Web-Portal Solution for Supporting In-Country Reviews

Michael Oettli and Tasos Panagis

nlg GmbH
Regensburg, Germany
moettli@nlgworldwide.com

Abstract. As a leading language service provider to the Healthcare industry for many years, nlg GmbH has observed the needs and identified problems of Healthcare clients in regards to the mandatory and regulated in-country review of translated content.

In Europe, Directives such as the Medical Device Directive (MDD) 93/42/EEC describe the localization requirements for Instructions for Use as well as Safety and Warning information for Medical Devices. Each device must be accompanied by the information needed to use it safely and to identify the manufacturer, taking account of the training and knowledge of the potential users.

If documentation is translated into the required language of the importing country, the manufacturer should have procedures to ensure the accuracy of translated content in connection with the source language. This requirement is usually met through an in-country review process. It is a necessary quality assurance step before final product approval in a foreign country.

Keywords: Verification, In-Country Review, Localization Automation, Customized Technology, Health Care.

1 Current Problems and Challenges

An effective in-country review process involves a native speaker who reviews a translation by comparing the source and target language content word by word to ensure that product-related corporate terminology as well as country-specific terminology is correctly used.

Reviewers of medical device documentation should know the respective product very well through use of that product, and typically should be clinicians, product managers, application specialists or other people working in the company in different roles such as sales or marketing.
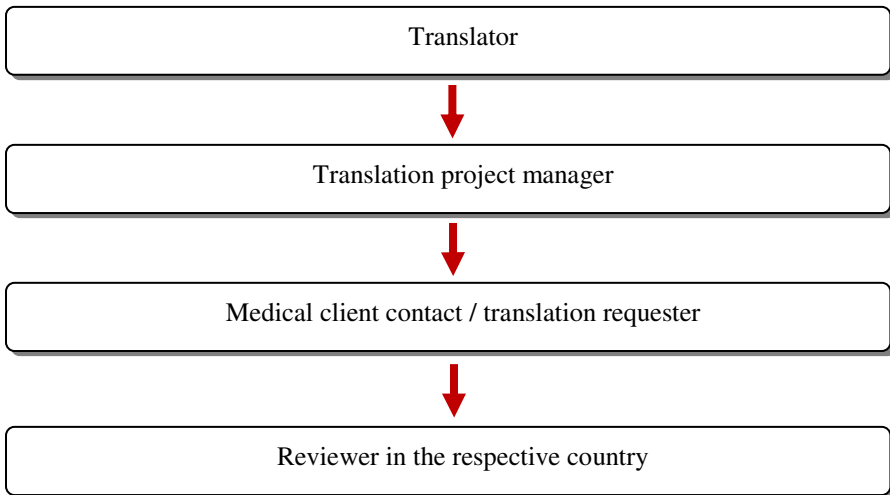
On the other hand, reviewers are not linguists and do not usually review translations for the same product line on a regular basis. This often results in a lack of consistency because the reviewer does not use approved terminology and is not aware of previously translated product versions.

In many cases the review process is very time-consuming and not always transparent to all parties involved in the process. Overview and control of the entire process are often totally missing.

In most cases the process is not standardized. The way in which corrections are communicated back by the reviewers often depends on the IT infrastructure available to them. Therefore the output format varies tremendously from client to client and even from reviewer to reviewer, which makes the job of a Language Service Provider difficult when it comes to incorporating these corrections. Reviewers provide feedback as:

- Scanned PDF files with handwritten comments
- MS word documents with tracked and/or untracked changes
- Excel lists with multiple columns (source sentence, translated target sentence, corrected target sentence etc.)
- Annotated PDF files with comments and corrections etc.

The incorporation of corrections may therefore be very difficult and extremely time-consuming. Usually the corrections and comments must be sent back to the respective translators to be checked for linguistic accuracy and consistency. Then the corrections need to be incorporated into the final translation files and the translation memory database must be updated. If the translator has questions or concerns about a correction, contact with the reviewer must be established following the predefined communication chain and process responsibilities, which often looks like this:

Translator

↓

Translation project manager

↓

Medical client contact / translation requester

↓

Reviewer in the respective country

2   New Approach: Web-Based Portal Solution

In order to address these problems and automate the in-country review process, nlg developed and has implemented the Next Level Review System in customized versions for various nlg Healthcare clients. A customized version of the system was recently delivered to Siemens Healthcare under the brand name SOVT (Siemens Online

Verification System). The efficiency gain in regards to the review process also led nlg to the rollout of the system for non-Healthcare companies, too.

The Next Level Review System is a web-based server-client solution, which can be integrated in the client's TMS[1] and CMS[2] environment. It provides connectivity of all parties involved in the review process, offering total control and a full overview of the review process and progress at all times.

Each process step is documented, the audit trail is clear and readily available and all relevant data reports can be generated quickly and easily directly from within the system. The Next Level Review System also includes a digital sign-off function which the reviewer uses after finalizing the review job to confirm the completeness and accuracy of the translated document. This sign-off functionality has a default mechanism which can be customized to each client's existing approval system and which supports a sign-off stamp and finalization forms. Most fields in these finalization forms are custom fields and can include any information relevant to the review process that has been stored in the system.

Reviewers can work either online or offline (with or without an Internet connection). They must be online to receive incoming projects/requests, but as soon as they are ready to start reviewing, Internet connectivity is not required. A sophisticated synchronization system allows multiple reviewers to work on a shared review project at the same time. It also updates the system regularly, providing real-time progress status of the review project to all involved parties. The reviewers don't have to be online all the time. They may continue work offline while traveling, at home, at their own convenience. As soon as they get back online, either to update or deliver a project, the system automatically detects the connection and synchronizes information. All conflicting changes from different reviewers are reported before they are submitted and reviewers can communicate via the system to agree on which changes to merge or discard.

The review system supports nlg bilingual file formats (mainly a combination of XLIFF and HTML5) and is supported by a variety of file parsers. Through these parsers, formatted source and target documents are displayed in a WYSIWYG mode. The reviewers incorporate their corrections directly into the target documents, which triggers automatic updates of the connected project translation memory database. By working in a WYSIWYG editor the end-user has the ability to view the close-to-final layout of the document, containing graphics, animations (when possible and supported), links and all other elements that can be included in a document.

The review system displays project-specific terminology which is automatically identified in the source and target content (if not modified), providing essential information to the reviewer on whether a term should or should not be used. It also allows the reviewer to consult the associated translation memory database and use search functionality to find previously translated content.

---

[1] TMS is a Translation Management System that supports the management of translation workflows and also contains a translation memory database that stores all translated sentences (source and target) to be reused at a later date.

[2] CMS is a Content Management System that is connected with an authoring environment (such as an XML editor) and which allows the author to reuse existing content from the CMS.
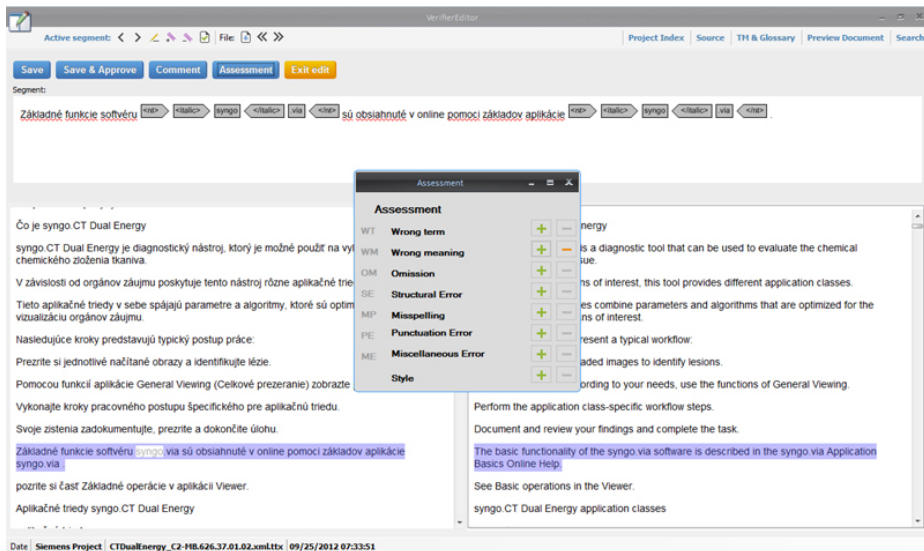
Fig. 1. Side-by-side view in the review editor

Connectivity to an advanced QA (Quality Assurance) engine allows the reviewer to get back specific reports on the linguistic quality of the content they revise. Spell checking, inconsistencies, term reports, etc. can be automatically generated.

A default QA engine is embedded in the system which takes care of structure, tagging and other potential file-related errors. This prevents the delivery of "broken" files and issues during any back process (imports back to systems, etc.).

Managers have direct access to various reports generated by the review system:

- Assessment report (based on SAE J2450 metrics)
- Modification report (documents all changes made to translations)
- QA report (displays errors/inconsistencies made by reviewers)
- Comment report (lists all comments made regarding terminology)

These reports are stored in the system and are accessible 24/7 for download even if a project has been finalized.

The Next Level Review System has significantly reduced the overall review cycle time. The coordination of the review process and the assignment of review projects to selected reviewers have become very easy and much more efficient. Control over the process and the availability of reviewers is given at any time.

Managers can schedule upcoming projects in advance and get acceptance or rejection from reviewers in time to reschedule. They can also monitor unavailability of reviewers due to various reasons, like vacation. This allows the proactive selection of resources for upcoming projects, making sure that work will be completed in a timely manner.

Managers also have the rights (and responsibility) to manage all user accounts and keep them up-to-date regarding contact information, language specific settings, etc.

They can also create/modify and activate/deactivate users that have been added by a network administrator.

Taking into consideration the need for security and requirements for safe data exchange, the Next Level Review System in its customized version is installed and operated within a Microsoft Windows Network Domain. All users that connect and use the system must be valid users of that domain.

Via a special administration panel, client-side network administrators can set up and configure the users who will have access to the system, making sure that unauthorized users will not have access. External users need to be able to connect to the system via VPN (provided by the client's network administrators) and be valid domain users.

The customized version of the review system can connect to a specified mail server. All communication, notifications, automated mails, etc. take place via this mail server, which means that all mail will be delivered without risk of being blocked by any protection mechanisms.

3   Development

In accordance with standard nlg procedure, development of the Next Level Review System was based on the principles of Agile software development[3], and more specifically the Scrum[4] practice. The goal is to quickly have working releases of the product, and also deliver in various stages and milestones with no need for end-users to wait for the full product.

Development work is split and assigned to various teams to ensure speed and efficiency.

The core team is the internal nlg GmbH software development team, which is responsible for the architecture, design, interface concepts, database schemas, technology that will be used (programming/scripting languages) and prototyping.

The client-side product owner may get involved in the prototyping stage, to provide valuable feedback.

Sprint planning, user story breakdown to development tasks and all documentation required for a Sprint is also managed by the core team.

This team currently consists of one Scrum master and 4 dedicated developers, one of which acts as a software architect.

As soon as the core team has prepared material that can be outsourced, qualified external software development teams undertake the task of executing the work according to defined criteria, specifications, priorities and deadlines.

The end client is actively involved in all stages (except the actual code writing). The client-side product owner is responsible for reviewing all requirements and design concepts, and needs to approve these before work continues.

User stories are reviewed and approved by the client. Prioritization is also set by the client-side product owner.

---

[3] http://en.wikipedia.org/wiki/Agile_software_development
[4] http://en.wikipedia.org/wiki/Scrum_%28development%29

As soon as versions of working software are prepared, the client performs usability tests as well as acceptance tests, and provides feedback to the core development team. All external teams are managed and monitored by the core team's manager and assistant manager. All teams report back on a daily or 2-day basis.
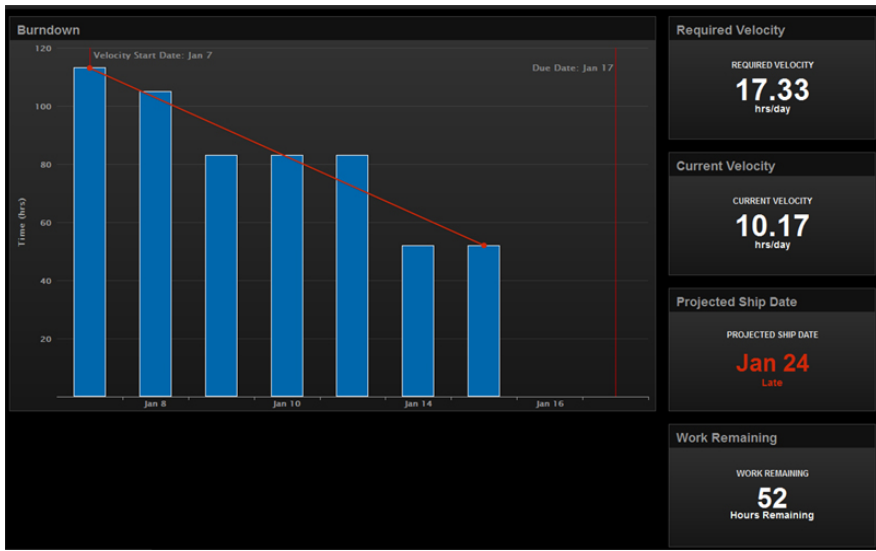

Fig. 2. Sprint burn-down chart

All teams involved in development work in 2-week development sprints (10 working days), unless there is need to extend the Sprint length. Sprints can be extended for a variety of reasons, such as larger stories, harder tasks, research tasks, low availability of resources, etc.

All work is logged and managed in the nlg GmbH development project management application, a third-party system that has been configured to work with Scrum. Using this system, all participants report their work time, enter comments, add/edit tasks or user stories, etc.

The core team has 15-minute stand-up meetings at the start of each day to determine if everything is running smoothly, detect any issues and decide upon a course of action (such as relocating tasks, change of priorities, obstacles, etc.).

During the entire development process the client-side product owners have an up-to-date overview with the ability to generate reports, add features, change priorities, enter comments and in general become actively involved in the development of the product.
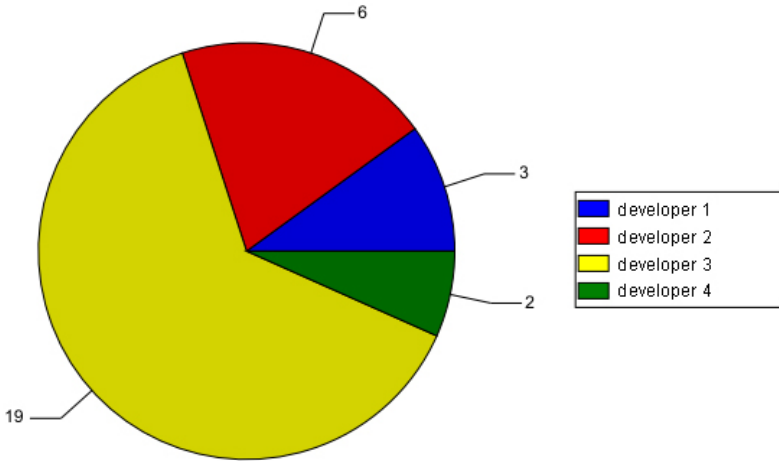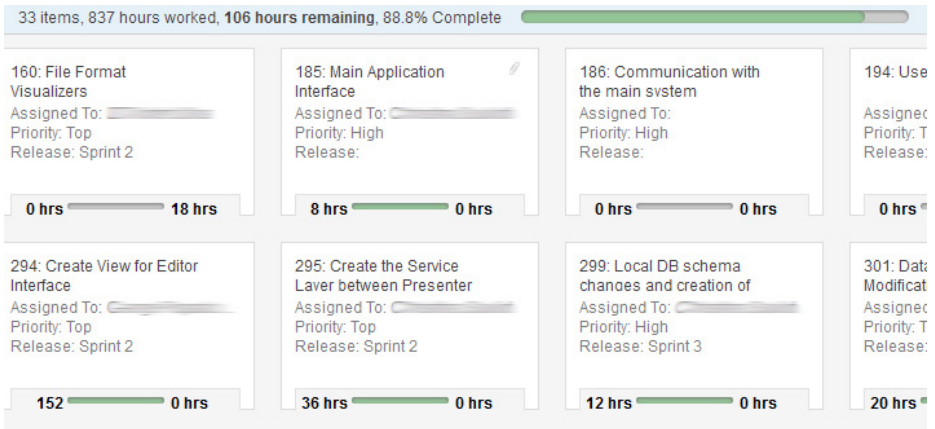
Fig. 3. Story assignment per developer

Fig. 4. List of user stories and % completed

This functionality is provided through the client portal of nlg GmbH's development project management system (mentioned above). In accordance with the access rights granted, clients can interact with nlg scrum team and participate in decision-making, planning, releases, etc.

4   Conclusions

Working closely with the end users, a development team can create solutions to automate not only specific steps in the localization process, but also complete sections or the entire localization workflow. This is how nlg worked together with its clients to create customized technology solutions that streamline time-consuming and uncontrolled process steps.