RWS Life Sciences

Partnering for Global Success

RWS Life Sciences is a leading global provider of language solutions exclusively for the life sciences industry. For over 30 years, we have built a reputation of excellence through solving the most complex and demanding multilingual challenges in linguistic validation, clinical, regulatory, and medical devices.

Clinical Trial Management

Translations are an essential component of moving global clinical trials forward. Our expert knowledge and exclusive focus on the life sciences industry allows our team to handle any translation request with confidence.

Linguistic Validation

Whether intended for a patient (PRO), clinician (ClinRO), or observer (ObsRO), our translations are accurate and culturally and conceptually equivalent to the source instrument. Our experience in translating Clinical Outcome Assessments (COAs) encompasses a variety of therapeutic areas, including cardiovascular, allergy/respiratory, oncology, gastroenterology, inflammation, neurology, infectious diseases, and vaccines.

Medical Devices

The translation of information for use in conjunction with a medical device requires highly specialized insight into the many regulations that govern it. We have a team of highly specialized translation experts and linguists dedicated to managing the unique nuances of medical device projects including labeling, product manuals, patents and more.

Regulatory Affairs Expertise

Our Life Sciences expertise and knowledge of global regulatory requirements as well as the nuances of localized translations means accuracy and reliable consultancy for our clients.

E-learning and Training

An educated team is a more agile team; that is why we support global life science companies by accurately translating their multilingual e-learning programs.

Marketing Communications

We are adept at performing high level translations for your vital marketing materials with accuracy and consistency across your entire product line and brand.

Why RWS Life Sciences?

Experts in the most difficult and complex language challenges with over 30 years of industry experience

A network of over 7000 professional translators

99% on time delivery with 98% right the first time

Certified quality processes:

- ISO 9001
- ISO 13485
- ISO 17100

Support for over 500 language combinations

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Centralised Procedure and Linguistic Review

RWS Life Sciences is a leading global provider of language solutions exclusively for the life sciences industry. For over 30 years, we have built a reputation of excellence through solving the most complex and demanding multilingual challenges in linguistic validation, and clinical, regulatory, and medical device localization.

QRD - Quality Review of Documents

RWS ensures compliance with requirements for QRD template text and formatting by performing rigorous review of the Product Information (PI) in all 24 EMA languages. The EMA and our clients demand the highest quality procedures in our review of documentation and we ensure that we live up to that standard.

Appendix V Submission

We manage the administrative tasks involved in preparing the Appendix V files for submission. Our team takes care of these time-consuming tasks to reduce the burden on the client and provide peace of mind and assurance of final submission quality.

Member State Review

Our veteran Centralised Procedure team works within a tried and true methodology to handle the Linguistic Review stage and negotiate changes proposed by Member State reviewers. We can therefore minimize the challenges that may arise during this stage of the approval process.

Why RWS Life Sciences?

Beyond Translation:
Our experienced teams go beyond the basics to deliver full Procedure Management and consultation to help you keep your deadlines and budget on track.

Custom Solutions:
We build solutions tailored to your specific procedure needs, including around-the-clock service and a customizable online portal optimized for Centralised Procedure work.

Subject Experts:
Our linguists are subject matter experts with extensive experience with EMA requirements including QRD template text and timelines.

Our Methodology

International pharmaceutical companies depend on RWS to guide them through the regulatory requirements associated with translating pharmaceutical product information for regulatory submission and consumer use. We have designed a number of internal standard operating procedures to align with the EMA's requirements and to have the flexibility to support our clients' varied internal processes. At a minimum, all translations containing pharmaceutical product information go through a series of highly defined steps, including pre-translation file preparation, translation (conducted by two highly qualified linguists), quality control (e.g., verification of QRD template text), final pre-production review, in-country review, and certification.

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RWS Life Sciences is a leading global provider of language solutions exclusively for the life sciences industry, For over 30 years, we have built a reputation of excellence through solving the most complex and demanding multilingual challenges in linguistic validation, clinical, regulatory, and medical devices.

Our success is directly related to our superior quality freelance translators and our ability to foster prosperous relationships with them.

Are you quality driven?

Do you have a passion for solving complex language challenges?

If you are a language expert specializing in the life sciences industry, consider joining our team of highly qualified freelance translators. Due to the highly regulated nature of our clients' industry, we have rigorous standards and quality processes you will be required to meet.

Our language experts to work on our projects in:

- Clinical Trial Management
- Regulatory Affairs
- Medical Device
- Linguistic Validation
- E-learning & Training
- Marketing & Communications

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Scan this QR code to access the Freelance Opportunities in the Career section of our website.

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Linguistic Validation

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Linguistic Validation

Whether intended for a patient (PRO), clinician (ClinRO), observer (ObsRO), or Performance (PerfO) our translations are accurate and culturally and conceptually equivalent to the source instrument. Our experience in translating COAs has expanded across a variety of therapeutic areas, including cardiovascular, allergy/respiratory, oncology, gastroenterology, inflammation, neurology, infectious diseases and vaccines.

COA Value-Add Services

We manage the entire life cycle of your COA translations. Our approach provides an array of support services designed to save you time and increase your ROI including COA repository management, copyrights and licensing management and more.

eCOA Specialization

As more studies require electronic COA administration, you need an expert partner to help you navigate new challenges. Our deadline-driven project management approach ensures that all stakeholders work collaboratively, and that study teams do not encounter eCOA surprises.

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Developer Relations

We understand the complex nature of creating COAs for inclusion in multinational clinical trials. Our meaningful relationships with instrument developers have led to the creation of COA instrument websites. These websites are designed to facilitate the availability and use of these instruments. Each site contains a description of the instrument, instructions for obtaining permissions to use the instrument, an updated list of available translations, developer biographies, related research and more.

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Regulatory

RWS Life Sciences is a leading global provider of language solutions exclusively for the life sciences industry. For over 30 years, we have built a reputation of excellence through solving the most complex and demanding multilingual challenges in linguistic validation, clinical, regulatory, and medical devices.

Regulatory Affairs Expertise

Pharmaceutical product information is vital to the safety of patients, and important to the medical professionals who inform patients about product characteristics, usage, and effectiveness. We understand the critical need for 100% accuracy and consistency when translating pharmaceutical product information, therefore we not only follow the regulated processes for conducting the translation of these materials, but we have also developed our own augmented quality control measures.

Accuracy

Translating product materials accurately is our number one priority. Our industry specialization, regulatory knowledge and terminology expertise ensures it is always done correctly and on time.

A Global Perspective

We adhere to the translation methods required by global regulatory authorities. For example, we have a significant amount of experience managing the translation of drug labels and SmPCs.

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- ISO 17100

Support for over 500 language combinations

Our Methodology

We successfully guide many international pharmaceutical companies through the regulatory requirements associated with translating pharmaceutical product information for regulatory submission and consumer use. We have also designed a number of internal standard operating procedures to dovetail with the European, Asian and U.S. regulatory bodies' requirements for document types containing this content. At a minimum, all translations containing pharmaceutical product information go through a series of highly defined steps including translation conducted by two highly qualified linguists, multilingual multimedia production, an additional quality control edit, final pre-production review, in-country review and certification.

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Medical Devices

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Medical Device Expertise

Our team of highly specialized translation experts and linguists are dedicated to managing the unique nuances of medical device projects including labeling, product manuals, patents and more. We know that patient safety, regulatory compliance, quality, scalability, and price are top priorities. As a result, we have dedicated an entire section of our Quality Management System (QMS) to the translation of medical device content.

Quality

Our ISO 13485 certified translation processes, routine risk assessment procedures, technology solutions and intelligent use of translation memory ensure that clients receive the highest quality translations available.

Custom Solutions

Our singular focus in translating documentation for the life science industry has made us experts in analyzing clinical trial documents so we can deliver the most appropriate translation method.

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Our Methodology

RWS Life Sciences is the leading provider of translation solutions for many international medical device companies. We have designed internal standard operating procedures that dovetail with the requirements of European, Asian, and U.S. regulatory bodies for varying document types containing medical device content. At a minimum, all translations go through a series of well-defined steps including a translation conducted by two highly qualified linguists, multilingual multimedia production, an additional quality control edit, final proofread, and certification.