

# The challenge of managing regulated content at a global scale

A complete guide



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## At SeproTec we work to be a trusted partner for companies with a global presence.

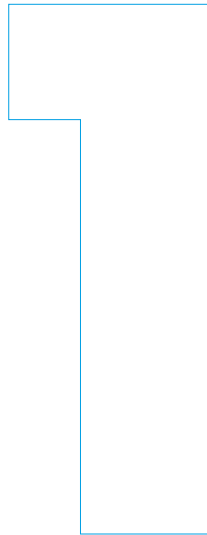
**Effective communication** in the business context is crucial, even more so when it's done on a global scale and against the backdrop of growing competitiveness such as we see today.

The task becomes even more daunting if the content of the communication is particularly **difficult** or requires **specialization**. That includes content with **legal or technical** information, also known as regulated content.

Correctly managing that content can also enable companies working in industries with regulated content to access the **valuable opportunities** of international expansion.

The key is to have an **effective, centralized communication infrastructure** that ensures messages are conveyed transparently and correctly, legally speaking, to the target market. This brief guide aims to give you some tips on how to set about this, so that you can make steady progress in international markets.





## WHAT IS REGULATED CONTENT MANAGEMENT?

**Regulated content management** refers to a specific type of business communication management in which a company works with materials (documents or messages) with legal and/or technical content.

The concept alludes to a set of tasks for the multilingual management of **technical documentation** that, due to their nature, requires **additional guarantees** as to its accuracy and that must also be sent through **specific channels**.

One example of a regulated content management task is the translation and delivery of documents with certified and sworn translations, an exercise in which the translator certifies and guarantees that there is full equivalence between the original document and its translation.



# 2

## SPECIFIC CHALLENGES OF REGULATED CONTENT MANAGEMENT

- Companies must be able to ensure that the content is **understandable** and **accurate** and that it complies with any applicable **regulations**.
- This content is published across **various platforms**. Some of these communications are public (social media, email campaigns, websites, diverse multichannel interactions with customers, etc.) and others private (staff access to technical documentation, public administrations, etc.).

The role of regulated content management in these cases is to provide guaranteed specialized **translations** and to ensure that the content is **available** in all the necessary localizations.







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# 3

## SOME COMPANIES THAT REQUIRE REGULATED CONTENT SERVICES

All internationalized companies at one point or another need to generate legal or regulated content in other languages, regardless of the industry they work in, although certain sectors create more regulated content than others.

### 3.1. Legal and insurance

Multilingual legal document management helps in areas such as **certified and sworn translation, transcription** for legal purposes, and **intellectual property** matters.

### 3.2. Banking

Retail, private, and investment banking may require the work of translators, interpreters, and proofreaders for the multilingual management of their communications. Messages to **investors**, the **CNMV** (Spanish Securities & Exchange Commission), **subsidiaries**, and **customers** are just some of the formal communications that require the utmost precision and accuracy.



### 3.3. Energy

Energy companies work in **regulated markets**, so regulated content has to be managed both in nuclear and fossil energies and in renewables.

Some typical documents included in this management are:

- Audit documentation
- Technical specifications
- Tenders
- Feasibility studies
- Environmental studies
- Drawings
- Product specification sheets
- Installation manuals
- Sustainability reports







- Safety sheets and plans
- Legal regulations and contracts
- Patents
- Financial reports
- CSR reports

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### 3.4. Health sciences

The healthcare industry and its many related areas is also a highly regulated area where content must be exceptionally technically accurate.

This includes booming sectors such as **biotech, medical devices, chemicals, dietary supplements, food supplements, and the healthcare** industry more widely, areas whose participants range from private companies to medical and teaching personnel as well as government authorities.

In all of these cases, companies commonly require access to up-to-date documentation available in a multitude of languages translated by specialized professionals and that is completely reliable.

Managing complex documents (like those related to the chemical industry) requires efficient and technologically advanced multilingual services.

Companies in this industry often also have to comply with strict **quality controls** and recruiting procedures linked to governmental authorities.



The most common documents translated for this industry are:

- SPCs
- DMFs
- PILs
- IFUs
- ICFs
- Clinical trials
- Patents
- Pharmacovigilance documents
- Pharmacoeconomic reports
- Legal documentation
- Websites, microsites, and apps
- Medical articles and scientific publications
- As well as all kinds of marketing materials for the pharmaceutical, medical, veterinary, and biotech industries.



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### 3.5 Manufacturing industry

The automotive and aeronautical industries are two key areas that require regulated content management to generate accurate and legally compliant **multilingual documentation**.

The **automotive** industry, for example, often requires help with documents such as distribution guides and portals, diagnostic and maintenance guides, DITA authoring systems, EDM/PDM systems, manuals, and AECMA SPEC 1000D technical documentation.

In the **aviation** industry, translation and localization make the difference in correctly carrying out a multitude of activities. Design, construction, and maintenance manuals, safety and emergency documentation, and air traffic control and customs procedures are just some of the regulated content documents that aviation companies have to handle.

### 3.6 Cosmetics industry

There are a number of documents that require maximum legal accuracy in the context of cosmetics:

- The Product Information File (PIF)
- Container and packaging labels in compliance with the regulations of each country or region, such as the **Fair Packaging and Labeling Act** (FPLA) in the United States.
- Notifications on the product to the European Commission (CPNP portal) and to the Spanish Forensic Sciences and Toxicology Institute (INTCF) in the case of products classified as hazardous. In the U.S., the Federal Food, Drug, and Cosmetic Act (FD&C Act) has to be followed.
- Communication of unwanted and serious side effects to the competent authority
- Manufacturing license statement





### 3.7 Food industry

- Verification of product compliance with legal frameworks regarding food (claims, labeling, ingredients, formulation, etc.), particularly with regard to health claims
- Generation of applications for health registration for companies
- Creation of packaging texts aligned with the specific legislation for food packaging for each country



### 3.8 Gaming industry

- Protection under intellectual property law of the programming code, video game text, visual elements, etc.
- Protection of user data and privacy
- Legalization of publishing contracts





## BEST PRACTICES TO MANAGE REGULATED CONTENT CORRECTLY

Translating regulated content is a challenge in terms of terminological accuracy and ensuring complete correspondence.

- **Technical ability and specialization.** Translating regulated content is a challenge in terms of terminological accuracy and ensuring complete correspondence. This requires having human resources specialized not only in the translation of texts and interpretation but also in the specific work area at hand. A translation of legal texts, for instance, will benefit from having graduates in law on board to ensure there are no technical inaccuracies. Experience and trustworthiness in these fields will guarantee a solid final result.
- **The right work processes.** Implementing efficient project management processes must be added to the knowledge described in the previous paragraph. This is where, for example, the automatic content management platforms described below come into play. This also includes access to proprietary and structured terminology resources (e.g., glossary development) that make work easier and provide



the basis for achieving top-tier levels of terminology efficiency and consistency. This also provides execution and implementation guarantees, meeting targets and deadlines.

- **Quality assurance and procedures.** Compliance with standards such as ISO 9001, ISO 17100, and ISO 13485, specifically for medical devices, generates additional guarantees regarding the quality of regulated content management.
- **Commitment to confidentiality.** Centralizing each account under a designated team makes it possible to control the confidentiality agreements signed with all the resources involved. Ensuring the availability of modern information security systems is also essential.
- Software focused on **workflow** optimization. Controlling content with the right software can make process workflow more efficient, including authoring, translating, reviewing, and publishing, especially when a project is being translated for several markets at once.





# 5

## KEYS TO EFFECTIVE REGULATED CONTENT MANAGEMENT

### 5.1. Automation

Automation leads to **reduced costs** and relocation of **resources**, two important advantages which explain why companies from all industries are already investing in these types of tools.

In the case of regulated content management, there are several areas that can be optimized after applying automation.

There are the tools for **memories and glossaries**, which allow companies to access the capacity to handle large volumes of work maintaining accuracy, terminological coherence, and quality.

Digital **content management** tools are another important ally when managing regulated content. Content management software seeks to facilitate and automate all processes in this area. This is an important source of value, considering the potential that automation has to free human teams from their most repetitive tasks.

Thanks to this type of tools, website **translation and localization**, two key tasks for any of the above-mentioned companies that have to deal with regulated content, can be optimized.



## 5.2. Guaranteeing effective multilingual communication

There are a multitude of statistics and studies that prove how today proficiency in the native language and investment in translation are important business opportunities. Perhaps the most notable is the one that measured a **1.5% increase in revenues** for companies investing in translation. The Economist's recent data on corporate communication and its challenges is also worth noting: **64% of companies** say that language and cultural differences have been an obstacle to their expansion plans.



This is true for any type of company that is thinking about global expansion. However, being able to communicate in the customers' own language and doing so with precision and assurance is especially essential in a sensitive area such as regulated content.

Fortunately, the translation services available today make this process easier, opening the door to multilingual communication for companies and ensuring that it does not stand in the way of their growth.

In this sense, the winning combination consists of **teams** specialized in regulated content armed with **technological tools** aimed at streamlining the process.





## **SEPROTEC:** **YOUR PARTNER FOR REGULATED** **CONTENT MANAGEMENT**

At **SeproTec** we work to help companies that need to efficiently manage regulated content.

We offer our **language consulting**, translation, interpreting, and localization services to do so, all backed by decades of experience in the industry.

Our goal in regulated content management? To understand the ins and outs of each project and ensure consistent and accurate translations that meet all of your related requirements.

We focus our services to add value for our customers in the following areas:

- Specific and verifiable experience in translation and interpretation in industries such as energy, legal, financial, automotive, aviation, and especially in pharmaceuticals, biotechnology, clinical trials, and medical devices.
- Strategically located offices in **11 countries**, with eight production centers, ensuring close contact with each project and **24/7** availability.



- **Customized workflow and unique management software** that guarantees 24/7 continuity to accelerate go-to-market launches and meet the deadlines set by the regulatory authorities of each country.
- A team of **nearly 400 employees and thousands of certified collaborators**. We have **technical translators** in more than 120 languages in addition to language professionals specialized in different disciplines. We guarantee that our translators have the technical expertise that each job requires.
- Management processes certified by the ISO 17100, ISO 9001, and ISO 13485 **quality standards**.
- Use of industry-specific **technology** to streamline processes and reduce costs.

Would you like to see first hand why we've been recognized for years as one of the **top 30** in the world in our industry, according to leading market research agencies? [Get in touch with our team](#) and find out how we can help you find the regulated content management model your business needs.



## Our services

We provide a range of full-service solutions, tailor-made, to a client base that covers more than 13 vertical areas, including consumer goods, eLearning, energy, infrastructure & architecture, legal & financial, life sciences, marketing & advertising, public institutions, publishing & broadcasting, technology, travel & tourism and videogaming & entertainment.

- **Document translation.** Our team allows us to produce documents that read like originals written in the target language rather than translations.
- **Website Localization.** We are capable of working with any format available on the market today and we are busily researching new technologies that are just down the pipeline to help you localize your website into more than 120 languages.
- **Software Localization.** Software localization does not merely entail translation, but also cultural adaptation to the target market. We provide services for all phases of the software localization process from internationalization to translation, engineering and testing.
- **eLearning Localization.** SeproTec has countless hours of eLearning and multimedia localization experience, in over 120 languages, and we provide 24/7 support. Our vast global network of linguists and project managers will ensure a successful project providing huge savings for our customers.
- **Intellectual Property Translation and Services.** SeproTec's multidisciplinary team of translators, proofreaders, linguists, lawyers, and engineers has made us the leading company in the management and translation of intellectual property texts and the safest bet for patent translation.
- **Certified and Sworn Translation.** We authenticate and certify the translation as compared to the original in accordance with the legal requirements in each country.



- **Proofreading and editing.** We work with recognized language experts specialized in proofreading and editing texts, indispensable work to ensure a document's quality.
- **Terminology management.** Glossary, terminology database, and translation memory creation and maintenance by a team of professionals with expertise in managing terminology databases and adapting them to the different needs of our clients.
- **Machine Translation and post- editing.** Clients can choose a fully automatic machine translation service or opt to add a light or full post-editing service provided by a team of linguists and managers trained in post-edition.
- **Transcreation.** Carried out by a translator with knowledge and experience in copywriting, involves adapting the intent, style, tone and context of the piece to the target culture.
- **Transcription.** Video and audio recordings of conversations and comments made during hearings, conferences, seminars, interviews and other events often have to be put in writing, whatever the languages used within them. At SeproTec we have been doing transcriptions in over 120 languages.
- **Testing.** SeproTec provides a testing service that combines functional and language testing of a software product.
- **Multimedia Localization.** Our multimedia experts routinely handle dubbing, subtitling and voiceover projects, as well as digital and audiovisual localization.
- **Subtitling.** SeproTec has a team of professionals who translate the text, shorten it in compliance with subtitling requirements and insert the subtitles into the video footage with special subtitling software.



- **Dubbing.** Dubbing involves removing the original character's voice and replacing it with the dubbed audio. We work with actors and dubbers of many different nationalities with a wealth of dubbing experience to meet all our clients' needs.
- **Desktop publishing (DTP).** We have our own in-house desktop publishing department with Professional desktop publishers and Localization Engineers with proven experience.
- **Technical writing.** Our professional content writers specialize in technical writing, with a wealth of experience in producing instruction sheets, manuals, specifications and technical documentation.
- **Conference Interpreting (Simultaneous, Consecutive, whispered and liaison).** With a database of over 7,500 interpreters, categorized by language combination, interpreting style, field specialization and technical expertise, the company offers a wide range of interpreting services suitable for any kind of multilingual situation.
- **Public services interpreting.** SeproTec offers clients a team of interpreters ranging from official languages to rare dialects to support with court, security forces and corps, social services, healthcare, and cultural mediation interpreting needs.
- **Remote Simultaneous Interpreting (RSI).** A smart solution for simultaneous language interpreting at conferences, events and meetings around the globe, no matter where the events are located. We use the best conference interpreters around the world and advise our clients on the most convenient solution as far as the interpreting service platform that best suits their needs.





- **Video Remote Interpreting (VRI).** VRI bridges the gap between OPI and in-person interpreting solutions, reducing the time and cost associated with travel and adding the advantage of visual support to OPI services.
- **Over the Phone Interpreting (OPI).** Instant over-the-phone professional assistance in 80 languages that is simpler, more convenient and more cost-effective than in-person interpreting services.
- **Sign language.** We boast a wealth of experience with different public bodies and fields of specialization (courts, police stations, care centers, social services, educational centers, congresses, private companies, training courses and more).
- **Equipment rental.** SeproTec has simultaneous translation booths that meet UNE 1093:1984 and UNE 1094:1984 standards, public address systems, infrared equipment for simultaneous interpreting, infoport briefcases and all the material needed to make the event run smoothly.



A provider of multilingual services, SeproTec Multilingual Solutions is one of the top 30 companies in the world in its sector. The company offers a broad range of translation, localization and interpreting services for businesses and, through its subsidiary SHIP Global IP, also provides intellectual property management services through a technology platform developed specifically for the IP sector. The company provides its services internationally and has production centers strategically located to ensure 24/7 service, 365 days a year.

With Nazca Capital as a shareholder since 2021, SeproTec is internationalized and has obtained official certifications thanks to its processes and management systems for translation services, quality control and environmental management (UNE-EN ISO 17100, ISO 13485, ISO 9001, and ISO 14001).

[www.seprotec.com](http://www.seprotec.com)