CASE STUDY MDR Regulatory Knowledge And Language Expertise



WHY LANGUAGE SCIENTIFIC?

Radiobotics, a medical device company specializing in solutions for musculoskeletal (MSK) radiology, faced a unique regulatory and linguistic challenge. They developed their own AI-driven LLM to handle translations internally but needed an experienced partner to review and certify those translations for compliance with the EU's Medical Device Regulation (MDR).

Accuracy, regulatory expertise, and rapid turnaround were essential. Radiobotics turned to Language Scientific for their deep MDR knowledge, life sciences focus, and flexibility in adapting to a review-only workflow. Unlike other providers insisting on translating from scratch, Language Scientific seamlessly integrated into Radiobotics' existing processes, providing precisely the level of service required.

The Problem

As Radiobotics prepared to deploy their Al-driven medical device solutions across multiple EU markets, they needed patient-facing and regulatory materials reviewed and certified in various European languages. Although their in-house LLM produced initial translations, the company required expert validation to ensure compliance with MDR's strict requirements and to account for linguistic nuances that automated systems might miss.

Given the mission-critical nature of medical device documentation, errors could have led to regulatory delays, compliance risks, and reputational harm. Radiobotics needed a partner who could deliver speed, precision, and deep domain expertise.

RESULTS

Improved Compliance, Reach, and Engagement



Achieved on-time, accurate, and compliant translations for all required European languages



Ensured materials met stringent MDR standards without disrupting Radiobotics' internal AI translation workflows



Improved operational efficiency with streamlined quoting and project management processes

ACTIONS TAKEN

- Reviewed and certified translations produced by Radiobotics' internal AI-driven system
- Provided specialized linguists with deep MDR and medical device expertise
- Offered flexible services tailored exclusively to review and certification, rather than insisting on conducting the initial translations
- Delivered proposals, quotes, and project completion quickly and efficiently
- Implemented collaborative processes for consolidated feedback and digital change tracking, while maintaining confidentiality

"Overall good communication and you always deliver on time." - Head of QA Radiobotics