Vistatec Establishes Global IFU Localization Framework for Medical Device Manufacturer

Client

Our client is a medical device manufacturer with annual revenue of upwards of $80 million. Its products are distributed in 60+ countries and supported by multiple manufacturing sites worldwide.

The company had recently received regulatory approval for several new products, which required that the Instructions for Use be translated into 30 languages.

At the time, the organization did not have a centralized localization program, and previous translation work had been handled by multiple suppliers and internal teams. Vistatec was engaged to support the rollout of a structured global IFU localization program for these new product launches.

Critical Challenges

The client approached Vistatec after experiencing quality and compliance issues with previously translated IFUs. In-market feedback had identified terminology errors, formatting problems, and inconsistencies across languages.

Several factors contributed to the complexity of the project:

- Previous IFU translations contained terminology inaccuracies, inconsistent abbreviations, and significant formatting errors. Existing content could not be reused due to these quality concerns.
- The client did not have documented translation processes.
- Source English files included typos, missing text, and inconsistent terminology. The client requested guidance on what should remain in English, how to handle acronyms, and how to handle units of measure.
- Layout formatting did not allow for multilingual expansion, causing rework during localization.

Critical Challenges

- The client had no approved glossary, style guide, or translation memory for the new products.
- Multiple internal stakeholders were required to approve terminology and regulatory wording

The client required an ISO compliant localization framework that could ensure accuracy, consistency, and audit readiness across all languages.

Solution

To address quality, compliance, and formatting issues, Vistatec defined a structured global strategy for IFU localization. The approach focused on correcting the English source, standardizing terminology, and creating a repeatable workflow that could support all languages and future product releases.

Source File Remediation and Layout Preparation

Vistatec first rebuilt the English files and redesigned the layout for multilingual expansion. Tables, diagrams, and formatting were adjusted so additional languages could be inserted without manual rework.

Terminology Standardization and Language Governance

A customer-specific glossary and language guide were then created using terminology from the client's product documentation and recognized medical standards. The guide defined rules for acronyms, units of measure, branding terms, and content that should remain in English. These assets were enforced through automated QA checks to ensure consistency and mitigate linguistic errors across all languages.

Centralized Query Management

To manage the high number of stakeholder queries, Vistatec centralized communication using its proprietary Athena Query Management Tool. Questions and approved answers were stored in a searchable system, so linguists could reuse validated decisions across projects.

Reusable Templates and Compliant Delivery

Reusable templates were created for IFU layout, allowing the same structure to be applied across new products. Final deliverables were supplied as fully packaged, print-ready multilingual files produced under ISO 9001, ISO 17100, and ISO 13485-compliant workflows, with a Certificate of Translation Accuracy provided for each project.

Results

The structured workflow immediately improved both quality and efficiency. Because the English source files were corrected before translation, linguists encountered fewer issues and required fewer queries during production. The revised layout allowed additional languages to be inserted without extensive desktop publishing work, **reducing both time and cost**.

Reusable templates enabled the use of the same format across multiple products, and automated QA checks ensured full compliance with the approved glossary and language guide in every language. All files were delivered print-ready, and the client did not need to make any final adjustments before release. This was a significant change from their previous experience with other suppliers.

The improved workflow shortened the client's internal release cycle by approximately three weeks. Template reuse **reduced technical production costs by 20 percent** and saved an additional week of formatting time on each project. Centralized query management also made it easier to gather input from multiple stakeholders without slowing the process.

The client's next audit was completed successfully, with no findings related to translation or documentation quality.

Client Feedback & Partnership Impact

"Thank you so much for the IFU work. It has been a lifesaver for our verification process, and you have refined our IFUs, which is remarkable."

The success of the IFU program strengthened the client's confidence in a centralized localization model. As new products are developed, Vistatec is now engaged earlier in the process to prepare source files, define terminology, and plan multilingual rollout.

The workflow has also been extended to additional packaging and labeling materials, and the scope of collaboration continues to grow as product lines expand. The client now operates under a scalable, compliant framework that supports global regulatory content across all markets.

Learn more about Vistatec Life Sciences today!

Visit vistatec.com/life-sciences