure its certification agreement requires that the GCP Professionals comply at least , with the specific requirements in the Scheme document.			
4.5 Responsibility for decision On Certification				
4.5.1	The PrCB shall be responsible for, and shall not delegate its decisions relating to certification, including the granting ,maintaining ,recertifying ,expanding and reducing the scope of the certification, and suspending or withdrawing the certification and if required shall have an			



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	independent decision – maker for the purpose.			
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4.6 Publicly Available Information

4.6.1	The PrCB shall maintain a website for providing information about the Scheme and its certification activities under the Scheme.			
4.6.2	The PrCB shall maintain and make publicly available information describing its certification processes for granting , maintaining ,extending ,renewing ,reducing, suspending or withdrawing certification and about the certification activities and geographical areas in which it operates.			
4.6.3	The PrCB shall make publicly available information about applications registered and certifications granted, suspended or withdrawn			
4.6.4	The PrCB shall make publicly available its processes for handling appeals and complaints.			

Annex 1 : CERTIFICATION PROCESS

Clause	Description	QM/Procedure no/Document no/Format no with clause no .,where a particular requirement is addressed (CB to provide details)	Compliance Y/N	At review comments



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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 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.			
2.1.3	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.			
2.1.4	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.			
2.1.5	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 .			
2.1.6	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.			
2.1.7	Applications from applicants who have misused the earlier certification			



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	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.			
2.1.8	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 CI 3.1.7 and 3.1.8			
2.1.10	The PrCB shall reject or close all applications under the following conditions <ul style="list-style-type: none"> a) If deficiencies observed in the application are not completed within one month ; b) If the applicant does not take the evaluation 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 Evaluation Process

2.2	The criteria for evaluation shall be as per the requirements listed in the Minimum Standard of Competency in the specific domain for which the GCP Professional undertakes the evaluation. The evaluation to be either online or face to face.			
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2.3 Assessment Method



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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 evaluation.			
2.3.3	The overall pass percentage for the successful candidates shall be 70 %			
2.3.4	The evaluation method to be based on ISO 17024			
2.4 Evaluation Team				
2.4	There shall be a minimum of 2 Evaluators .			
2.5 Examiner Competence				
2.5.1	1. The evaluators 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 (evaluators or trainers or question paper setters) to have overall collective competence for all 6 domains			
2.5.2	The evaluators shall record their results on the structured evaluation sheet for each candidate.			
2.6 Evaluation Process				



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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 evaluations as and when the number of candidates is optimum as a minimum. The PrCB at its discretion may evaluate 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 evaluations, including those appearing for a re-assessment and the means of evaluation at least 15 days before the evaluation. The PrCB shall make publicly available through its website the dates for the evaluation and the names of the candidates.			
2.6.4	The names of the candidates shall be communicated well in advance to the evaluators 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 examination 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 examination or reimburse the applicable application fee.			
2.6.6	The names of the candidates shall be communicated well in advance to the examination centre (if any) where the examination is planned to be carried for identification of conflict of interest			



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	.Any conflicts identified concerning the candidates shall be suitably eliminate ,minimized or managed by the PrCB .			
2.6.7	The PrCB shall inform the candidates of the name of the evaluation 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 evaluation, the PrCB shall provide them with the option for another evaluation or reimburse the applicable application fee.			
2.6.8	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.			
2.6.9	The PrCB shall ensure that the assessment and certification process is such that they are fair , valid and reliable across test 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 evaluation(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;			



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	<p>b) Availability of necessary documentation as proof of the means of evaluation chosen to assess the candidate;</p> <p>c) Any other requirements prescribed by the Scheme owners.</p> <p>The candidate should obtain at least 70% to be awarded certificate.</p>			
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 evaluating 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 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 Professionals.			



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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 Owners to inform the approved PrCB's of the transitions, the transition policy and the time for completing the process of transition.			
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3. CERTIFICATE

3.1	<p>The PrCB shall provide a certification document to the certified GCP professional. The certificates shall contain, as a minimum, the following information:</p> <ol style="list-style-type: none"> The name of the certified person ; A unique identification; The name of the certification body; A reference to the certification scheme , standard or other relevant documents ,including issue date ,if relevant ; The scope of the certification including ,if applicable ,validity conditions and limitations ; The effective date of certification and date of expiry. 			
3.2	<p>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.</p> <p>The formal certification documentation shall include the signature of the individual(s) of the PrCB assigned such responsibility where permitted by law, other</p>			



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	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 examination as in initial certification for all certified professionals.			
5.3	The PrCB shall send the renewal notice to the certified GCP professional at least 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			



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	compliance to certification criteria during the entire certification cycle ,before a decision on the renewal of the certificate .			
5.6	<p>The performance of the certified GCP Professional shall be reviewed based on the surveillance assessment :</p> <ul style="list-style-type: none"> 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 professionals.			
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 professionals			



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	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 evaluation 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 of the certificate .			



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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			
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	<p>provisions of this certification scheme like claiming or displaying the scope of certification other than that granted ,or any fraudulent behavior is established .</p> <p>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;</p> <p>c) Any administrative requirement like payment of a fee or timely provision of information</p>			
8.2	PrCB shall cancel the certificate at the request of 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 issue 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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Name of PrCB's representative		Date :
Name(s) of assessor(s) :		
1.		Date :
2.		Date :