



Clinical Translation: Managing Regulatory Content with a Single Localization Partner

How pharmaceutical and medical device companies can reduce complexity, strengthen compliance, and improve submission efficiency across Asian markets.

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The Regulatory Challenge in Asia

Japan (PMDA)

Precise terminology and standardized submission formatting required.

China (NMPA)

Carefully localized clinical and technical documentation aligned with local regulatory language.

South Korea (MFDS)

Evolving documentation standards for medical devices and biopharmaceuticals.

Taiwan & Singapore

Multilingual coordination between English and local language regulatory submissions.

The Hidden Costs of Multiple Vendors

Distributing clinical translation across several vendors creates serious operational risks - inconsistent terminology, fragmented workflows, and delayed submissions, directly impacting regulatory approvals and market entry timelines.



Problem #1: Inconsistent Terminology

Medical Device IFUs

User interfaces and Instructions for Use require exact alignment.

Multi-Country Trials

Terminology must be consistent across all regional submissions.

Multi-Authority Review

Inconsistencies trigger review flags from regional regulators.

Different vendors may translate identical medical concepts differently across protocols, informed consent forms, labeling, and adverse event documentation.

- ⊗ In one regional submission involving Japanese, Simplified Chinese, and Korean, a sponsor discovered inconsistent device terminology across vendors, requiring a costly reconciliation phase before submission.

Problem #2: Fragmented Workflows & Regulatory Risk

Workflow Overhead

Separate timelines, QA processes, communication channels, and file handling procedures.

Compliance Exposure

Fragmented governance complicates audit trails, version management, and change tracking.

Industry research confirms vendor consolidation is rising among life sciences companies - centralized workflows improve turnaround predictability and reduce overhead. In clinical environments, even minor delays can become expensive.





The Single-Partner Advantage

A single localization partner replaces fragmented vendor coordination with a unified workflow: Centralized project governance, shared terminology, and consistent regulatory alignment across all Asian languages and markets.

Centralized Project Management

01

Unified Terminology

One shared glossary and translation memory across all target languages.

02

Consistent QA

Centralized quality assurance and formatting standards for every document type.

03

Coordinated Updates

Protocol amendments implemented simultaneously across Japanese, Chinese, and Korean submissions with full version control.

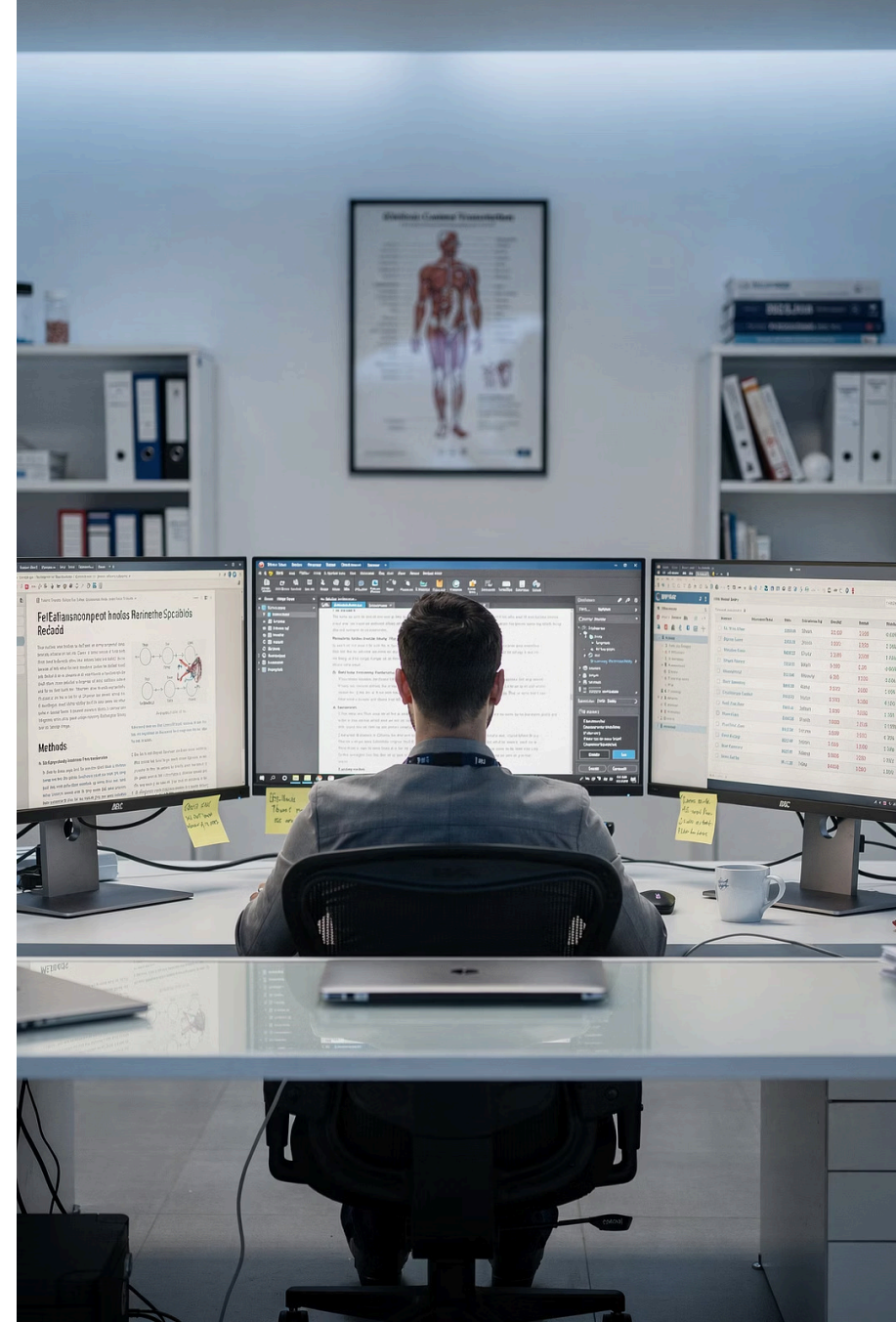
Clinical Expertise + Technology

Specialized Teams

Translators structured around subject matter expertise, not general pools, covering medical terminology, clinical trial processes, regulatory structures, and local authority expectations.

Compliance Infrastructure

- Centralized terminology databases
- Automated QA validation
- Regulatory version tracking
- Multilingual desktop publishing





CASE STUDY

Japan PMDA Submission: Cardiovascular Device

A global medical device manufacturer consolidated a full PMDA submission - clinical evaluation reports, risk management docs, IFU, software localization, and post-market surveillance materials, under a single managed program with 1-StopAsia.

Workflow Improvements & Outcome

Key Workflow Gains

One Terminology DB

Shared across all document types -technical and patient-facing.

Parallel Workflows

Translation, review, QA, and formatting ran simultaneously.

Client Results

- Submitted on schedule despite late-stage revisions
- Reduced internal coordination time
- Faster response to regulatory changes
- Better visibility into project status

Best Practices for Clinical Regulatory Translation in Asia

1

Standardize Terminology Early

Create approved multilingual glossaries before translation begins to reduce downstream review cycles.

2

Consolidate Vendor Management

Fewer providers means better visibility, accountability, and consistency across quality, timelines, and compliance.

3

Prioritize Regional Expertise

Japan, China, South Korea, Taiwan, and Southeast Asia each maintain distinct regulatory expectations.

4

Build Translation Into Planning

Involve localization teams early, especially for large-scale multi-market programs.

Navigating Asian Markets with Confidence

Centralizing project management, terminology governance, clinical expertise, and regional regulatory knowledge improves submission readiness while reducing operational burden, directly influencing speed and quality of market entry in Japan, China, South Korea, and beyond.

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