



Regulatory Filings for FDA, EMA and Others

If You Don't Understand It, You Can't Translate It!

At a glance

Regulatory filings for the FDA, EMA, and global regulatory agencies require precise translations of medical device documentation, including dossiers, technical files, clinical data, and compliance materials. Accurate translations streamline regulatory review, accelerate market entry, and ensure international compliance and acceptance.

Key metrics



40%

Reduction in global regulatory review timelines



99.7%

On Time Delivery



100%

Regulatory Compliance

CHALLENGES



Regulatory filings involve highly detailed, technical, and complex documentation requiring exact translation aligned with specific regulatory requirements. Translation inaccuracies can result in submission rejections, regulatory audits or compliance risks. Ensuring consistency, precision, and adherence to diverse regulatory frameworks and standards across multiple languages under tight submission deadlines adds significant complexity to the translation process.

SOLUTIONS



AI-optimized translations combined with specialized regulatory linguists ensure precise, compliant translations for global regulatory filings.



Regulatory Translation Experts



12 Step Quality Control Process



Scalable To Meet Your Needs

BENEFITS



1

Accelerated Global Market Entry

Accurate translations expedite regulatory reviews and approvals, significantly shortening international commercialization timelines.

2

Enhanced Regulatory Compliance

Precise translations minimize regulatory queries and audit risks, ensuring smoother and more efficient regulatory acceptance globally.

3

Reduced Operational and Financial Risks

Reliable translations prevent costly regulatory rejections, delays, and corrective actions, safeguarding market strategies and reputation.



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