Quality assurance in medical translation

Iain Matheson, Barbara Kollmer[1]
[1] Dora Wirth Languages Ltd, London, UK

doi: 10.56012/qjes2321

Correspondence to:
Barbara Kollmer
barbara@dwlanguages.com

Abstract

Quality assurance (QA) is an important part of the translation process; its ultimate aim is to ensure that a high-quality translation is produced. Traditionally, QA was very much a task undertaken by humans, but recent years have seen the advent of a variety of automated tools to facilitate the process. This article focuses on QA in relation to medical translation in the language service provider (LSP) setting and provides some examples from human and automated QA. We show that there is a place for both approaches to QA at the current time.

Quality assurance in medical translation

Quality assurance (QA) is an important part of the translation process and aims to ensure a high-quality product that meets the requirements of the party that requested the translation. This article focuses on the processes involving QA in relation to medical translation in the language service provider (LSP) setting and on aspects to consider when performing human QA and using tools for automated QA.

Why QA matters

Medical translations may be required for a variety of reasons: drug registration, adverse event reporting, documentation for patients in clinical trials, instructions for use for medical devices, and scientific research, among others. It is essential that the information is correct to ensure patient safety. Incorrect dosage instructions, for example, may lead to medication errors and poorly translated instructions for use may lead to incorrect device use. Translations of scientific research needs to ensure that the information has been correctly imparted. These examples indicate the need for a rigorous QA process to pick up any errors to avoid such issues, which could result in cost and reputation penalties for the LSP and, indeed, for the client, or compromise patient safety.

The International Standard ISO 17100 "Translation services – requirements for translation services" sets out the specifications to be followed to provide quality translations. Where ISO certification is not present, it is likely that the LSP will very often already be fulfilling many of the specifications and processes described in the standard.

To achieve a quality medical translation, suitably experienced translators and the most appropriate linguist are essential. While a medical qualification is not by any means a prerequisite, for some texts, such as discharge letters, medical reports, or descriptions of surgical procedures, which may be heavily jargon-laden or use abbreviations known only to the initiated, having a medically trained translator can be helpful. Where this is not possible, a third review step by an individual with subject-matter expertise may suffice.

Likewise, for medical devices texts, it may be advantageous to use a translator with a

technical or engineering background. Translations of product information (summaries of product information/labelling/package leaflets) intended for submission to the European Medicines Agency (EMA) require adherence to the quality review of documents (QRD) templates, the associated annexes, and reference documents (e.g., abbreviations, stylistic matters). In addition, Medical Dictionary for Regulatory Activities (MedDRA) terms for adverse reactions/undesirable effects and standard terms compiled by the European Directorate for the Quality of Medicines & HealthCare (EDQM) for dosage forms, routes, and methods of administration, must be followed for the languages in which they are available. Failure to comply with this reference material could result in delayed or denied marketing authorisation for a medicinal product if the translation is not of sufficient quality. These reference documents ensure translation consistency and quality. It is very important that dosage instructions and methods of administration are translated accurately to avoid errors that could impact patient safety. Similarly, for texts intended for study participants, it is important that the correct register is used so that the medical terms are understandable to patients or laypeople.

When the translation is complete, it then needs to be revised by a second translator, with a word-for-word check of the target text against the source text, a process also referred to as bilingual editing. The reviser therefore needs to be equally well qualified or as experienced as the translator, if not more so, depending on the approach used by the LSP. For example, some LSPs may use junior translators who are less experienced but will ensure the revision is performed by a well-established senior medical translator. For language combinations where there are few native speakers with the adequate expertise, a document may need to be translated and revised by non-native speakers of the target language. Typically, this could be the case for translations from the Baltic languages or Hungarian into English. In this case, a review by an English native speaker with subject-matter expertise is strongly recommended, to check the terminology for correctness, and polish the English so that the translation has the requisite quality.

Despite the translator's and reviser's best efforts, the translation may still contain errors or omissions and thus final QA steps are necessary to check for various aspects.

These can range from more formal checks, such as running a final spell check and ensuring that the formatting is consistent with the source, to more in-depth checks of the translation against the source text, depending on the processes applied by the LSP and the nature of the document.

In the medical field, eliminating numerical errors is of particular importance in the context of dosages and administration frequency to avoid medication errors. Checks for adherence to mandatory terminology or common errors may also be included at this stage.

> For less experienced translators, seeing the revisions made to their translations can be a useful learning process.

A critical part of the QA process is also that any ambiguities or unclear text in the source language are resolved to the greatest possible extent, in particular where there is a potential impact on patient safety, and that remaining doubts are highlighted in the translation. This part may also necessitate further discussion with the linguists involved and/or the client.

With the priority being the delivery of a high-quality translation to clients, returning the final quality-controlled document to less experienced translators can be a useful learning process.

Typical things to look out for during "human" QA

It is not always possible or appropriate to use automated QA tools in the translation process. When performing "human" QA, it can be useful to consider common or potential problems. The examples given here are based on our long experience of the QA process.

1. Prefixed words with opposite meanings that are easily mixed up such as hypertension/hypotension, or hyperglycaemia/hypoglycaemia.
2. Some terms may be referred to on an alternating basis within the same text and in a similar context and end up being mixed up in the translation, such as "renal and hepatic" and "kidneys and liver".
3. Sometimes, because certain concepts often appear together in a medical text, the translator automatically enters the usual concept, whereas the source might be slightly different (such as "in liver or renal impairment" as opposed to the source "in liver or respiratory tract impairment").

4. Similar concepts and related terms that may appear within the same text may give rise to copy/paste errors or to accepting a suggestion from the memory when using a CAT tool, e.g., "critically ill adults with fever" in one place and then incorrectly used elsewhere, instead of "critically ill children with fever".
5. Similar sounding words may lead to the wrong one being used (e.g. "intravascular" instead of "intramuscular", which could have serious patient safety implications if not picked up, or "pivotal study" instead of "pilot study").
6. The word "not" may be inadvertently overlooked or even added by mistake, and may have safety implications in instructions about how to administer a medicinal product or the population in which it may or may not be used.
7. When checking lists, such as adverse reactions, it is useful to count through them as it is very easy to inadvertently omit one from long lists.
8. Seemingly "insignificant" words may be missed in long sentences, e.g., "at least" in the sentence "… is indicated for the treatment of patients who have progressed after *at least* two courses of chemotherapy for advanced disease".

Where automated QA tools can help and where they can't

The vast majority of translators and revisers work with computer-assisted translation (CAT) tools nowadays. Not all scenarios lend themselves to the use of CAT tools, but where this is feasible, a number of tools are available to automate some QA features. Needless to say, fully automated QA is not sufficient in a field where it is critical to render the meaning of the source text accurately. So what can QA tools do?

- Automated QA tools are a valuable and time-efficient asset to check the final translation output for consistency, i.e., whether the same string of text (or segment) has been translated in the same way throughout the document. Where term bases are available, the QA tool can also be utilised to check for adherence to any mandatory terminology. Similarly, QA checks against translation memories confirm whether consistency with previously translated text has been maintained.
- Automated checks for matching numbers in source and target are an important "safety belt" in a medical context, in particular where dosages are provided to patients. It should be remembered, however, that any automated checks are never 100% reliable. A German case report may be referring to a patient "im 28. Lebensjahr", (in the 28th year of life), which correctly translates as the patient being "27 years of age". An automated QA tool could incorrectly flag this up as a numerical error in the translation.
- Automated QA checks can correct other aspects such as punctuation, spaces, capital letters, and length of segments, and they can be customised further to check for more specific reglularly occurring problmes.

Needless to say, fully automated QA is not sufficient in a field where it is critical to render the meaning of the source text accurately.

Disclaimers

The opinions expressed in this article are the author's own and not necessarily shared by his employer or EMWA.

Disclosures and conflicts of interest

The authors declare no conflicts of interest.

Author information

Iain Matheson has an MB ChB from the University of Aberdeen (Faculty of Medicine), and also has a BA in Interpreting and Translating (German and Russian) from Heriot-Watt University. He has been working in medical translation and editing for more than 25 years, including 16 years in an LSP setting.

Barbara Kollmer has a state-qualification as a translator in English and French and has been involved in quality control at Dora Wirth Languages Ltd. for 28 years.