GMPC Certificate Audit Procedure
GMPC 认证审核程序

1. Purpose 目的

• This instruction is to ensure that the requirements for ESTS GMPC Certification (for ISO22716 standard and GMPC (US) standard) are clearly defined, documented and understood. Any difference in understanding is resolved. It is also to ensure that the activities leading up to are carried out in a controlled manner.
本指南旨在确保 ESTS 针对 ISO22716 标准和 GMPC (US) 标准的 GMPC 认证要求得到明确界定、记录和理解，消除理解上的差异。同时，确保相关认证活动以受控的方式开展。

2. Scope 范围

• This instruction applies to all GMPC Certification audits including audits against ISO22716 standard and GMPC (US) standard.
本指南适用于所有 GMPC 认证审核，包括针对 ISO22716 标准和 GMPC (US) 标准的审核。

3. Reference 参考

• Not applicable. 不适用。

4. Responsibility 职责

• It is the responsibility of the GMPC Program Manager to monitor all phases of audit process and ensure the audit is successfully completed. Auditor conducts the audit according to the audit plan.
GMPC 项目经理的职责是监督审核过程的所有阶段，并确保审核成功完成。审核员根据审核计划开展审核工作。

5. Procedure 程序

5.1 Prior to the audit, the auditors shall
在审核前，审核员应：

• Familiarize themselves with the Applicant and information of the facility to be audited
熟悉申请方及其待审核场地（工厂）的相关信息；

• Perform documentation review (refer to below details)
进行文件评审（参考以下详细内容）；

• Prepare an audit plan in line with the classification of the product, roles and responsibilities of the audit team and accompanying persons such as observers or translators shall be identified
根据产品分类、审核团队成员的角色和职责，以及陪同人员（如观察员或翻译人员）的安排，制定审核计划；

• Send the audit plan to the Applicant
将审核计划发送给申请方；

• Obtain travel and accommodation arrangement from Customer Service Personnel (hereafter refer to CS)
从客户服务人员（以下简称 CS）获取差旅和住宿安排信息；

• Obtain Job number from CS
从 CS 获取工作编号；

• Prepare an audit folder including GMP Audit File Checking Form, Checklist, Gift and Gratuities

Policy, Meeting Attendance Sheet for opening/closing meeting and other required materials
准备审核文件夹，包括 GMP 审核文件检查表、检查清单、礼品和馈赠政策、首次/末次会议签到表以及其他所需材料；

- Review the applicable Checklists including, as relevant, any product safety or legal requirements
  检查适用的检查清单，包括任何适用的产品安全或法律要求；
- Ensure technical expert is accompanied by an auditor if technical expert need to be used.
  如需技术专家，确保技术专家由审核员陪同。

5.2 Pre-audit 预审核

5.2.1 If requested, a pre-audit would be undertaken to establish the readiness of the Applicant in meeting the applied scope.
如有要求，将进行预审核，以确认申请方符合所申请的认证范围要求的准备情况。

5.2.2 The CS contacts the Applicant to arrange the date of the visit and transportation as well as accommodation.
CS 与申请方联系，安排审核到访日期以及交通和住宿事宜。

5.2.3 At the opening meeting, the auditor shall:
在首次会议上，审核员应：

- Verify the scope and the standard to be applied
  核实审核范围及适用的标准；
- State that this is a pre-audit, the purpose of which is to establish that a system is in place and that there will be no decision regarding certification as a result of this visit
  说明这是一次预审核，其目的是确定申请方是否已建立相关体系，并说明此次预审核不会作出任何认证决定；
- Explain the reporting method and the different grades of non-conformance
  解释报告方法以及不符合项的不同等级；
- Request a guide who is able to assist in directing the auditor to the relevant personnel and reminding the auditor for any safety issues in facility
  要求申请方安排一名向导协助审核员接触相关人员，并提醒审核员审核场地的安全问题；
- Invite any questions
  邀请提问；
- Record details, including the participants of the opening meeting
  记录会议详情，包括首次会议的参会人员信息。

5.2.4 During the plant tour, the auditor shall:
在工厂参观过程中，审核员应：

- Use the audit checklist
  使用审核检查清单；
- Record any finding
  记录任何发现的问题。

5.2.5 Documentation review:
文件评审：

- Review the quality manual and the associated documents with regard to the applied scope
  评审与认证申请范围相关的质量手册及相关文件；
- Note the samples reviewed and identify any non-conformances that may exist
  记录评审的样本文件，并识别可能存在的不符合项。

5.2.6 Report writing:
报告编写：

• Non-conformance, if any, would be raised during pre-audit. A pre-audit report would be issued five working days after the audit.
如果存在不符合项，将在预审核中提出。预审核报告将在审核结束后的五个工作日内发出；

• The auditor shall not give any indication of pass or fail but may indicate in the report what the potential level of the non-conformities would be if the same findings are found during initial audit.
审核员不应给出通过或不通过的任何暗示，但可以在报告中指出，如果在初次审核中发现相同问题，会对应哪个潜在的不符合项等级。

5.3 Initial audit 初次审核

5.3.1 Documentation review 文件评审

• The auditor shall review the documentation of Applicant to ensure compliance with the applicable standard and the scope.
审核员应审核申请方的文件，以确保其符合适用标准和认证范围的要求。

• Documentation review could be conducted on-site or off-site.
文件评审可以在现场或非现场进行。

• If documentation was carried out off-site, documentation review report should be submitted, it is the responsibility of the facility to make sure all the findings are closed.
如果文件评审是非现场进行的，应提交文件评审报告。被审核方有责任确保所有发现的问题均已关闭。

• If pre-audit is conducted, documentation review shall already be done. It is not necessary to conduct a separate documentation review during initial audit.
如果进行了预审核，则应已完成文件评审。在初次审核期间，无需单独进行文件评审。

5.3.2 Upon arrival, the auditor shall:
抵达现场后，审核员应：

• Explain our company policy in anti-bribery as per the latest version of “Integrity Policy” and provide the Gift and Gratuities Policy to the company representative for signing.
根据最新版本的“廉政政策”，向被审核方解释公司的反贿赂政策，并让其公司代表签署礼品和馈赠政策。

• Ask the facility to prepare the Auditing-2017-004-V0X-Certificate Information Confirmation Form-ISO22716 & GMPC US for making certificates.
让申请方准备“Auditing-2017-004-V0X-Certificate Information Confirmation Form-ISO22716 & GMPC US”（证书信息确认表），用于证书制作。

5.3.3 At the opening meeting the auditor shall:
在首次会议上，审核员应：

• Record the participants of the opening meeting.
记录参会人员。

• Thanks for selecting ESTS Certification service.
感谢申请方选择 ESTS 的认证服务。

• Introduction of the audit team members to the Applicant’s representatives.
向申请方代表介绍审核团队成员。

• Verify the scope and standard to be applied and read out for the agreement of the Applicant.
核实申请的认证范围和适用标准，并在会上说明，请申请方确认。

• State that this is an audit, the purpose of which is to establish that an effective system is in place and complies with the requirements.
说明这是一次审核，目的是确认申请方是否建立了有效的管理体系并符合要求。

• Confirm that auditees will be available as per the plan.
确认受审核方人员是否按计划安排到位。

• Establish that everyone is aware that the audit is taking place.
确保所有相关人员知晓审核正在进行。

• Explain audit will be based on sampling.
解释审核将基于抽样进行。

• Explain the reporting method and the different grades of non-conformance and the result of different grades of non-conformances.
解释报告方法、不同等级的不符合项及其相应结果。

• Request a guide who is able to assist in directing each auditor to the relevant personnel and look after the safety of the evaluator.
要求安排一名向导，协助审核员接触相关人员并负责审核员的安全。

• Emphasize confidentiality.
强调保密性。

• Invite any questions.
邀请提问。

5.3.4 During the audit, the auditor shall:
在审核过程中，审核员应：

• Use the audit checklist
使用审核检查清单；

• Record any finding
记录任何发现的问题；

• Where critical non-conformity is found, the auditor must inform the Applicant's representative of it. The audit may be terminated or switched to pre-audit with agreement of the Applicant.
如果发现关键不符合项，审核员必须通知申请方代表。经申请方同意，审核可能会终止或转为预审核。

5.3.5 Audit team meeting before closing meeting
末次会议前的审核团队会议

• After on-site assessment, all the audit team members shall sit together and review/discuss all the recorded findings.
现场评估结束后，所有审核团队成员应共同回顾和讨论所有记录的发现。

• The audit team members shall determine which findings shall be reported during the closing meeting and also the classification.
审核团队成员应确定哪些发现将在末次会议上报告，并确定其分类。

• The audit team shall ensure that the reported findings shall be documented in a clear, concise manner and are supported by objective evidence.
审核团队应确保报告的发现记录清晰、简洁，并以客观证据为依据。

• The audit team shall confirm the arrangement for future audits, such as scope, audit duration, frequency of surveillance, audit team competence.
审核团队应确认后续审核的安排，例如范围、审核时长、监督审核频次及审核团队能力。

5.3.6 Write Corrective Action Plan Report (CAPR): The Lead Auditor shall record all findings on the CAPR. Two copies shall be prepared, one is for organization, and the other one will be kept as part of the audit report.
编写纠正措施计划报告（CAPR）：主审核员应在 CAPR 中记录所有发现，一式两份，一份交给申请方，另一份作为审核报告的一部分进行留存。
5.3.7 Different Grades of Non-conformance (NC) 不符合项的等级划分
5.3.7.1 Critical 关键不符合项
There is a critical failure to comply with a safety or legal issue.
存在与安全或法律问题相关的严重不符合情况。
5.3.7.2 Major 重大不符合项
a) There is a substantial failure to meet any requirement of the standard and/or
严重不符合标准的任何要求；且/或
b) A situation which, on the basis of available objective evidence, raises significant doubt as to the conformity of the product being supplied and/or
根据现有客观证据，对所供应产品的符合性存在重大疑问；且/或
c) System breakdown.
管理体系失效。
5.3.7.3 Minor 轻微不符合项
a) Where absolute compliance to any requirement has not been met, but on the basis of objective evidence the conformity of the product is not in doubt.
未完全符合任何要求，但根据客观证据，产品的符合性不存在疑问。
b) Isolated incident.
独立事件。
5.3.8 Closing meeting 末次会议
• Record the participants of the closing meeting.
记录参会人员。
• Confirm the scope and standard applied.
确认审核范围和适用标准。
• State that this was an audit, the purpose of which was to establish that an effective system was in place and that the audit was carried out by sample and cannot therefore exclude the presence of further non conformances.
说明这是一次审核，目的是确定申请方是否建立了有效的管理体系，审核是基于抽样进行的，因此不能排除存在其他不符合项的可能性。
• Explain the different grades of non-conformance.
解释不符合项的等级划分。
• Read out the non-conformances identified during the evaluation including their grade and obtain signatures to indicate acceptance.
提出在审核过程中发现的不符合项，包括其等级，并请申请方签字确认。
• Where appropriate, notify the Applicant's representative that the follow-up visit or re-audit should be conducted.
如适用，通知申请方代表需要进行后续访问或重新审核。
• Agree with the Applicant when they can submit the proposed corrective actions of the findings raised by the audit team for review, if applicable. Corrective actions will be verified for effectiveness at the next visit.

如适用，与申请方协商，确定其何时可以提交针对审核团队提出问题的纠正措施以供审核，纠正措施的有效性将在下次访问时进行验证。

• State the on-site audit result such as recommendation of certification but emphasize that the final decision will be made following the next technical review by report reviewer.
说明现场审核结果，例如认证建议，但强调最终决定将在报告评审员对报告进行技术评审后作出。

• Emphasize confidentiality again.
再次强调保密性。

• Invite any question.
邀请提问。

5.3.9 Reporting & Follow-Up 报告与跟进

5.3.9.1 Corrective Action Plan Report (CAPR) 纠正措施计划报告（CAPR）

CAPR is requested to be submitted if the Applicant fulfills all the following criteria in the audit result:
如果申请方在审核结果中满足以下所有条件，则应提交 CAPR：

• No critical NC
无关键不符合项；

• not more than three major NCs
重大不符合项不超过 3 项；

• not more than twenty-five minor NCs (For the definition of different grades of non-conformance, please refer to section 5.3.7)
轻微不符合项不超过 25 项（关于不同等级不符合项的定义，请参见 5.3.7）。

Lead auditor should review or assign an auditor to review submitted CAPR, and give comments on the CAPR. Upon receipt of the submitted documentation and/or records or photos, designated auditor shall review them to make sure that corrective actions are satisfactory. Auditors should mark in the CAPR if they accept the proposed action and evidence or not. For audit results fulfilling the certification criteria, it's mandatory for the auditor to verify the correction and corrective actions. Verification of NC's shall be completed within 6 months from on-site audit date, otherwise, another initial on-site audit shall be conducted.
主审核员应评审或指定审核员评审所提交的 CAPR，并对 CAPR 提出意见。收到提交的文件、记录或照片后，指定的审核员应评审这些材料，以确保纠正措施令人满意。审核员应在 CAPR 中标注是否接受所提出的措施和证据。对于符合认证标准的审核结果，审核员必须验证纠正情况与纠正措施。不符合项的验证应在现场审核日期后的 6 个月内完成，否则需重新进行初次现场审核。

5.3.9.2 Where the Applicant has been reaffirmed in compliance with the requirements of the relative standards, Lead Auditor or his assigned auditor shall finish the Certification Audit Report.
如果申请方被再次确认符合相关标准要求，主审核员或其指定的审核员应完成认证审核报告。

5.3.9.3 The Certification Audit Report shall include standard applied, scope of audit, audit summary and next audit date.
认证审核报告应包括适用标准、审核范围、审核总结以及下次审核日期。

5.3.9.4 Follow-up Audit 跟进审核

On-site follow-up audit shall be conducted if the Applicant fulfills the following criteria in the audit result:
如果申请方在审核结果中满足以下条件，则需进行现场跟进审核：

• No critical NC, major NCs more than 3 and/or minor NCs more than 25 OR

无关键不符合项，但重大不符合项超过 3 项和/或轻微不符合项超过 25 项；

• No critical NC, major NCs not more than 3 and minor NCs more than 25 OR
无关键不符合项，重大不符合项不超过 3 项，但轻微不符合项超过 25 项；

• Other situations that auditor considers as necessary for follow-up audit with the approval of GMPC Project Manager or his designated person.
审核员认为有必要进行跟进审核的其他情况，并经 GMPC 项目经理或其指定人员批准的。

When the follow-up audit is necessary, the process shall be as below:
当需要进行跟进审核时，流程如下：

• The auditor should send the complete Certification Audit Report of this initial audit together with GMP Audit File Checking Form, Audit Plan and CAPR to report reviewer. Corrective action plan is not necessary to be filled in the CAPR in this stage.
审核员应将本次初次审核的完整认证审核报告连同 GMP 审核文件检查表、审核计划和 CAPR 一起发送给报告评审员。在此阶段，CAPR 中无需填写纠正措施计划。

• After sending the Certification Audit Report to facility for scheduling follow-up audit, the auditor should ask the facility to fill in corrective action plan in the CAPR. The proposed corrective actions shall be reviewed and agreed by the auditor before the follow-up audit.
将认证审核报告发送给申请方以安排跟进审核后，审核员应要求申请方在 CAPR 中填写纠正措施计划。在跟进审核之前，审核员应评审并同意所提出的纠正措施。

• The auditor will determine the audit man-day according to the on-site audit situation and audit result. The scope of follow-up audit should be restricted to follow up the corrective actions of the NCs identified in the previous audit. Auditor should complete the old CAPR of initial audit by judging if the corrective actions are considered to be satisfactory and the related NCs should be closed. The closed CAPR should be scanned and kept.
审核员应根据现场审核情况和审核结果确定审核人天数。跟进审核的范围应仅限于跟进上一次审核中发现的不符合项的纠正措施。审核员应通过判断纠正措施是否令人满意来完成初次审核的旧 CAPR，并关闭相关不符合项。关闭的 CAPR 应扫描并留存。

• Auditor should fill in the GMP Audit File Checking Form, the closed CAPR, any new CAPR of follow-up audit (if applicable) and Certification Audit Report.
审核员应填写 GMP 审核文件检查表、关闭的 CAPR、跟进审核的新 CAPR（如适用）以及认证审核报告。

• If all NCs are closed, a recommendation of certification would be submitted. If any NCs from initial audit were not closed, a re-audit shall be arranged. Any abnormal/special situation should be reported to GMPC Program Manager for review and approval.
如果所有不符合项均已关闭，则提交认证建议。如果初次审核中的任何不符合项未关闭，则需安排重新审核。任何异常/特殊情况应报告给 GMPC 项目经理进行评审和批准。

5.3.9.5 Re-audit 重新审核

Re-audit shall be conducted if the Applicant fulfills the following criteria in the audit result:
如果申请方在审核结果中满足以下条件，则需进行重新审核：

• Critical non-conformance happened and/or
出现关键不符合项；且/或

• NCs were found not closed during the follow up audit.
在跟进审核中发现不符合项未关闭。

The procedure and scope for re-audit will be the same as full audit. The duration of a re-audit shall be the same as the previous full audit.

重新审核的程序和范围与全面审核相同。重新审核的时长应与之前的全面审核相同。

5.3.10 Certification Recommendation 认证建议

5.3.10.1 A recommendation of certification shall be submitted if all the corrective actions are satisfactory.

如果所有纠正措施均令人满意，则提交认证建议。

5.3.10.2 Report reviewer is responsible for reviewing each audit report to ensure it is accurate and complete in accordance with standard, guideline, work instructions and that correct format have been used prior to submission to client. The assigned report reviewer should not be the auditor involving directly in the audit.

报告评审员负责评审每一份审核报告，确保其准确、完整，符合标准、指南、工作指导书的要求，并在提交给客户之前使用正确的格式。指定的报告评审员不应是直接参与审核的审核员。

5.3.10.3 After passing report review, report reviewers or delegated person should pass the following to GMPC Program Manager or his/her delegate for certification recommendation:

审核报告通过评审后，报告评审员或其指定人员应将以下文件转交给 GMPC 项目经理或其指定人员进行认证建议：

- GMP Audit File Checking Form (including initial audit and follow-up if applicable)
  GMP 审核文件检查表（包括初次审核和跟进审核（如适用））；
- Audit plan (including initial audit and follow-up if applicable)
  审核计划（包括初次审核和跟进审核（如适用））；
- Certificate Information Confirmation Form-ISO22716 & GMPC US.
  ISO22716 & GMPC US 认证信息确认表；
- CAPR (including initial audit and follow-up if applicable)
  纠正措施计划报告（包括初次审核和跟进审核（如适用））；
- Certification Audit Report (including initial audit and follow-up if applicable)
  认证审核报告（包括初次审核和跟进审核（如适用））；
- Documentation Review Report (if applicable)
  文件评审报告（如适用）。

5.3.11 Certification Issuance 认证发放

5.3.11.1 The certificate number shall be generated and shared with the auditors through the booking information.

应生成证书编号并通过订单信息共享给审核员。

5.3.11.2 The numbering format of ISO22716 certification is assigned in the format of CN-CGMP-YYXXXX and the numbering format of GMPC US certification is assigned in the format of CN-GMPC-YYXXXX, where YY stands for the year that the facility was granted the certification, XXXX stands for the serial number of the certification audits from 0001 to 9999 received in the current year. For example:200306 is the 306th certification audits completed in 2020.

ISO22716 认证的编号格式为 CN-CGMP-YYXXXX，GMPC US 认证的编号格式为 CN-GMPC-YYXXXX，其中 YY 代表申请方获得认证的年份，XXXX 代表当年收到的认证审核序列号，范围为 0001 至 9999。例如：200306 表示 2020 年完成的第 306 次认证审核。

5.3.11.3 GMPC Program Manager or his/her delegate completes GMP Audit File Checking Form and saves the audit plan, Certificate Information Confirmation Form-ISO22716 & GMPC US, Certification Audit Report, and CAPR onto public server.

GMPC 项目经理或其指定人员应完成 GMP 审核文件检查表，并将审核计划、ISO22716 & GMPC US 认证信息确认表、认证审核报告以及 CAPR 保存至公共服务器。

5.3.11.4 Program Manager shall provide relevant certification recommendation to the CS staff for

certificate making. All certificates are valid for 3 years.
项目经理应向 CS 人员提供相关的认证建议，以便制作证书。所有证书有效期为 3 年。
5.3.11.5 CS is responsible for printing out the certificate and mailing the certificate to certified facility. Softcopy of certificate together with the copy of the Certification Audit Report will also be sent to certified facility.
CS 负责打印证书，并将其邮寄至获证工厂。证书的电子版以及认证审核报告的副本也将发送至获证工厂。

5.4 Surveillance audit and renewal audit 监督审核和换证审核
At least once a year, surveillance audits shall be done except in recertification years. Proper planning should be made to enable renewal being completed before the certificate expiry date. The whole audit procedure for both surveillance audit and renewal audit will be the same as the one for an initial audit except for the document review. Complete requirements of the standard(s) covered by the certificates are assessed during each surveillance audit. Special attention should be paid to the following:
除换证年份外，监督审核每年至少进行一次。应合理安排计划，确保在证书到期前完成换证审核。监督审核和换证审核的整个审核程序与初次审核相同，但文件评审除外。在每次监督审核中，将评估证书涵盖的标准的全部要求。特别需要注意以下几点：

- First surveillance audit shall be arranged within 12 months from the certification decision date (i.e. issue date of the certificate granted after initial audit).
  首次监督审核应在认证决定日期（即初次审核后颁发证书的日期）起 12 个月内安排。
- Upon arrival, check if there is any change from last audit (e.g. personnel, location, scope). If the changes would affect the registration, the auditor shall revert to GMPC Program Manager or CS for advice.
  抵达审核现场后，检查自上次审核以来是否有任何变化（例如人员、地点、范围）。如果这些变化会影响认证注册，审核员应向 GMPC 项目经理或 CS 咨询建议。
- Ask the facility to provide the CAPR, and check on-site if all points raised in the previous audit were closed. Auditor shall fill in all the information required, take back the original and leave the copy to the facility.
  要求被审核方提供 CAPR，并在现场检查上次审核中提出的所有问题是否已关闭。审核员应填写所有所需信息，带走原件，并留下复印件给被审核方。
- When renewal audit, certification recommendation and decision are repeated in the same way as initial audit and a new certificate registration form was needed while it was not necessary in surveillance audit.
  换证审核时，认证建议和决定的流程与初次审核相同，需要填写新的证书注册表，而监督审核则不需要。
- Provided any critical or major nonconformity lead to re-audit or follow up audit during the surveillance audit, the audit cannot be switched to pre-audit and should be completed on-time and then a special follow-up could be arranged afterwards. Suspension should be considered when this case was encountered. For any case of suspension or withdrawal (if appropriate), the Suspension / Withdrawal Form shall be completed. The form is reviewed by the GMPC Program Manager or his/her delegate similar to certification recommendation.
  如果在监督审核中发现任何关键或重大不符合项导致需要重新审核或跟进审核，则审核不能转为预审核，而应按时完成，之后可以安排特别的跟进审核。在这种情况下，应考虑暂停认证。对于任何暂停或撤销（如适用）认证的情况，应填写暂停/撤销表。该表由 GMPC 项目经理或

其指定人员评审，类似于认证建议的流程。

- When all activities for renewal are completed before existing certification expiry date, the issue date of next certification would be the date of certification decision while the expiry date of next certification cycle is based on that of the existing certification. If not, validity of existing certification cannot be extended and this shall be informed to client for the possible consequences.

如果在现有认证到期前完成了所有换证活动，下一个认证的颁发日期将是认证决定的日期，而下一个认证周期的到期日期将基于现有认证的到期日期。如果未能在现有认证到期前完成换证，现有认证的有效性不能延长，应告知客户可能的后果。

- When all activities for renewal are done after the existing certification expiry date but within 6 months, certification could be restored. The effective date of next certification would be the date of certification decision while the expiry date of next certification cycle is based on that of the existing certification.

如果在现有认证到期后但不超过 6 个月内完成了所有换证活动，可以恢复认证。下一个认证的生效日期将是认证决定的日期，而下一个认证周期的到期日期将基于现有认证的到期日期。

5.5 Hard copy filing 纸质文件存档

All the related documentations and records should be kept in the public server for each audit, including but not limited to:

每次审核的所有相关文件和记录应保存在公共服务器中，包括但不限于：

- CAPR
  纠正措施计划报告（CAPR）
- Gift and Gratuities Policy Form
  礼品和馈赠政策表
- GMP Audit File Checking Form
  GMP 审核文件检查表

Retention period of all documentations and records is at least the current cycle plus one full certification cycle.

所有文件和记录的保存期限至少为当前认证周期加一个完整的认证周期。

Report reviewer shall check the package against the GMP Audit File Checking Form to see if all required materials are filed.

报告评审员应根据 GMP 审核文件检查表核对文件包，确保所有所需材料均已存档。

6. Remark: One man-day is counted as 8 hours excluding one hour lunch time. 0.125 man-day is counted as 1 man-hour.

备注：1 个人天按 8 小时计算，不包括 1 小时午餐时间。0.125 个人天按 1 工时计算。

6. Change Notification 变更通知

6.1 Notice of changes by ESTS

ESTS 所发的变更通知

If there is any new requirement of the Program Owner or Administration Organizations, as well as ESTS's own requirements, Operation Director shall determine if it is necessary to inform the client for the change. CS would inform the client for the changes (if necessary) such as

如果项目所有者或管理机构有新的要求，以及 ESTS 自身的任何要求，运营总监应确定是否需要通知客户变更情况。如需通知， CS 应向客户通报变更内容，包括：

- The description of the nature and extent of the changes

变更的性质和范围描述；
- The transition rules
  过渡规则；
- The effective date of the change
  变更的生效日期；
- The process for maintaining existing certifications
  维持现有认证的程序；
- The need for the signing of an amended Certification Contract.
  签署修订的认证合同的必要性。

6.2 Notice of change by clients 客户变更通知

As per the terms of the Certification Contract established between ESTS and the certified client, ESTS shall be kept informed in a timely manner of all changes that may affect the capability of the client's management system to continue to fulfil the requirements of the audit criteria or other normative document(s) used for certification. The client needs to submit a formal application for the change with Change Notification Form (CNF) to ESTS for further processing. The GMP Project Manager will review the change and determine the further action, such as

根据 ESTS 与获证客户之间订立的认证合同条款，ESTS 应被及时告知所有可能影响客户管理体系持续符合审核准则或其他用于认证的规范性文件要求的变更。客户需要通过提交变更通知表（CNF）向 ESTS 提交正式的变更申请，以便进一步处理。GMPC 项目经理将评审变更并确定后续行动，例如：

- On-site audit is needed (a new full audit or a limited audit), in case of the facility address change, scope / product change, etc.,
  需要进行现场审核（新的全面审核或有限审核），例如工厂地址变更、范围/产品变更等；
- A new certificate is needed,
  需要新的证书；
- A new Certification Contract is needed,
  需要新的认证合同；
- No change, or
  无需变更；或
- Other actions
  其他行动。

The related personnel should be informed of the change and action if necessary, for example the auditor should be informed of any new requirement when conducting the audit etc.

必要时，相关人员应被告知变更和行动，例如审核员在进行审核时应被告知任何新的要求等。

7. Forms and Documents 表格与文件

#	Form / Document No. 表格/文件编号	Form/ Document Name 表格/文件名
1	CERT-2020-049-V0X	GMP Audit File Checking Form GMP 审核文件检查表
2	CERT-2020-048-V0X	Corrective Action Plan Report for ISO22716 & GMPC ISO22716 & GMPC 纠正措施计划报告
3	CERT-2020-040-V0X	Audit Plan for ISO22716 & GMPC

		ISO22716 & GMPC 审核计划
4	CERT-2020-042-V0X	Cosmetic GMP (US) Audit Checklist 化妆品 GMP (US) 审核检查表
5	CERT-2020-043-V0X	GMP Documentation Review Report GMP 文件评审报告
6	CERT-2020-044-V0X	ISO22716&GMPC US Certification Audit Report ISO22716 & GMPC US 认证审核报告
7	CERT-2020-041-V0X	ISO22716 Audit Checklist ISO22716 审核检查表
8	CERT-2020-052-V0X	ISO22716 & GMPC Change Notification Form ISO22716 & GMPC 变更通知表
9	Auditing-2013-001-V0X	Meeting Attendance Sheet 会议签到表
10	Auditing-2013-007-V0X	Gift and Gratuities Policy 礼品和馈赠政策