Lionbridge Launches Comprehensive 'EU MDR and IVDR Language Guidance'

Essential guidance on language requirements under the EU Regulations features AI strategies to help medical device manufacturers optimize language outcomes

Guidance serves as a comprehensive resource for medical device manufacturers and other Economic Operators (EOs).

WALTHAM, MA, UNITED STATES, June 17, 2025 /EINPresswire.com/ -- Lionbridge, a global leader in translation and localization solutions, has published "EU MDR and IVDR Language Guidance," a comprehensive resource for medical device manufacturers and other Economic Operators (EOs). This industry language guidance is expertly designed to assist in understanding and managing the intricate language requirements of the European Union's (EU) new Medical Device Regulation (MDR, 2017/745) and In Vitro Diagnostic Medical Device Regulation (IVDR, 2017/746).

> Our guidance clarifies language stipulations and introduces real-world solutions to streamline processes with AI, enabling manufacturers to meet regulatory demands efficiently and effectively."
> *Pia Windelov, Vice President of Life Sciences Strategy, Lionbridge*

The EU's 2017 regulatory overhaul significantly transformed the medical device sector, shifting from the repealed EU Directives of the 1990s to harmonized, binding regulations. The evolution from a pre-market focus to a full life cycle approach under the MDR and IVDR has increased documentation and translation demands, aiming to enhance health protection and streamline the internal EU market.

Pia Windelov, Vice President of Life Sciences Strategy at Lionbridge, spearheaded the development of the guide, recognizing the critical role of precise language in the EU's multilingual market.

"Our goal is to empower both European and international medical device manufacturers, along

with other EOs, to confidently navigate these complex multilingual demands and think strategically about language outcomes throughout the device's life," said Windelov.

The "EU MDR and IVDR Language Guidance" is divided into three sections:

1. Multilingualism in the EU Regulatory System: An exploration of the EU's unique multilingual environment and the implementation of language requirements across Member States.

2. Language Requirements under MDR and IVDR: A clear, systematic presentation of language requirements and recommendations for medical and in vitro diagnostic medical devices.

3. AI Life Cycle Language Strategy for MDR and IVDR: Innovative guidance on leveraging Artificial Intelligence (AI) and Large Language Models (LLMs) to optimize language outcomes through a risk-based strategy, ensuring effective multinational communication and market reach.

This timely resource also addresses the heightened need for plain language due to new transparency and disclosure rules, offering strategic insights on using AI to achieve safe, effective, and compliant language outcomes.

"Lionbridge's 'EU MDR and IVDR Language Guidance' is an invaluable and practical tool for any medical device manufacturer looking to successfully place their devices within the challenging regulatory landscape of the EU," said Windelov. "Our guidance clarifies language stipulations and introduces real-world solutions to streamline processes with AI, enabling manufacturers to meet regulatory demands efficiently and effectively."

The industry language guidance is now available for download here. For more information, visit https://www.lionbridge.com/life-sciences.

About Lionbridge
Lionbridge partners with customers to break barriers and build bridges all over the world. For over 25 years, we have helped companies connect with their global customers and employees by delivering translation and localization solutions in 350+ languages. Through our world-class platform, we orchestrate a network of passionate experts across the globe who partner with brands to create culturally rich experiences. Relentless in our love of linguistics, we use the best of human and machine intelligence to forge connections with our customers' clients. Based in Waltham, Massachusetts, Lionbridge maintains solution centers in 24 countries. Learn more at https://www.lionbridge.com.

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