Translation of Good Laboratory Practice Study Reports: Questions and Answers

Guidance for Industry

DRAFT GUIDANCE

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For questions regarding this draft document, contact (CDER) Office of Study Integrity and Surveillance at CDER-OSIS-GLP@fda.hhs.gov or 240-402-6002, (CBER) Office of Communication, Outreach and Development at 800-835-4709 or 240-402-8010, (CDRH) Office of Device Evaluation at 301-796-5550, (CVM) Office of New Animal Drug Evaluation at AskCVM@fda.hhs.gov, (CFSAN) Office of Center Director at CFSANBIMO@fda.hhs.gov, (CTP) Small Business Assistance at 1-877-287-1373, or Office of Regulatory Affairs (ORA) at ORAPolicyStaffs@fda.hhs.gov.

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Contains Nonbinding Recommendations

Draft — Not for Implementation

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Translation of GLP Study Reports: Questions and Answers Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance provides information to sponsors and nonclinical laboratories regarding the language translation of study reports for studies conducted in compliance with good laboratory practice (GLP) regulations (21 CFR part 58).[2,3] GLP studies include, but are not limited to nonclinical toxicology studies, safety pharmacology studies, and device safety studies received by different FDA Centers. When study reports of GLP studies are translated from their original language into English, adequate documentation is critical to ensure accurate and complete study data are submitted to FDA. This question-and-answer document is intended to clarify FDA's recommendations concerning the translation of study reports from a non-English language into English for studies conducted in compliance with GLP regulations. We expect that the recommendations for translating GLP study reports described in this guidance will increase our stakeholders' understanding of the documentation needed to ensure study reports translated from the original language into English are clear, accurate, complete, and truthful.

This draft guidance does not address the reliable translation of other study reports submitted to support a marketing authorization, including studies that are not conducted in compliance with GLP regulations, but the concepts described in the guidance may be informative for the translation of study reports from those studies that are intended for submission to FDA to support a marketing authorization. FDA may issue guidance regarding questions & answers for the

[1] This guidance has been prepared by the Office of Study Integrity and Surveillance in the Center for Drug Evaluation and Research in cooperation with the Center for Biologics Evaluation and Research, Center for Devices and Radiological Health, Center for Veterinary Medicine, Center for Food Safety and Applied Nutrition, Center for Tobacco Products, and Office of Regulatory Affairs at the Food and Drug Administration.

[2] An accurate and complete translation is a regulatory requirement if any part of the application submitted to FDA is in a foreign language (21 CFR 312.23 (c) and 21 CFR 514.1(a)).

[3] We support the principles of the "3Rs," to reduce, refine, and replace animal use in testing when feasible. We encourage sponsors to consult with us if it they wish to use a non-animal testing method they believe is suitable, adequate, validated, and feasible. We will consider if such an alternative method could be assessed for equivalency to an animal test method.

translation of other study reports submitted to FDA in support of marketing authorizations as appropriate.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

Studies conducted in compliance with GLP regulations (21 CFR part 58) are sometimes conducted by testing facilities located outside of the United States. In instances where the GLP study report is generated in a non-English language, the study report is often translated into English for submission to FDA. When translating a study report into English from a study conducted in compliance with GLP regulations, the translation should be clear, accurate, complete, truthful, and follow written processes and procedures. The sponsor should ensure that the translated report is an accurate representation of the original GLP study report.

III. QUESTIONS AND ANSWERS

Q1: What is a translated GLP study report?

A1: For purposes of this guidance, a translated GLP study report is an English language study report rendered from a GLP study that was conducted in a non-English speaking country/region where the original study report was generated in the testing facility's native language. The translated GLP study report is not an amendment to the study report, but rather the original study report in its entirety translated from the original language into English. The translated GLP study report should be the clear, accurate, complete, truthful representation of the original report text and tables with captions, including but not limited to, the study summary, materials and methods, results, discussion, and conclusion sections and should use the same format, tables, appendixes, and amendments as the original report. It is understandable that different words/sentences may be used to translate a report into English; however, the content should be an accurate and complete representation of the original study report.

Q2: What qualifications should the translator(s) hold?

A2: English translation should be performed by a translator or translators with education, training, experience, or combination thereof, in English and in the original language being translated. The translator(s) should be familiar with translating medical and scientific documents into English. The requirements and qualifications of the translator(s) should be clearly described in written processes and procedures (see Q4 below).

Q3: Should a translation statement be included in the translated GLP study report?

A3: Yes, the translator(s) should generate a signed and dated translation statement or certificate, separate from the translated GLP study report, which should be placed immediately in front of the translated study report cover page.

The translation statement or certificate should include the following:

- Name of the person(s) that performed the translation and their affiliation
- Translator(s) qualifications
- Date(s) the translation was performed
- Statement signed by the translator(s) attesting that the translated document is a clear, truthful, accurate, and complete representation of the original GLP study report.

Q4: Should written procedures be in place for the translation of GLP study reports?

A4: Yes, the sponsor or testing facility, as applicable, should have written procedures in place for GLP study report translation for studies conducted in compliance with GLP regulations. These written procedures should include requirements for translator qualifications and requirements for the translation, such as documentation, verification of translation accuracy, and completeness checks. Current written procedures should be available to, and followed by, the translator.

Q5: Should the translated final study report be retained by the sponsor or testing facility?

A5: The translated GLP study report should be retained along with the original study report by the sponsor or testing facility, as applicable. Communications related to the translation should be documented and retained by the sponsor or testing facility who was responsible for the translation.

Q6: Should the final study report amendments be translated separately from the original final study report?

A6: Yes, each amendment to the original final study report should be translated as a separate document. The final study report and all versions of final study report amendments should be kept as separate individual documents.

Q7: Should GLP study report tables and appendixes be translated?

A7: Yes, the entire GLP study report, inclusive of all tables, appendixes, contributing scientist reports, and protocol and any amendments, should be accurately and completely translated into English. Data tables should include the same tabular data, with the same format and translated text, including but not limited to table headers, units, tissue names, captions, and footnotes, as in the original report.

Q8: Should the translated GLP study report be reviewed for completeness?

A8: Yes, the complete translated GLP study report should be reviewed by a second person (e.g., testing facility staff, sponsor staff), apart from the translator, to check the report format, tabular content, and figures (graphical representation of data) for completeness. This second person does not need to be fluent in scientific and medical terminology or English. The review for completeness should be performed on the final version of the translated study report. If issues are identified during the completeness check, the translated study report should be returned to the translator for review and revision, as appropriate. If changes are made to the translated report in response to the review, another completeness check should be performed. The process should be documented and retained with the study records and report.

Q9: Should the translated GLP study report include signatures?

A9: The translated GLP study report should not be signed. The translated GLP study report should include, at a minimum, the typed names of the study director, quality assurance auditor, and testing facility management and the signature dates from the original final study report.

The study report translator should sign and date the translation statement, which is separate from the translated study report, as outlined in A3 above.