

TransPerfect MDS Offers AI solution for MDR and IVDR content compliance

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AI Technology Backed by ISO 18587 Certification supports lower cost and faster turnaround for language services for device labeling and post-market surveillance



TransPerfect Medical Device Solutions (MDS), the world's largest provider of language services and process automation technology to the device industry has announced the division's certification to ISO 18587 for the application of artificial intelligence (AI) in medical device translation. TransPerfect's AI solutions are specifically designed to support the requirements of Medical Device Regulations (MDR) and In-vitro Diagnostics Regulations (IVDR) with special emphasis on labeling and post-market surveillance.

AI-Enabled Services Solve MDR and IVDR Challenges

Industry-wide, the cost of implementing the EU's new MDR and IVDR requirements is estimated at nearly \$20 billion. A significant portion of that cost is due to new content requirements. Says TransPerfect MDS President Marc Miller, "Two critical areas affected by MDR and IVDR are labeling – including translations – and post-market surveillance. The new regulations will create a substantial, permanent increase in the volume and velocity of content in both of these areas. The only practical way to address this increase is through automation and AI."

Clients Seeing Positive Results from Implementing AI-Enabled Processes

Rainer Degener, Director of EMEA Customer Service at IBA Dosimetry, GmbH, commented, "What first attracted me to TransPerfect's AI solutions was the cost savings while maintaining the same level of translation quality. Now that we have successfully converted our process to AI, I'm happy to report we've realized 15% savings and 30% turnaround reduction with the same quality. Overall, my experience has been that the AI-supported process works even better than expected!"

TransPerfect MDS helps manufacturers meet the daunting volume increases and turnaround challenges for labeling and post-market surveillance with structured content, process automation, and AI as part of its EnCompass Solution. In addition, TransPerfect's Rapid Prototyping Program enables device makers to build an evidence-based business case for management approval.

The specialized division also recently introduced an AI portal for MDR and IVDR post-market surveillance to provide cost- and time-efficient translation of PMS data. Compatible with 30+ file formats, including scanned images and PDFs, the portal supports more than 40 languages and helps manufacturers manage the increased volumes and faster turnarounds required under MDR and IVDR.

The division's certification to ISO 18587 ensures that processes and output for AI-enabled translation meet specific requirements and provides clients with confidence that AI technology has been implemented according to best practices to support quality and patient safety.