Language Services

SAMPLE · FICTITIOUS PROJECT

Sample project file: audit-ready regulatory translation

The six records an auditor can ask for, shown for one illustrative medical device project. Every regulated project at Translation Excellence produces this file.

> **For illustration only.** The client, device, people, and dates are fictitious. Linguists are identified by ID, as in a real file shared for a supplier audit. Your project file follows this structure; its format is agreed at the start of your program.

1 Project specification

Proves: the scope, markets, regulators, and required steps were agreed in writing before work began.

Project no.	TE-SAMPLE-0001
Client	Example Medical Co. (fictitious)
Source document	Instructions for Use, infusion pump model 400, document IFU-0427, **Revision C**, English, 38 pages
Target languages	German (de-DE), French (fr-FR)
Market and rule	European Union. Information supplied with the device in the official language(s) set by each Member State (EU MDR Article 10(11))
Required steps	Translation · independent revision (ISO 17100) · client in-country review · final QA · certificate of accuracy. Back-translation: not required. Machine translation: not approved for this project.
Reference files	Client glossary v3; translation memory from IFU-0427 Rev. B; client style guide
Agreed by	Client regulatory affairs lead and TE project manager, specification signed before work began

2 Approved glossary (excerpt)

Proves: terminology was set and approved by your reviewers, not chosen by each translator.

English source term	German (de-DE)	French (fr-FR)	Status
Instructions for Use	Gebrauchsanweisung	Notice d’utilisation	**Approved**
infusion pump	Infusionspumpe	pompe à perfusion	**Approved**
occlusion alarm	Okklusionsalarm	alarme d’occlusion	**Approved**
flow rate	Förderrate	débit	**Approved**
single use only	Nur zum einmaligen Gebrauch	À usage unique	**Approved**

Approved by the client’s in-country reviewers before translation began. Changes during the project are logged and re-approved.

3 Linguist qualification record

Proves: the translator and reviser met ISO 17100 qualification requirements for the subject.

Role	Linguist ID	Works into	ISO 17100 qualification basis	Subject competence
Translator	DE-T-0142	German (native)	Degree in translation	Medical devices: instructions for use, labeling
Reviser	DE-R-0087	German (native)	Degree in another field plus documented professional translation experience	Biomedical engineering; medical device documentation
Translator	FR-T-0219	French (native)	Degree in translation	Medical devices and pharmaceutical labeling
Reviser	FR-R-0064	French (native)	Documented professional translation experience	Clinical and medical device documentation

Supporting evidence (degrees, experience, references) is kept on file and shown to auditors on request. Linguists sign confidentiality agreements before receiving client content.

4 Revision record

Proves: a second qualified linguist compared the translation against the source.

Language	Reviser	Scope	Terminology	Accuracy	Style	Status
German	DE-R-0087	Full text compared with source, all 38 pages	2 corrected	1 corrected	3 corrected	**All resolved**
French	FR-R-0064	Full text compared with source, all 38 pages	1 corrected	0	4 corrected	**All resolved**

Each correction is recorded in the bilingual file with the original wording, the change, and the reason, so the translator’s and reviser’s work can be told apart.

5 Review log

Proves: your reviewer’s comments were recorded and resolved, and agreed changes were made.

#	Language	Location	Reviewer comment	Decision
1	German	Section 4.2	Use the client’s preferred term for “bolus dose”	**Accepted; glossary updated and re-approved**
2	French	Section 7.1	Match the warning wording used on the device label	**Accepted**
3	French	Section 2.3	Suggested a shorter phrasing	Not applied: it dropped a qualifier present in the source. Reason sent to the reviewer, who agreed.

6 QA checklist and certificate of accuracy

Proves: final checks were completed before release, and the translation is attested as complete and accurate.

- ✓ Translated from source Revision C (matches the specification)
- ✓ All text translated, including tables, figures, and warnings
- ✓ Numbers, units, and tolerances match the source
- ✓ Approved glossary terms applied throughout
- ✓ Revision completed and all corrections resolved
- ✓ Client review comments closed
- ✓ Layout, symbols, and cross-references checked
- ✓ Files delivered by secure transfer

Certificate of accuracy (sample)

Translation Excellence, Inc. certifies that the attached German and French translations of document IFU-0427, Revision C, are complete and accurate translations of the English source, produced by qualified linguists and revised by a second qualified linguist under our ISO 17100 certified process.

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Project manager (signature) Date