RWS

medical & in vitro diagnostic device services

Solutions for Life Science

The translation of information related to the production, distribution, and use of medical and in vitro diagnostic devices is incredibly important for companies serving a global population—and it presents its own set of challenges. Translating information for medical and in vitro diagnostic device companies requires not just linguistic skill, but also a deep understanding of the industry and highly specialized regulatory knowledge.

Expert Services for Medical and In Vitro Diagnostic Device Companies

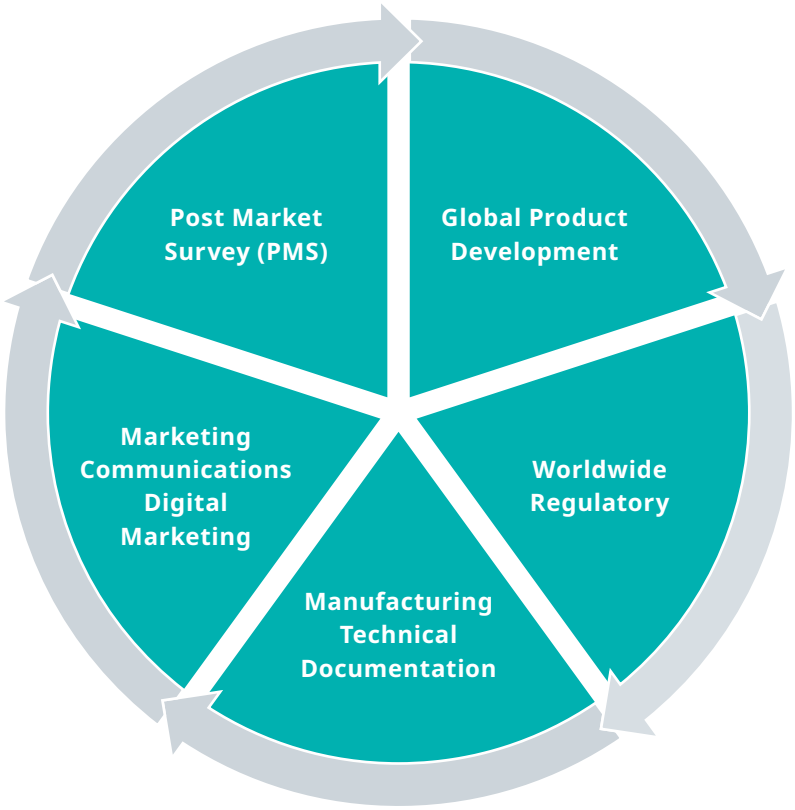
Our global team of account managers, project managers, tested linguists, reviewers, terminologists, linguistic engineers, solution architects, and subject matter experts have deep translation, localization, and regulatory experience. With them at your side, you can trust RWS to deliver your translated multilingual content quickly, correctly, and in compliance with the Medical Device Regulation 2017/745 (MDR) and the In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR).

We understand that you need to work with a partner that has extensive industry experience, can deliver a team of highly specialized translators who are both linguistic and subject matter experts, and can provide insights and validation regarding the many complex regulations that govern the development and trade of medical and in vitro diagnostic devices around the world. We know that high-quality, compliant content is critical for your work at every stage of the value chain, from R&D to production to patient engagement, and we offer a full suite of consulting, engineering, and business intelligence services to complement our linguistic work.

You need a partner that can balance innovation and speed with regulatory compliance and quality. We are that partner.

End-to-End Medical and In Vitro Diagnostic Device Expertise

Our team of medical and in vitro diagnostic device subject matter experts understands how products move from development through regulatory approval, manufacturing, and distribution, and we have the expertise and experience to assist with your content needs at every step.



We Translate...

- ✓ Instructions for Use (IFUs)
- ✓ Operating Manuals
- ✓ Installation Manuals
- ✓ Regulatory Compliance Documents
- ✓ Software Applications
- ✓ Package Inserts and Labels
- ✓ Patents
- ✓ Manufacturing Procedures
- ✓ Data Sheets
- ✓ Multilingual Websites
- ✓ Marketing Materials

Our Medical and In Vitro Diagnostic Device Services

We're your partner at every step, from design and manufacturing to commercialization. While we're known for our linguistic expertise, we offer a full suite of complementary services to help you design, implement, and analyze the most efficient and effective processes. Our services include:

Consulting

- Global operating set-up
- Quality improvement
- Terminology concepts
- European MDR and IVDR compliance
- Machine translation
- Centralization of language management

Engineering & Technology

- Data preparation & file engineering
- DTP & Graphics Editing
- DPF File Creation & Management
- Content Management Systems
- Machine Translation & Linguistic Engineering
- Digital Marketing Services

Linguistic

- Translation & localization in 260+ languages
- Transcreation and in-country copywriting
- Linguistic review
- Post-editing
- In-Country Review (ICR)
- IFU readability verification
- IFU optimization and consolidation
- MDR/IVDR compliance verification
- Certificates of accuracy
- Terminology & style guides
- Subtitling and voiceover
- Interpreting

Administration & Business Intelligence

- Project management
- KPIs
- Activity reporting
- Spending and saving analysis
- QBRs

The EU MDR and IVDR

If you're like many medical and in vitro diagnostic device companies, the EU's Medical Device Regulation (MDR) and In Vitro Device Regulation (IVDR) have posed new complications and challenges. Under these regulations which are designed to ensure the highest possible safety and quality standards for medical and in vitro diagnostic devices in Europe, companies have a greater number of requirements to follow. You now need to provide more clinical evidence, ensure accuracy and availability of product documentation and labeling content in all 24 EU languages, follow stricter requirements for IFUs, and translate all operating manuals, marketing materials, patient information manuals, clinical performance information, interfaces for software products, and more. It's a lot to handle.

We can help.

At RWS, we've been working with clients to prepare for the new regulations for the past five years. We offer specialized, ISO-certified services to ensure MDR and IVDR compliance and audit-ready technical documentation, including:

- ✓ Source File Analysis
- ✓ MDR and IVDR Compliance Check
- ✓ IFU Optimization
- ✓ Certificates of Accuracy
- ✓ Management of In-Country Review (ICR)

Each of these specialized processes helps you get your product to market faster while reducing risk. When we translate IFUs, for example, we don't just provide a translation—we optimize the entire IFU creation process and verify compliance according to:

- ✓ Machinery Directive 2006/42/EG
- ✓ DIN EN 82079 Creation of User Manuals
- ✓ ANSI Z535, Presentation of Safety Instructions

The result for you?

- ✓ Reduced translation and printing costs
- ✓ Risk mitigation
- ✓ Better user experience
- ✓ More consistent global branding

RWS in Action

We recently worked with a leading medical device company to update its IFU repository and translate the documents into 20+ languages in preparation for MDR compliance.

As part of our process, we:

- Verified MDR compliance
- Optimized the IFU creation and translation process
- Handled the in-country review process for the client
- Created and verified terminology

As a result, our client realized cost-saving, efficiency, and quality benefits, including:

- ✓ Reduced in-country review cycle time by over 50%
- ✓ Reduced translation budgets by 15%
- ✓ Increased MDR compliance and audit readiness by identifying missing IFU content
- ✓ Reduced translation and printing budgets by shortening IFUs by up to 25%
- ✓ Consistently translated target languages through terminology harmonization
- ✓ Created a consistent and professional IFU aesthetic for enhanced global branding and improved user experience

Learn more about how we can become *your* trusted partner.

Contact us at lifesciences@rws.com

Who is RWS

RWS is a world-leading provider of technology-enabled language, content management, and intellectual property services whose customers include the top 20 pharmaceutical companies worldwide. We help our customers to connect with and bring new ideas to people globally, by communicating business-critical content at scale and enabling the protection and realization of their innovations.

For further information, please visit: www.rws.com

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