Why Life Sciences Localization Grew 147% in Six Months

What it means for your vendor selection and why the criteria that worked 18 months ago are no longer enough.

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The Big Picture

A 147% Surge and It's Not About Volume

At first glance, a **147% increase** in life sciences translation volume looks like a scaling problem. More markets, more languages, more content.

But the data tells a different story. This growth is driven by **regulatory expansion**: IVDR, MDR, and SaMD compliance frameworks.

For procurement teams, that distinction changes everything about how you evaluate vendors.

What's Actually Driving the Growth

Device Reclassification

Stricter IVDR/MDR frameworks reclassified thousands of devices, triggering mandatory documentation overhauls.

Expanded Documentation

Each product now generates significantly more regulated content per SKU, per market.

Broader Jurisdictions

Mandatory multilingual submissions now span a wider set of regulatory authorities globally.

Continuous Updates

Previously approved materials require ongoing updates, each triggering a new compliance cycle.

The Procurement Shift

The question has changed.

Old Question

"Can this vendor handle our volume?"

New Question

"Can this vendor handle **regulated content at scale** without introducing compliance risk?"

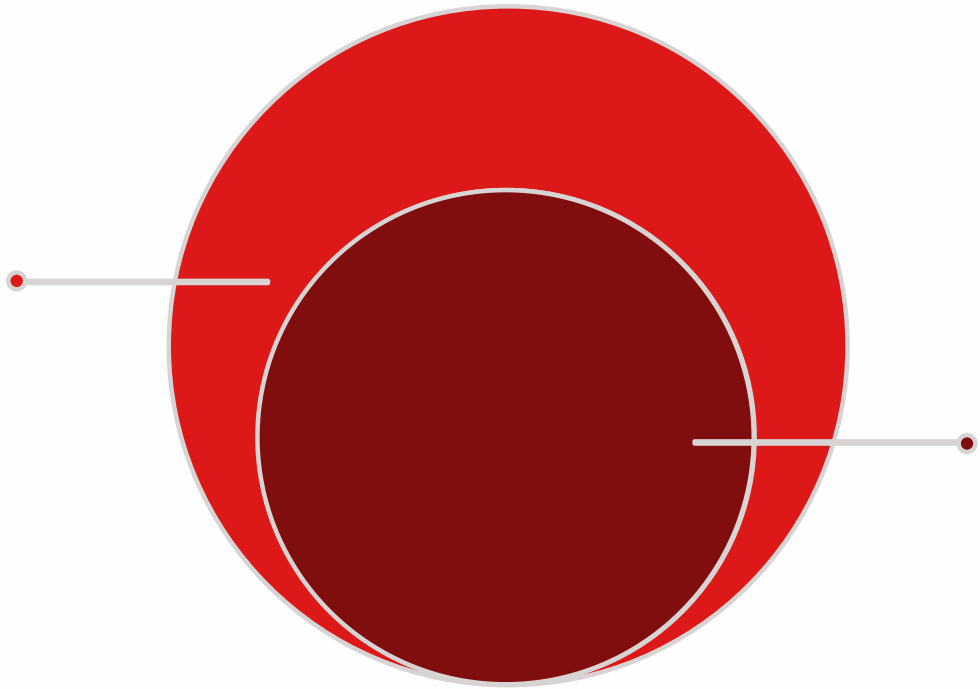
That's a fundamentally different evaluation and most vendor selection frameworks haven't caught up yet.

Why Standard TEP Is No Longer Enough

Most vendor frameworks still assume Translation → Editing → Proofreading is sufficient. For regulated content under IVDR and MDR, it isn't.

Compliance-Grade

Enhanced with governance and regulatory adherence features.



Standard TEP

Core transaction and execution processing capabilities.

Without compliance-grade process infrastructure, TEP becomes a **production process**, not a compliance process. That distinction is exactly where most vendor evaluations fall short.

Compliance-Grade Requirements

Four Elements That TEP Alone Cannot Deliver

1

Linguistic Sign-Off (LSO)

A named, accountable expert who not only contributes but **owns** the final output.

2

ICR Arbitration

Structured resolution of in-country reviewer feedback, not informal comment handling.

3

Subject-Matter Accountability

Linguists who are domain-qualified in medical, clinical, or regulatory content.

4

Terminology Governance

Centralized control of approved terms, enforced consistently across languages and updates.

The Hidden Weakness in Standard Vendor Selection

Traditional criteria are **necessary but no longer sufficient**. Most LSP evaluation frameworks still revolve around:

- ISO certifications
- Turnaround time & cost per word
- Language coverage & capacity claims

Vendors that *pass* these criteria may still operate with production models that cannot support compliance-grade life sciences translation. Issues go undetected during onboarding and surface during submission or audit.

THE STRESS TEST

Asian Language Production: Where Weaknesses Become Visible Fastest

Japanese, Korean, and Simplified Chinese workflows operate under **stricter practical requirements** not because vendors are weaker, but because the compliance environment demands more.

A standard TEP model creates friction. A compliance-grade model requires defined arbitration, version-controlled terminology, and documented audit trails.

Most vendor selection frameworks don't test for any of this.

What Changed in the Last Six Months

Three Structural Shifts That Redefine Vendor Capability

Volume Is Now Tied to Regulation

This isn't optional growth. It's mandatory output. Failure is now a **regulatory risk**.

Quality Is Defined by Defensibility

"High quality" now means traceable decisions, justified terminology, and documented reviewer resolution.

Capability Is About Systems, Not Just People

Even excellent linguists cannot deliver compliance-grade outcomes consistently without the right process infrastructure.

Updating Your Vendor Selection Approach

You don't need to rebuild your entire vendor list. You need to **update how you evaluate partners,** especially for regulated Asian language work.

That starts with replacing generic capability questions with **operational, testable, compliance-focused questions** that reveal whether a vendor operates at a production level or a compliance level.

The Five Questions to Ask Every Vendor

Surface Production-Level vs. Compliance-Level Operations

1

Linguistic Sign-Off

How do you implement LSO for regulated content? **Red flag:** "The proofreader does final review."

2

ICR Arbitration

What is your process when reviewers disagree? **Red flag:** "We consolidate comments and send them back."

3

Terminology Governance

How do you enforce terms across languages and updates? **Red flag:** "Managed per project" or "client-provided glossaries."

4

Subject-Matter Accountability

How is domain qualification verified in your linguist pool? **Red flag:** "All linguists are native and experienced."

5

Audit Trail

What documentation can you provide for a completed project? **Red flag:** "We can provide tracked changes if needed."

The Risk Has Shifted Upstream

> The key takeaway from the 147% growth in life sciences localization is this: vendor capability is now about **enabling compliance outcomes**.

Your evaluation framework must evolve to ask: **"Can they defend what they produce?"** That's a higher bar, but now the only relevant one.

TAKE THE NEXT STEP

Don't take regulatory risks with your medical translations.

Ensure your process meets the new IVDR/MDR standards. Work with a partner built for compliance-grade life sciences localization.

Visit Our Website **Ensure Compliance**

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