seprotec

Streamlining Multilingual Regulatory Workflows in Life Sciences

Case Study

Translation | Interpreting | Intellectual Property

UNITED BY WORDS

Objective

To implement a scalable and regulatory-compliant translation workflow for IFUs, complaint documentation, and quality documents ensuring fast turnaround times, cost efficiency, and full compliance with EMA, FDA and PMDA requirements.

Challenge

Managing multilingual documentation presenting complex operational and compliance challenges:

- Managing updates and new translations into more than 30 languages
- Handling complex DTP formats (FrameMaker, InDesign)
- Ensuring strict file naming, reporting, and signed release documentation
- Integrating local market feedback into translation memories
- Securing sensitive regulatory and complaint data

Implementation

Drawing on its extensive Life Sciences expertise, Seprotec has implemented a tailored workflow:

- **Dedicated Life Sciences Governance:** A specialized project team acts as a single point of contact, coordinating translators, reviewers, DTP specialists, and validation stakeholders across all markets.
- **Structured Multistep Quality Process:** All translations are performed under the four-eyes principle (translation + revision), followed by QA checks and final layout validation to ensure submission-ready accuracy.
- **Standardized Post-Editing Workflow:** For selected content types, specialized linguists post-edit machine-translated content to ensure accuracy and compliance while improving turnaround times.
- **Integrated In-Country Review & Feedback Loops:** Local market feedback is systematically captured and reintegrated into translation memories and terminology databases to ensure long-term consistency and continuous improvement.
- **Multilingual DTP & Final Compliance Check:** Specialized DTP teams ensure formatting accuracy, barcode integration, language-specific layout adaptation, and final validation for regulatory submission.

Results at a glance

- Reliable delivery into more than 30 languages simultaneously
- Regulatory compliance and submission readiness
- Fast turnaround times through optimized workflows
- Long-term cost savings via optimized translation memory usage

Our client

A leading international medical device manufacturer operating across Europe, North America, and Asia-Pacific.

The company develops complex products in the fields of endoscopy and surgical technologies and must deliver compliant, multilingual documentation in more than 30 languages worldwide.

Seprotec (formerly tsd Technik-Sprachendienst) has been supporting this client as a trusted language intelligence partner since 2018, ensuring regulatory-ready documentation across all target regions.