

Precision You Can Prescribe

Supporting Global Pharma with Compliant Multilingual Content

- ◆ *Ensuring every word meets strict FDA, EMA, and PMDA standards*
- ◆ *Protecting patient safety through accurate, audit-ready translations*
- ◆ *Delivering multilingual content with precision, compliance, and speed*

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Client Profile

Global Pharmaceutical Leader

A Fortune 500 pharmaceutical company expanding into new markets with breakthrough therapies requiring simultaneous global regulatory approvals.

Key Requirements

- Regulatory submissions across multiple jurisdictions
- Clinical trial documentation in 15+ languages
- Market entry spanning North America, Europe, and Asia
- Compliant localization for highly sensitive content



The Challenge

In pharmaceutical localization, precision isn't optional—it's life-critical. Translation errors can delay drug approvals, trigger costly recalls, and compromise patient safety.

Regulatory Compliance

FDA, EMA, and PMDA standards across all markets

Speed to Market

Fast rollout of clinical trial materials in 15+ languages

Data Security

Strict protection for unpublished research and proprietary data

Agile Management

Flexible workflows for last-minute regulatory changes

The Solution

1-StopAsia engineered a comprehensive localization framework specifically designed for pharmaceutical excellence and regulatory compliance.

01

Certified Processes

ISO 9001, 17100, 18587, and 27001 certified workflows ensuring quality and security

02

Specialized Linguists

Pharma-trained translators with regulatory and clinical expertise

03

Compliant Formatting

Multilingual DTP maintaining regulatory layout requirements across all languages

04

Agile Delivery

Flexible project teams synchronized with client development cycles



Measurable Impact

Strategic partnership delivering tangible results across regulatory submissions, operational efficiency, and market expansion.

18

Languages Delivered

Simultaneous EMA and
FDA submissions
achieved

30%

Faster Turnaround

Accelerated document
delivery reducing time-
to-market

22

Markets Enabled

MSL training and sales
materials localized
globally

Standardized SDS workflows now minimize audit risks while ensuring consistent quality across all regulatory documentation.



Certified Excellence

Trust backed by internationally recognized quality and security standards, ensuring your most sensitive pharmaceutical content meets global regulatory requirements.



ISO 9001

Quality Management Systems



ISO 17100

Translation Services Requirements



ISO 18587

Post-Editing Machine Translation



ISO 27001

Information Security Management



Why Precision Matters



The Stakes Are Life-Critical

In pharmaceutical localization, a single mistranslation can delay clinical trials, trigger product recalls, and most importantly, compromise patient safety.

→ Regulatory Precision

Ensuring compliance across all global markets

→ Operational Reliability

Maintaining audit-ready documentation standards

→ Global Trust

Delivering consistent, compliant communication worldwide

"When precision, compliance, and responsiveness are non-negotiable, pharmaceutical leaders trust 1-StopAsia to deliver multilingual content that's audit-ready and regulator-proof."

Partner with the localization experts who understand that in pharma, there's no margin for error—only excellence.



The background of the entire page is a faded, high-angle photograph. In the center, Mount Fuji rises majestically above a dense urban landscape. To the right, the corner of a traditional Japanese temple is visible, featuring multiple tiers of dark, tiled roofs with characteristic upturned eaves and red-painted wooden railings. The overall tone is serene and professional.

Ensure Compliance Today

Get Audit-Ready Translations

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