

LIFE SCIENCE TRANSLATION



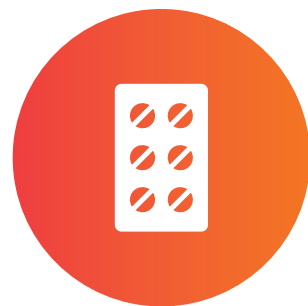
LIFE SCIENCE TRANSLATION



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WHAT IS LIFE SCIENCE TRANSLATION?



Pharmaceuticals



Healthcare



Medical devices

Life science companies need a high volume of translation, often in several languages, to launch pharmaceutical products in a new market, provide treatment using the language a patient understands, or export medical devices. This can include technical documentation, marketing content, packaging, and patient information.

High-quality translation is essential for life science companies – it’s always important to ensure translations are accurate or patients

can be harmed or the company may be confronted with legal or financial repercussions. A potential mistake, such as typing the wrong amount of a drug dose, or omitting the word *not*, can have devastating results. This is why life science companies rely on translations performed by linguists who are subject matter experts, translation companies that follow proven processes to reduce and eliminate errors, and translation technology that enhances the work of both.

Computer-assisted translation technology augments the capabilities of professional translators. Combined with translators’ creativity and subject matter expertise, translation tools greatly enhance efficiency and quality. Translation tools such as memoQ have a robust array of functionality including:

- A state-of-the-art translation memory, to automatically identify and re-use language repetition.
- Terminology management to document terminology decisions and make them easily accessible to translators and reviewers.
- Quality assurance modules to automate the process of finding and managing linguistic translation problems.
- A wide variety of built-in and customizable file filters that enable translators to access text for translation while preserving the original layout.

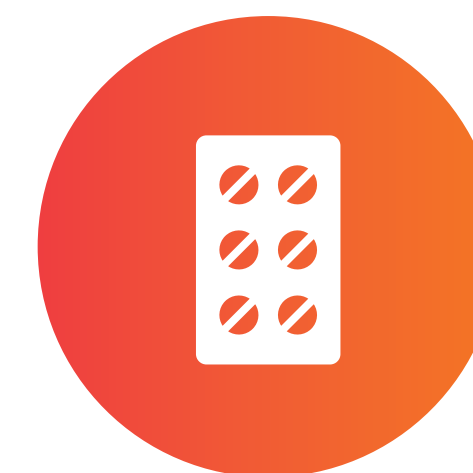
Subject matter expertise is not the only requirement for life science translation, though. Life sciences is one of the most heavily regulated industries in the world, so translators must also understand relevant industry and local regulations. Translation companies are legally required to comply with regulations that are meant to protect patient confidentiality and health records (for example, HIPPA, the Health Insurance Portability and Accountability Act, in the USA).

International standards such as ISO 9001, ISO 27001 or ISO 17100 address translation quality and information security and are followed by prudent language service providers worldwide. European and national regulatory bodies also have specific translation terminology requirements, adding yet another layer of complexity to life science translations.

With the evolving industrialization of life sciences, companies need to embrace the exponential changes in technology to change the way they work, conduct research, innovate, manufacture and distribute products, and meet consumer expectations.

Deloitte’s Global Life Science Outlook 2018

WHAT NEEDS TO BE TRANSLATED?



Pharmaceuticals

Clinical Research Organizations (CROs) and pharmaceutical companies conduct scientific trials around the world to study medical conditions and treatments and their effects, side effects and pharmacological interactions. To conduct these trials and market drugs in other countries, pharmaceutical companies need a multilingual approach, making translation a fundamental step throughout a clinical trial.

COMMON DOCUMENTS THAT NEED TO BE TRANSLATED (excerpt):

- Signed Agreements (CDA and SA)
- Study Protocol and Amendments
- Regulatory Authorities Documents
- Informed Consent Forms (ICF)
- Patient Information Leaflet (PIL)
- Subject Information Sheet (SIS)
- Case Report Forms (CRF)
- Investigator's Brochures
- Summary of Product Characteristics (SmPCs)
- Patient Diaries
- Laboratory Manuals
- Packaging
- Labeling
- Clinical Study Report (CSR)
- Common Technical Documentation (CTD)



Healthcare

Linguistically diverse populations need to receive critical health information in a language they can understand. For example, in the United States, there are currently over 21 million people with limited English proficiency. Understanding a medical situation, following treatment instructions, or reading drug labels can be difficult for them. To avoid dangerous consequences due to miscommunication, it is of utmost importance to translate these documents:

- Informed Consent Forms
- Medical Records
- Patient Questionnaires
- Lab Test Results
- Hospital Release Forms
- Aftercare Patient Instructions



Medical devices

To market medical devices, companies must conduct clinical trials for some countries, e.g. for the USA. In the EU it is not necessary, a self-declaration of conformity is sufficient. Although clinical trials for pharmaceuticals and medical devices differ in the way they are designed and carried out, both need proper terminology in translation for accuracy, understandability, and compliance with the various industry and international standards and regulatory obligations.

COMMON DOCUMENTS THAT NEED TO BE TRANSLATED (excerpt):

- Operating, Maintenance and Installation Manuals
- Development Safety Update Reports (DSURs)
- Instructions for Use
- Regulatory Compliance Documents
- Software Application Interfaces and Documentation
- Package Inserts and Labels
- Patents for Medical and Surgical Devices
- Manufacturing Process Descriptions
- Suspected Unexpected Serious Adverse Reactions (SUSARs)

WHAT IS THIS EBOOK ABOUT?

Most life science companies already operate in global markets and understand that translation is key to their global success. There are always newcomers to the industry, though, some of whom are still learning about the translation process. This eBook provides an overview of life science translation in story form. We narrate a process typically followed by people in two key roles using fictional people and situations at fictional companies: a medical device company, FirstAidCo, and their translation partner, RightPhrase.

Based on real life examples obtained in interviews with several industry experts, we present various challenges these companies face with the localization process, especially translation, and offer solutions. You will find challenges facing both the life science company and the translation partner, so no matter what your role is you can find relevant information.

WHAT IS THIS EBOOK NOT ABOUT?

This eBook is not a manual. Most professionals already working in life science translations are competent and knowledgeable, and this eBook is not aimed at them. It is more apt to help those

who are new to this field, but we hope that even those who have experience with localization will find something useful here.

HOW IS THE EBOOK STRUCTURED?

The eBook starts by introducing FirstAidCo and Matilda, the technical documentation manager who also handles translation. Let's pretend that Matilda is working for a company producing medical devices. As there are a lot of similarities in the workflow, if you work in another segment of the pharmaceutical industry you can use this as an example as well. In this section, you will learn about the challenges Matilda faces from start to finish. Among the most troublesome are her lack of time to manage translation as well as her documentation workload, the struggle to create a lasting partnership with a translation company, the difficulties in measuring the quantity and quality of translation, and her worries about security risks throughout the entire process.

Luckily, Matilda finds a reliable translation partner, RightPhrase, where Clive works as a recently appointed project manager (PM) for life sciences. Clive has his own challenges in managing projects

in this vertical market. Most critical are finding the right translators, managing terminology, processing frequent document updates, and addressing issues with translation quality.

At the end of the translation process, we show how RightPhrase wraps up FirstAidCo's translation project.

Then, to conclude the eBook, we provide basic information on relevant ISO standards.



tips
& tricks

ALONG THE WAY, LOOK FOR TIPS AND TRICKS ON:

- Improving communication between the client and the translation agency;
- Conformance to ISO standards.



FirstAidCo

LIFE SCIENCE COMPANY



RightPhrase

TRANSLATION COMPANY



choose one and click



FirstAidCo

LIFE SCIENCE COMPANY

WELCOME TO FIRSTAIDCO



INSIDE THE COMPANY

FirstAidCo is based in Boston, Massachusetts (United States of America), and is one of the largest suppliers of general first aid kits in the Americas and Europe. They export their products to four European countries, Canada, and Mexico. The packaging and product information is translated into the local language of each target market. In addition, marketing content, such as their website, brochures, and conference handouts, is sent to the local offices in these countries for translation and localization into a culturally adapted version. Matilda, the technical documentation manager, is responsible for the entire process.

GET TO KNOW MATILDA, THE TECHNICAL DOCUMENTATION MANAGER

Matilda's primary role is the development of technical documentation in English.

She has a bachelor's degree in biology and a master's degree in technical writing. Matilda is assigned translation management, and sometimes even translation and review, in addition to her main documentation job. As the company grows, the volume of translation soars, and now it is increasingly difficult for Matilda to handle translation for all documents and languages on her own.





Challenge 1

NO TIME FOR DEALING WITH TRANSLATION

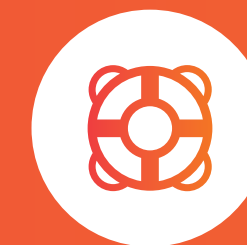
Matilda started working at FirstAidCo five years ago. At that time, the company had 15 products that were sold across the United States and eastern Canada. However, over the past two years, demand has been increasing for many of these products in Quebec, a French-speaking region. FirstAidCo decided to capitalize on this organic growth and accelerate market penetration, so now all content for the products must be translated into Canadian French.

Matilda's workload has always kept her busy, but the volume and complexity of the tasks were manageable at first. Now, however, the number of products released has tripled and their markets in Mexico and several European countries are also expanding, requiring translation into five languages, not just one. Even with a junior technical writer assigned to help her, Matilda is too busy to devote the time needed to managing translation for additional languages.

Early on, Matilda realized that it was essential to have some way of checking that the quality of the translations met certain standards. Until now, she had only two key indicators of success:

- How well the products sold in the target countries
- The opinions of the people working in the local offices

Matilda reports to the operations manager, who associates translation work with the local offices and doesn't understand how much impact it has on Matilda's workload. **Matilda believes she has enough work as a technical documentation manager and that another person should be hired to manage translation.** However, translation management remains her responsibility and she is looking for ways to do more with less time.



Solution 1

FINDING THE RIGHT TRANSLATION PARTNER

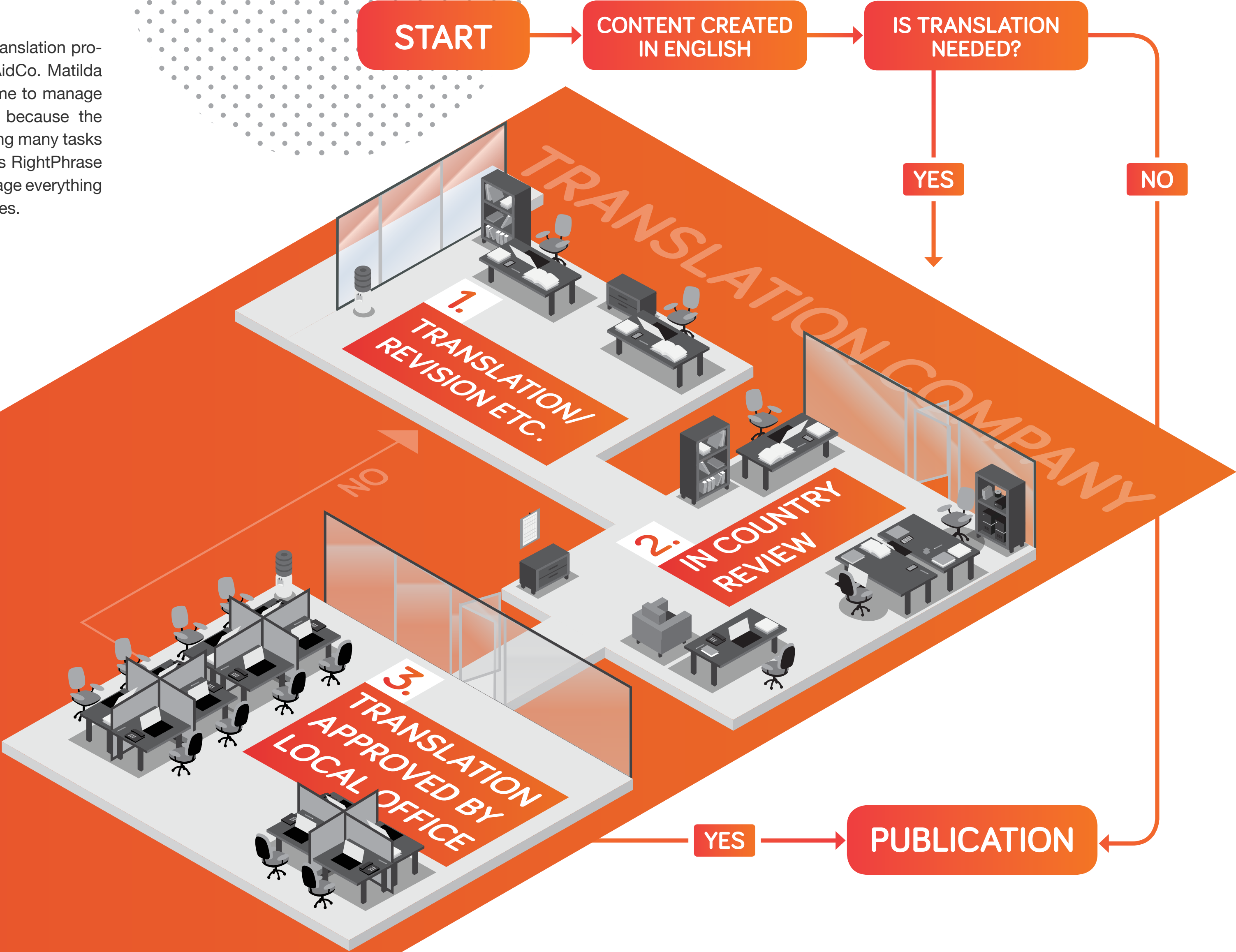
FirstAidCo made a few mistakes during their first few translation projects. Now errors are increasing as the volume of work increases. Matilda decides that it is essential to outsource translation to a translation company she can trust as a partner. She is not interested in spending time on the nuances of translation or the technology they use to handle projects. However, she wants them to have a process that both partners believe will reduce errors and deliver a high level of quality.

While most of FirstAidCo's products are available without a prescription, a mistranslation in the instructions for use could potentially cause injury. FirstAidCo could face serious market or legal repercussions. For this reason, Matilda needs to find a company she can fully trust. She chooses RightPhrase for the following reasons:

- 1 They are based in Albany, New York, sufficiently close to allow Clive, the project manager at RightPhrase, to visit several times a year.
- 2 RightPhrase has **memoQ server** technology, and FirstAidCo receives cost savings when using translation memories and term bases (terminology databases).
- 3 RightPhrase manages the in-country review process. They export a document with the source and target text and send this to the foreign offices of FirstAidCo. When the reviewer in the local office makes changes or comments, the translator will automatically be able to see them when the document is brought back into memoQ. Matilda will no longer need to spend her time handling documents going to and from in-country reviewers.
- 4 RightPhrase has recently been ISO 17100 certified, which Matilda believes incorporates the best process for life science translation.

5 Clive is easy to work with. Matilda likes knowing that if ever there is bad news, such as a translator being unable to meet a deadline, she will hear about it immediately from Clive. He reliably sends regular updates and reports on the work done.

The diagram below illustrates the translation process from the perspective of FirstAidCo. Matilda likes knowing that she has more time to manage the localization process internally because the translation company will be managing many tasks that previously were hers. She gives RightPhrase the content in English and they manage everything until it is approved by the local offices.





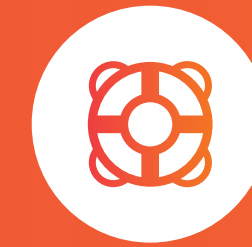
Challenge 2

LACK OF FRAMEWORK FOR WORKING WITH A TRANSLATION PARTNER

Matilda has decided to work with RightPhrase, but this is her first time cooperating closely with a translation company. So far, she has been doing almost all the translation management work, making decisions and executing tasks, so **she hasn't formally established many ground rules.**

Now she has a few uncertainties to clear up:

- How is RightPhrase going to provide quotes for the languages they need?
- What are the benefits of using translation memories?
- Will the translators working on her projects be qualified?



Solution 2

ESTABLISHING THE PARTNERSHIP

Before getting started with the first project, FirstAidCo and RightPhrase agree on the rates for the different languages and translation projects.

Next, they establish a workflow to launch and execute projects. Because RightPhrase was recently ISO 17100 certified, they have a process for launching projects that Matilda feels is a good fit. She relies on this process and Clive, the project manager at RightPhrase, to ensure her projects get off to a good start, are well-managed, and delivered with the expected high quality.

FOUR STEPS FOR ESTABLISHING A FRAMEWORK FOR A TRANSLATION PARTNERSHIP



Initial inquiry

Every project starts with a request from FirstAidCo. Matilda simply logs in to the **memoQ Customer Portal**, a platform that RightPhrase uses to handle incoming projects from their clients. Here, Matilda enters the details of her project and uploads the files to be translated. For each project she requests, Matilda receives an automatic provisional quote from the system, which Clive will then confirm or correct, if needed.

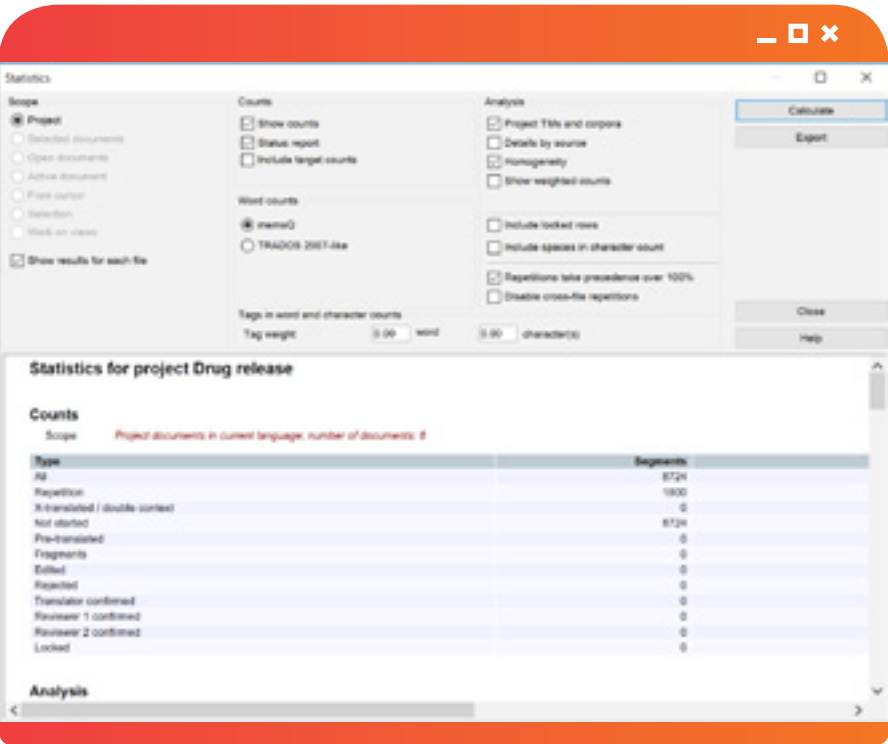
Clive’s most important task is to review the initial request and decide if they can deliver it. He sometimes needs to ask Matilda for additional details. If Clive and his team cannot deliver the translation when or as requested, for whatever reason, they will let the Matilda know as soon as possible, offering alternatives for getting the project done.



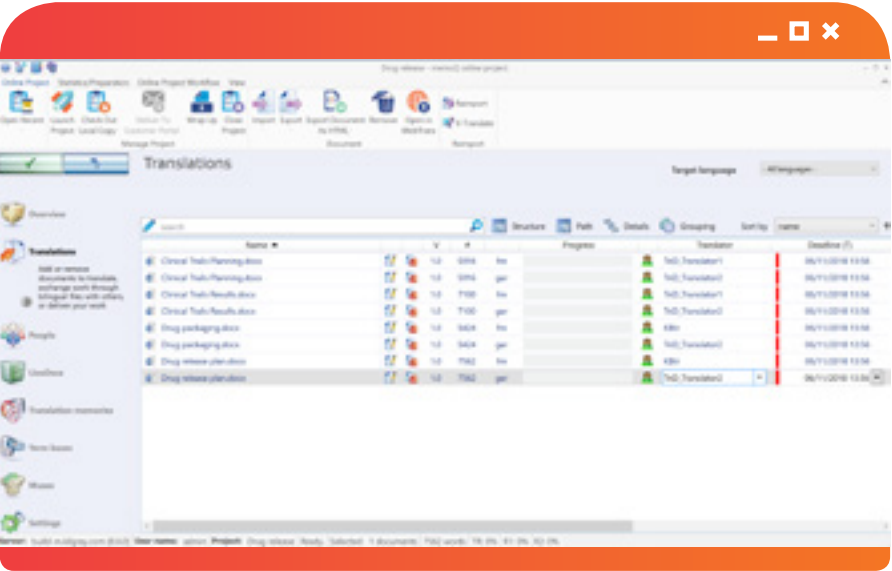
Scope and agreement

Once Clive confirms that they can deliver the project, he calculates the final cost estimate and sets a delivery deadline.

To calculate costs, Clive runs an automated analysis of the project. The **statistics** function in memoQ does this quickly.



When Matilda accepts the quote, Clive creates the translation project in memoQ using the files that Matilda uploaded to the **Customer Portal**.



In the sample project above there are 5 documents and each file is being translated into two languages (French and German).

As soon as translation is underway, the working translation memories begin to be populated. RightPhrase uses them to help translators work more quickly. The use of translation memories also has financial benefits for FirstAidCo. **Now, every time Matilda creates a new project, a translation memory is automatically assigned to it, and when the analysis is done the price of the translation project is reduced, sometimes by as much as 12%.**

Customer Portal

A translation project involves numerous exchanges of information and content. The customer sends the content, usually in a digital file, to the translation company. They exchange information about the content and the project requirements. During translation, the customer wants access to status information. The translated files are delivered to the customer when complete.

The **Customer Portal** is a web-based platform where the customer can commission a translation job, submit files for translation, and tell the translation company what they want done. The **Customer Portal** is a service offered by a translation company that they use to receive files for translation, give the customer a quote, provide the customer with status updates, and deliver the files.

The **Customer Portal** is a component of **memoQ server**, which makes it possible for the organization running the **memoQ server** to offer direct web-based project quoting, project creation, and monitoring services to its own customers. The **Customer Portal** is currently a business-to-business application, i.e., only organizations can order translations via its interface (an “organization” can be an external company or an internal department in the company that is running the **memoQ server**). The **Customer Portal's** web interface will appear to customers as part of the host company’s website or intranet and will be accessible from the internet (although it can be limited to an intranet).

03

Terminology management

Matilda has used an Excel sheet to manage terminology for the English content. However, when she visited the offices of RightPhrase six months ago, they showed her how they managed multi-lingual terminology for other clients. RightPhrase uses **QTerm**, part of the memoQ suite of translation tools. Clive imported Matilda's Excel sheet so **QTerm** now has her English terms plus all the languages they have been translated into. Matilda was relieved to see that her lists of terms that were not to be translated and terms that were not to be used in translations could also be managed in **QTerm**.

Shortly after this visit, Matilda suggests that the translation company should manage terminology for FirstAidCo's translation projects. This has now been agreed and both companies will use **QTerm**.

The companies also sign a standard Client-TSP (Translation Service Provider) agreement that states that the translation company will provide other resources to translators, including the use of the memoQ terminology management solution, **QTerm**.

QTerm

Proper terminology management in enterprises, non-governmental organizations, non-profits, and even governments has the same objectives as in product localization or commercial communications: making translation easier and supporting translators in producing consistent and high-quality translations. Therefore, terminology management needs to be a proactive, systematic, and multi-disciplinary process to be successful.

QTerm is the ultimate terminology management system—software used for storing, managing, and sharing terminology in an organization. With **QTerm**, companies and organizations can turn their terminology into a corporate asset. Using **QTerm** facilitates internal and external communication, increases brand awareness, improves the quality of technical communication, and cuts the costs resulting from misunderstandings.

04

Compliance

FirstAidCo must ensure, typically through their local offices, that their products comply with local regulations in each market where they do business. The translation company also ensures that translators are familiar with potential local compliance issues before they assign them to the project.

In addition, FirstAidCo is ISO 9001 certified. Their translation process is usually inspected as part of their ISO certification audit. (They had also considered becoming ISO 13485 certified but decided against it. ISO 13485 is a variant of ISO 9001 for medical devices, but ISO 9001 is a better fit for their continuous improvement processes.)

The translation company is also certified for ISO 9001 as well as for ISO 17100. The process outlined in ISO 17100 is used for FirstAidCo's projects.

EFFECTIVE COMMUNICATION

When Matilda started working with RightPhrase, she was concerned about too little communication. However, to her surprise, she initially had the opposite problem. The translation company kept her informed about almost everything that happened with her projects. At first this was appreciated by Matilda, since she liked the total visibility into the translation process. However, she soon discovered that if she receives 30 emails a

day from the translation company, she is unlikely to read most of them, but if she receives just one, she looks at it carefully.

This led Matilda and Clive to discuss the best approach for communication between the two organizations. The resulting framework for reporting and communication is illustrated in the table below.

TYPE OF COMMUNICATION	WHO NEEDS TO SEE IT?	NOTES
Major issue (one that can cause a delay in project completion)	Matilda and Clive (the project manager at RightPhrase who sees all communications)	If there is a potential delay, Matilda needs to know immediately.
Minor issues (unlikely to cause a delay in project completion)	Clive	Minor issues are recorded and if Matilda wants to see them she can.
Assignments	Clive	Matilda agrees that she will not see translator identities.
Instructions/Additional information from Matilda	Clive, team members	When applicable, Matilda will write instructions explaining known issues affecting specific translations.
Queries from RightPhrase team members	Checked by Clive, who will pass queries on to Matilda that he cannot answer himself	The translation company uses the communication functionality within memoQ to communicate with team members. When they raise a query, Clive enters his own, or Matilda's, response in memoQ. The information remains within memoQ for reference rather than getting stuck in e-mail or other systems.





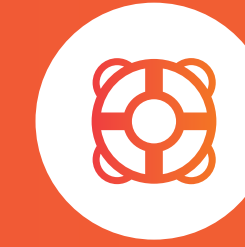
Challenge 3

LACK OF DATA AND CONTROL OF THE OUTSOURCED PROCESS

When they started working together, Clive would send Matilda a short status report at the end of each day. This worked well for a couple of months. Then, the number of projects and volume of translation escalated drastically as FirstAidCo began to sell in the European market.

Reporting became increasingly time-consuming for Clive, but Matilda insisted on regular updates, so she would always have the most current data for monitoring deadlines. For her, translation is only one part of the bigger goal of releasing localized products into new markets. She wants to have everything under control so that translation does not become the obstacle that jeopardizes product launches.

Matilda recognizes that Clive's reports help her measure and gather valuable data. The number of words translated per language across time is an indicator of the relevance of certain markets, and with this data she can forecast growth or decrease in localization demands.



Solution 3

AUTOMATING REPORTING

After working together for 15 months, Clive decides it is time to introduce a new reporting method, one that will save him valuable project management time. But he first must convince Matilda of the benefits of making a change.

He knows that memoQ already offers a series of built-in reports, and that he can automate some project tasks using a special feature called **project templates**. Clive hasn't used this functionality much, partly because he doesn't yet thoroughly understand how to make it work for him. So, he decides to invest time over two days to learn how to use automated processes to save him time on FirstAidCo's projects.

Clive's idea is to create a workflow that will tell memoQ to send an automatic email to Matilda whenever a project kicks off, when an analysis is run, when progress and post-translation analysis reports are run, and when projects are wrapped up.

REPORTS IN MEMOQ

ANALYSIS REPORT

Shows the scope of the project including the savings from **translation memories**, **LiveDocs**, and **homogeneity**. Summarizes the leverage and word count of the project.

PROGRESS REPORT

Shows a snapshot of the status of the project, and the individual translators, at the time the report is created.

POST-TRANSLATION ANALYSIS REPORT

After the project is completed, analyzes who contributed what segments, a crucial report for compensating translators fairly.

EDIT DISTANCE STATISTICS

Shows how many segments have been edited and the number of characters changed.

After watching tutorials and reading help files, Clive has almost finalized his automated workflows, but he doesn't know how to configure a few elements. He decides to speed up his learning curve by getting expert assistance, so he reaches out to the **memoQ Professional Services** team, who help him fine-tune the entire process.

Now the project templates are ready, and it is time to demonstrate the benefits to Matilda. After a long conversation, he convinces her by showing how this automated workflow allows for quick action on any issue. Plus, having the data delivered by the memoQ system directly to Matilda gets it to her more quickly and gives Clive more time for new projects Matilda is planning to launch soon.

PROJECT TEMPLATES IN MEMOQ

At the heart of memoQ is a desire to make the most productive use of users' time. The idea behind project templates and workflow automation in memoQ is a simple goal to make the project manager more productive. When creating a new project, there are many repetitive tasks. memoQ's goal is to reduce the number of clicks a project manager makes to launch a project.

Project templates help automate project creation steps and other repetitive tasks. Templates can also ensure that you adhere to a naming convention for projects and resources, making existing resources and projects easier to find and leverage for re-use.





Challenge 4

SECURITY RISKS

Security is a major concern for FirstAidCo, as it is for all life science companies. **If managed poorly, outsourcing translation processes to RightPhrase can be a security risk to Matilda and her team.** Even though she trusts Clive, she is fully aware that the files and information she shares with RightPhrase end up in the hands of translators in other parts of the world.

Matilda sometimes thinks that keeping translation in-house would eliminate such problems, but she would find it extremely difficult to staff a team of translators like the one Clive has put in place for her projects.

Information leaks and other potential security issues could jeopardize FirstAidCo, so Matilda and Clive decide to implement a workflow that has safeguards in place that will achieve the required levels of security.



Solution 4

ESTABLISHING A SECURE WORKFLOW

FirstAidCo has two different levels of security: high and very high. Everything RightPhrase will do requires at least the level of security FirstAidCo defines as high. This is because any tampering with the original or translated content could cause serious problems for the company.

Any material not previously released on the US website or relating to a new product is classified as needing very high security. In addition, they agree to apply very high security for specific products that may have unfavorable mentions in the media or if there is a threat of or pending legal action.

High security covers most of RightPhrase's work for FirstAidCo. There is a written procedure for

this body of work that is followed by everyone, including RightPhrase subcontractors. The main components of the procedure are:

- 1 The use of Secure Socket Layers (SSL) with the **Customer Portal** through which documents for translations are sent and received.
- 2 All translators working with RightPhrase have signed a Nondisclosure Agreement (NDA) that covers all the work they do for FirstAidCo. The agreement prevents the translators from posting any content online or using machine translation engines that use public content.
- 3 The translators must use memoQ for translation, and their individual licenses are connected to RightPhrase's **memoQ server** over SSL.

- 4 All tasks executed by the translation company will be traceable.
- 5 Once every 24 months, Matilda and her colleague from the FirstAidCo Information Technology department will audit these procedures for compliance by the translation company and its translators.

The very high security level applies when FirstAidCo launches a new product. They want to launch in multiple countries on the same day without their competitors knowing anything until after the official announcement. When there is high security work, the translators work in one of the local offices of FirstAidCo using computers available within the translation department.

FirstAidCo also defines who has what security clearance level:

USER ROLES	SECURITY RIGHTS
Project Manager at FirstAidCo	Access to all documentation. Covered by NDA as part of employment contract.
Project Manager at RightPhrase	Access to all material for translation. Covered by NDA as part of employment contract and also between FirstAidCo and translation company.
Translators	Access to all material they are assigned and need for reference. Covered by NDA with RightPhrase and also between FirstAidCo and translation company.
Reviewers	Access to all material they are assigned and need for reference. Covered by NDA with RightPhrase and also between FirstAidCo and translation company.
In Country reviewers (employees of FirstAidCo)	Access to all documentation. Covered by NDA as part of employment contract.

BACKING UP DATA

Data loss represents another security risk Matilda’s team discusses with the translation company. They analyze alternatives for preventing data loss due to hardware or software failures, malware attacks, or unexpected natural disasters. They decide that backing up data to restore in case of loss is the easiest option. RightPhrase agrees to run daily backups to ensure that any loss is limited to a single day’s work. They will use **memoQ backup** and schedule automatic daily backups.





RightPhrase

TRANSLATION COMPANY

WELCOME
TO
RIGHTPHRASE



INSIDE THE TRANSLATION COMPANY

RightPhrase is in Albany, New York (United States of America). Before partnering with FirstAidCo, they had translated instruction manuals and packaging for smaller medical device companies. RightPhrase also works with companies in several other industries including legal and manufacturing.

RightPhrase was not sure they would get work from a large and prestigious company like FirstAidCo. RightPhrase's hard work in documenting, their experience and processes paid off when FirstAidCo selected them as their translation partner. For RightPhrase, working with FirstAidCo represents a great opportunity, but it also means new challenges.

GET TO KNOW CLIVE, THE PROJECT MANAGER

Clive is a project manager at RightPhrase. He joined five years ago after having worked as a PM for a smaller translation agency. Here at RightPhrase, he has more responsibilities and has been able to develop his talent and customer-focused approach. Clive has successfully managed other high-profile projects, making him a good choice to be appointed by his manager for this new client.

If you recall from the introductory pages, the chief challenges for Clive are finding the right translators, managing inconsistencies in terminology, juggling updates to source content while translation is in progress, and addressing issues with translation quality.





Challenge 1

FINDING THE RIGHT TRANSLATORS

Vendor and resource management refers to the process of selecting and assigning translators, reviewers, and other team members for a translation project. The methodology for executing this process is extremely important, particularly for life science translation.

A good vendor management strategy involves setting appropriate qualifications and competencies for translators, selecting suitably qualified translators, and successfully managing and facilitating their work.

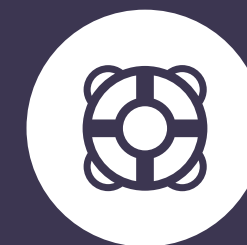
ASSESSING QUALIFICATIONS AND COMPETENCES

For life science translation projects, it is crucial to hire translators and reviewers who have the competencies required to translate with high quality for this vertical market.

RightPhrase is ISO 17100 certified and will follow requirements that the translated text must be reviewed by someone qualified to do the translation. They will select translators and reviewers who have similar experience and competencies.

RightPhrase will recruit translators who have the minimum requirements of a degree in Translation Studies, or a degree in some other subject plus 2 years' experience as a translator, or at least 5 years' relevant experience. RightPhrase typically seeks candidates with higher qualifications than the minimum whenever possible.

Competencies are also crucial. Clive expects the translators to have substantial experience with life science projects and to be proficient with computer-assisted translation tools like memoQ.



Solution 1

RECRUITING AND VENDOR MANAGEMENT

RECRUITING

RightPhrase follows these steps for selecting translators and reviewers for this project:

- 1 Set the qualifications and competencies required. In following ISO 17100, the translator and reviewer are required to have at least the following qualifications:
 - A degree in translation, linguistics or language studies or an equivalent degree that includes significant translation training, from a recognized institution of higher education.
 - A degree in any other field from a recognized institution of higher education and has the equivalent of two years of full-time professional experience in translation.
 - The equivalent of five years of full-time professional experience in translation.
- 2 Request a test translation from each candidate to assess the competence and quality of their translation work.
- 3 Select translators and reviewers with the preferred qualifications and competencies and assign the project to them.
- 4 Agree on terms and conditions.

In addition, RightPhrase specifies additional desired competencies in translation tools or other technical requirements.

MANAGING VENDORS

Like other language service providers, RightPhrase works with hundreds of translators regularly, and with many more occasionally. Derek is the company's vendor manager, and it is his job to:

- Anticipate the needs of the translation company and plan accordingly
- Create a process for recruiting translators
- Recruit translators
- Maintain a database of translators
- Handle any quality issues with translators
- Monitor updates from translators on their efforts to upgrade their skills and participate in continuing education

Clive works closely with Derek during the recruiting and selection process, and if a translator has performance problems during the project. As Project Manager, though, it is Clive, not Derek, who works directly with selected translators once the project gets underway.



Ideally, the LSP creates even “translator profiles”, together with the client. These specify the exact needs, and based on this, the LSP can create dedicated teams of linguists.

David Altmann, Director of Sales at NLG GmbH



Challenge 2

INCONSISTENT TERMINOLOGY

RightPhrase translates both the information sheets and the marketing material for FirstAidCo. When they began working with FirstAidCo, as part of their standard kick-off process, they asked for any resources FirstAidCo had available to help their translators reach the desired consistency and quality. FirstAidCo shared style guides developed by Matilda, including information on how to write about their products in specific contexts.

However, FirstAidCo did not have a multilingual term base. When RightPhrase started translating for them they found the following terminology issues:

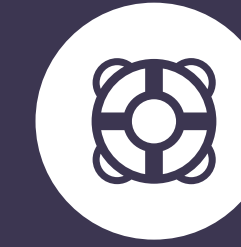
- There was one set of terminology to be used when translating legal/information content and another set to follow when translating marketing material.
- There were certain product names that FirstAidCo did not want translated. This included the name of the company. However, there were certain instances for which they decided to translate the product name.

- There were some commonly used phrases associated either with names of competitors' products or phrases used with competitors' products. FirstAidCo did not want to use phrases associated with competitors' products.
- There were obvious gains to be made by using terminology to increase leverage.



Another big issue we see in the case of big corporations that have done translations for many years and with many (changing) suppliers: "polluted" TMs, meaning: inconsistencies especially regarding terminology, and no harmony between the terminology in the TM on the one side, and the approved term list on the other side. This usually calls for a TM clean up.

David Altmann, Director of Sales at NLG GmbH



Solution 2

TERMINOLOGY MANAGEMENT

INVESTING EARLY IN TERMINOLOGY

To Clive, the objective of managing terminology is to help translators produce consistent, high-quality translations acceptable to the client. Based on his experience, Clive knew that making decisions about key terminology at the beginning of their relationship could save a lot of time and trouble later.

While in college, Clive read a paper by Joerg Schuetz and Rita Nuebel titled "Multi-purpose vs. Task-specific Application: Diagnostic Evaluation of Multilingual Language Technologies." The paper shows how the cost of terminology management varies at different stages of a translation project.

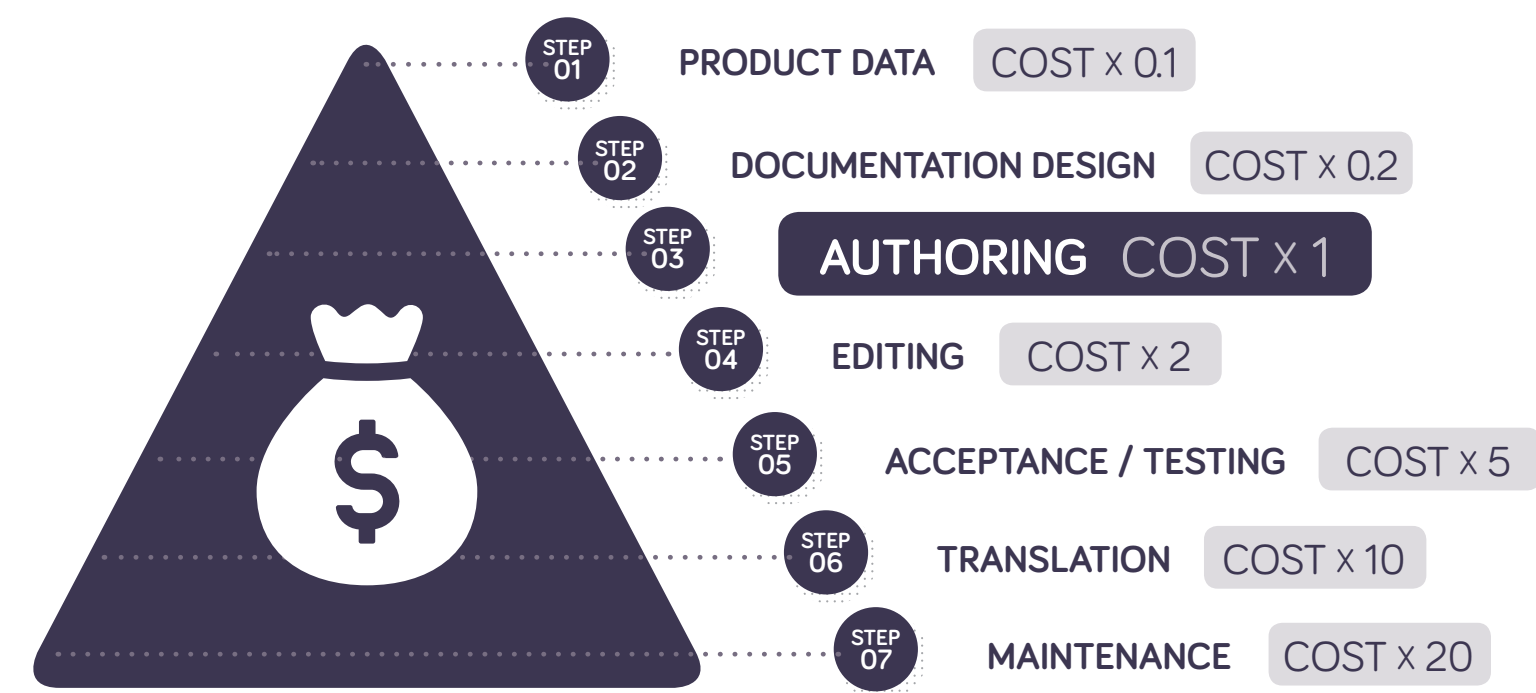


A number of studies has shown that terminology work typically pays for itself within the first two years, and this fact holds particularly true if validation is part of the terminology development cycle. Making client-validated terminology available to the translation service provider before translation begins enables them to reduce or eliminate in-country review and possibly other expensive QA steps, which would otherwise be necessary to ensure that the final translation product reflects the client's preferred terminology.

Uwe Muegge, Global Language Management at Arthrex



If the terminology decisions are made at the client’s product documentation stage, it will cost 50% of what it costs at the content authoring stage, and if done when the product data is being worked on, only 10%. However, if terminology management does not begin until after authoring, it becomes much more expensive. Terminology developed at the testing stage costs five times as much as at the authoring stage, and at the translation stage, ten times as much. If the product has already been released, it is 20 times more expensive to incorporate terminology changes.



Clive sets up a meeting with Matilda to discuss this topic. He convinces Matilda that terminology management needs to incorporate an all-inclusive approach and should take place before the translation begins, otherwise it could become expensive. During the meeting, they devise this solution:

- Create a list of terms that are important to FirstAidCo for marketing purposes.
- Create a list of terms that are important to FirstAidCo for legal and/or information documents. Because some terminology is commonly used throughout this industry, they add a list of terms already created by RightPhrase as a reference.
- Create a list of forbidden terms (terms that should never be used in a translation).

- Create a list of terms that are to remain in the original English.

In addition, they decide to create a list of terms that, when translated consistently, would increase the leverage they were getting from translation memories.

The two companies decide that RightPhrase will manage the term base. RightPhrase proposes using **QTerm**, giving access to those involved at FirstAidCo. They also agree that FirstAidCo will decide on and furnish a list of terminology for marketing and forbidden terms. Everything will be stored in **QTerm**.





Challenge 3

DOCUMENT UPDATES

One of the challenges facing FirstAidCo is releasing their products internationally as close as possible to the time of release in their home market.

The translation needs to be finished in time to print the packaging, instructions, and other material, which ideally would be three to four weeks before release. To meet that timing, the text to be translated should be made available to the translation company three months prior to the product release date.

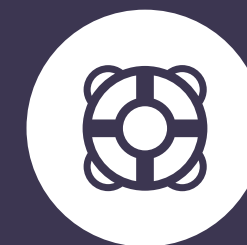
They both know it is difficult, sometimes even impossible, to get the English source content approved until the marketing and content teams see the new product. That usually happens closer to

the release date than desirable. In addition, there are usually last-minute changes to the marketing material and issues that surface when the product information is reviewed.

Realistically, the only choice is to begin translation knowing there will almost certainly be additions or changes along the way.

Another twist in the process is that FirstAidCo sometimes updates their content, but then later decides to revert to a previous version.

Having a solution to prevent chaos and eliminate time-consuming manual tasks will be key to keeping translation on schedule.



Solution 3

X-TRANSLATE AND VERSION CONTROL

Both companies agreed to prioritize packaging as the content to finalize first, since it also goes through the printing process, which takes extra time.

They also agreed on ways to use technology to reduce manual steps when handling content updates. RightPhrase uses **X-Translate** in memoQ. When they receive an updated source version from FirstAidCo, **X-Translate** automatically re-uses the previous translation and marks the new or revised content. The translator only needs to go through the marked revisions, not the whole document.

In addition, RightPhrase uses **memoQ's version control**, which involves creating a snapshot of the document at various times, making it easily possible to revert to a previous version.



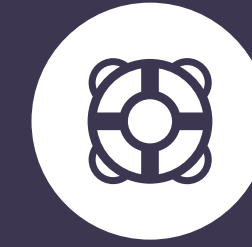
Challenge 4

UNRELIABLE QUALITY OF TRANSLATION

Since the beginning of the relationship with the translation company, Matilda has stressed the importance of quality for her projects. She knows that a poor translation could have a negative impact on the acceptance of FirstAidCo's products or become an embarrassment to the brand.

This isn't Clive's first project involving life science content, so he is familiar with these challenges. He understands that few other industries re-

quire quality assurance as much as life sciences. Misunderstandings because of translation mistakes or numeric errors have consequences that can range from minor injury to death. While most translation projects require only one review cycle, life science translations usually involve several steps to ensure accuracy. To meet the quality standards required by Matilda, Clive plans to use memoQ's highly-customizable **QA module** and **Linguistic Quality Assurance**.



Solution 4

DELIVERING QUALITY-ASSURED TRANSLATIONS WITH MEMOQ

memoQ server provides two approaches to Quality Assurance (QA), which can help projects complete faster and with fewer errors. There is automated **QA** functionality, which checks each document for machine detectable errors before it is delivered by the translator, and **LQA (Linguistic Quality Assurance)** functionality. **LQA** supports creation of a linguistic QA model that can be used on all projects.

To create this filter, Clive asks Matilda for input on the most frequent mistakes in her projects. He knows memoQ offers the ability to configure quality assurance in different categories (segments and terms, consistency, numbers, punctuation, whitespace, capitalization, characters, and inline tags), so they develop a list with typical examples for each of these.

Once the filter is set up, translators can run it at any stage of the project to find and fix errors (or ignore those that are not relevant).

Clive and Matilda agree to review the automated quality assurance settings monthly and make adjustments when they see room for improvement.

STEP
01

REVIEWING TRANSLATION QUALITY (AUTOMATED QA)

First Clive sets up a tailored quality assurance filter for FirstAidCo. memoQ's quality control module has a default configuration, but it is highly customizable and can be used for the translation memory as well as documents.

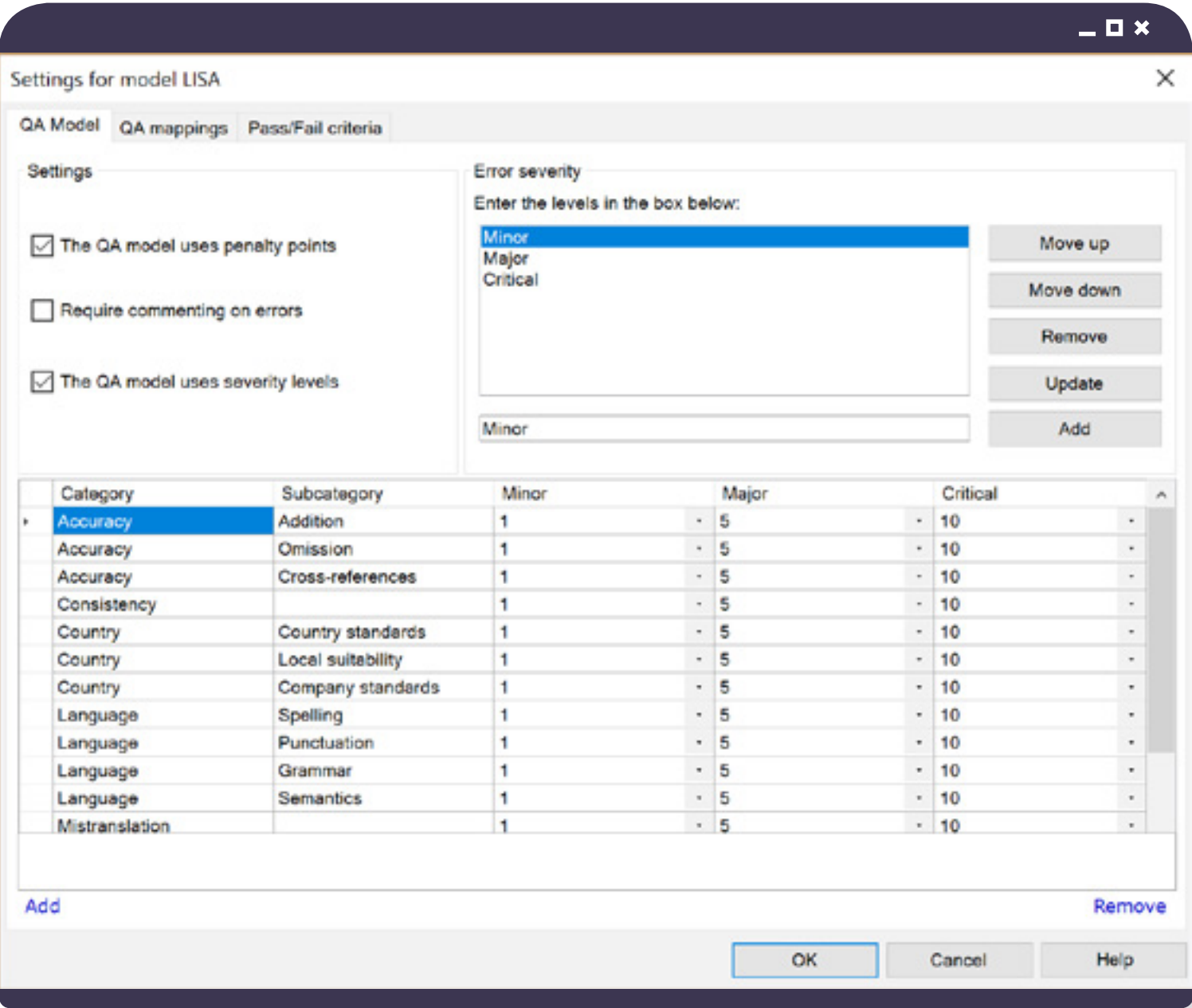
STEP 02

REVIEWING TRANSLATION QUALITY (LINGUISTIC QA)

Automated quality assurance is of enormous help to Clive and his team – it identifies many kinds of mistakes that are often missed by the human eye: double spaces, wrong capitalization, missing punctuation, and many other issues. However, Clive knows that automated quality assurance alone is not enough to eliminate all errors in Matilda’s projects, so the second stage involves another process known as **Linguistic Quality Assurance (LQA)**.

The **LQA** functionality in memoQ makes it easy to use an existing quality control model to check translations. Once defined, the model can be shared with project managers, translators, and reviewers, and all projects can be tested against it.

LQA provides Clive an effective way to manage quality in such a way that Matilda can see what his team is doing and how.



STEP 03

REVIEWING TRANSLATION QUALITY (IN-COUNTRY REVIEW)

Most life science translation is mandatory for regular purposes, necessary for the rightful use of a product and finally to market and sell a product in a specific locale. It is common to have a domain expert who is fluent in the target language review the translated content as part of the QA process. Called in-country review, this is often a difficult phase, particularly if the reviewer doesn’t understand the translation process or doesn’t agree with the content or terminology.

Clive is relieved there is technology to support the in-country review process. memoQ has functionality incorporated into the translation process that tracks reviewers’ changes and comments. This minimizes time and reduces errors that can often be introduced in a manual process.

In memoQ, the **Monolingual review** functionality exports translation documents as Microsoft Word or RTF files. These are sent to reviewers who use the Track Changes and Comment functionality in Word or other word processing programs. After review, memoQ manages re-importing the files into the translation system.

memoQ also has the option of a **Bilingual review** format, so the reviewer can see source and target text side by side in a two-column table. This option is exported from memoQ as an RTF document that can be opened in a variety of word processing programs.

To export a document for monolingual review, use the **Export button** on the **Documents ribbon** and select **Export**.

To re-import the document: If the document is open, close it. In the **Documents ribbon**, select the **Monolingual review button**, and then select **Import reviewed document**.

The reviewed document can also be imported by right-clicking on the document in the list of documents for translations.

When the document is imported, memoQ opens an alignment view where you see both the original segments and the proposed revisions. You can review them and when finished select **Apply review and close**. The reviewed target document will then replace the previous target document.



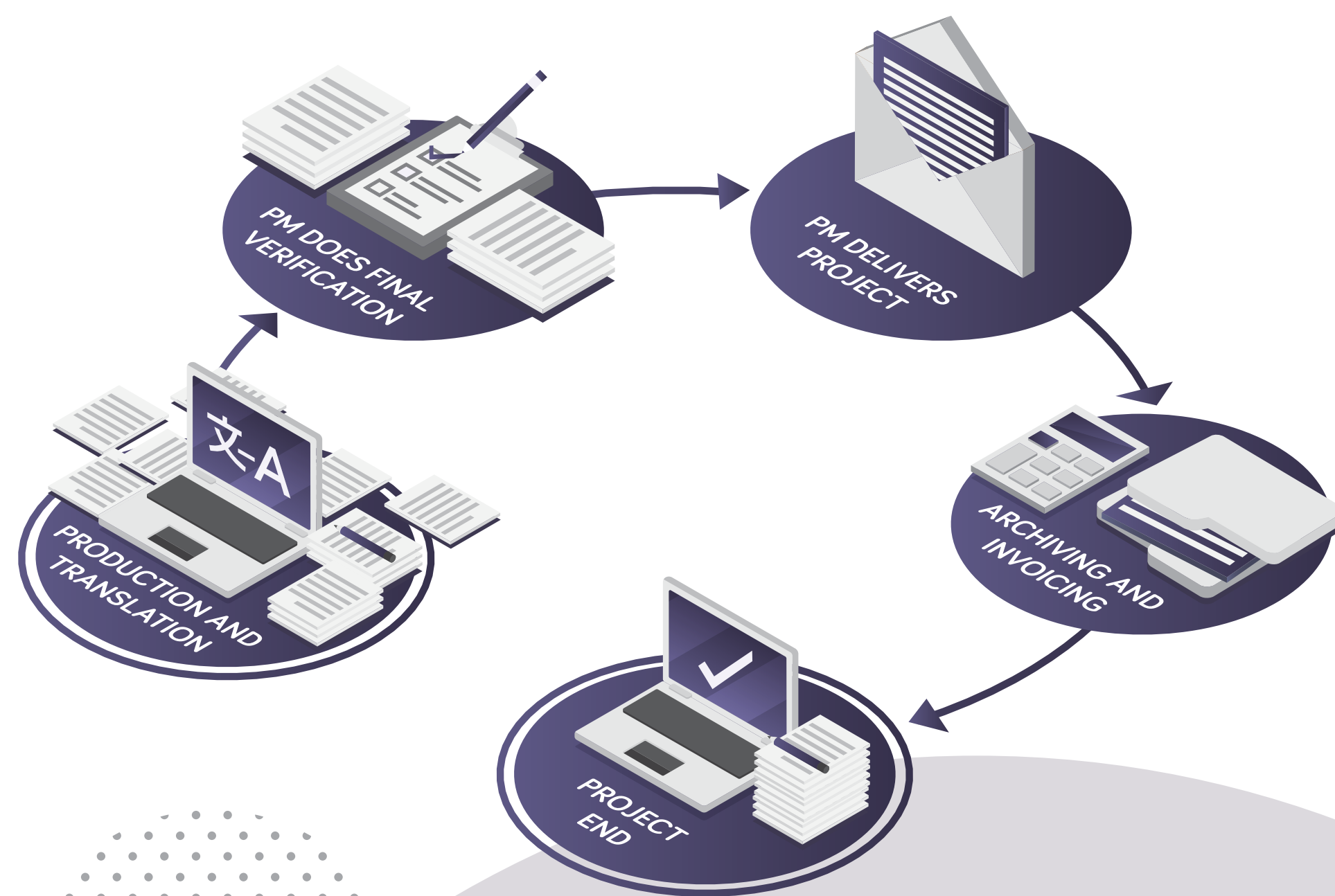
tips & tricks

It can also help to speed up translation cycle (because of fewer in-country review) if there’s a pre-approved list of key terms that should be translated already by the time the project starts.

David Altmann, Director of Sales at NLG GmbH

PROJECT CLOSURE

Closing a project sounds like the easiest of all tasks, but it is far from simple. As project manager, Clive needs to confirm that everything is finished to the satisfaction of his customer. It is very likely that the translation memories, terminology, and other resources will be used for the next projects from FirstAidCo, so he archives these. Finally, there is administrative work to do.





Final verification

Before delivering, Clive will run a series of checks to confirm that the results meet the requirements previously agreed with FirstAidCo. He goes back to the initial agreement and confirms that everything that was requested will indeed be delivered. Clive confirms that suggestions made during the in-country review stage were properly resolved. If a suggestion could not be implemented, he provides an explanation. Clive also checks that the correct file types are used for the translation files and that the content is formatted to meet FirstAidCo's specifications.



Archiving

RightPhrase uses a process that combines a working translation memory and master translation memory. From the start, the master translation memory with existing translations is assigned to the project so translators will have access to previous translations. A working translation memory is created for storing only new translation memory segments. At the end of the project, the translation segments that have been revised and approved are transferred to the master translation memory, which Clive will store for reuse with future projects for FirstAidCo.

The term base used for FirstAidCo is checked so that it will be ready and suitable for use again.

The project itself is then archived. RightPhrase usually archives a project six months after delivery, because this is a typical period during which many projects are revisited for various reasons. They use **memoQ archiving and restoring** features, which automates what can sometimes be a time-consuming process prone to human error.



Administration

RightPhrase holds a feedback meeting after the end of each project. It is usually an online meeting during which the team goes through the different stages of the recently completed project. Their goal is to learn from it and understand where improvements can be made. The meeting is usually attended by Clive, the translators, other team members at RightPhrase, and Matilda from FirstAidCo. Other people from FirstAidCo sometimes attend when they are directly involved in devising a solution to a problematic situation.

The translators working for RightPhrase are independent contractors. They usually send their invoice at the end of the project, although there may be interim invoices during a long project. Clive processes these and coordinates payments with the finance/accounting department. Clive is also responsible for preparing details to be included on the invoice for FirstAidCo that will be issued from the finance/accounting department at RightPhrase.

With these final administrative tasks completed, the project is finally closed.



STANDARDS

In this section we look at standards that are important to translation of life science content, all published by the International Organization for Standardization (ISO):

- **ISO 17100:** Translation services – Requirements for translation services
- **ISO 9001:** Quality management systems – Requirements
- **ISO 13485:** Medical devices – Quality management systems



In 2015, ISO published ISO 17100, the first international standard for translation. This standard sets a benchmark for a translation project and gives requirements that will help ensure good quality translation.

ISO 17100 provides the following:

- A framework for translation project workflows
- The qualifications and competencies that a translator or reviewer must meet
- The requirement that after translation the entire content is revised by someone qualified to do the translation
- Requirements for project communication and project management

Since its publication, many translation companies, particularly those offering services to life science companies, have become ISO 17100 certified.

In this eBook, we use a workflow based on ISO 17100 to illustrate best practices in life science translation.

We divided the workflow into three stages:

- Pre-production
- Production and translation
- Project closure



ISO 9001 is part of the ISO 9000 family of standards that includes:

- ISO 9000:2015 Quality management systems - Fundamentals and vocabulary
- ISO 9001:2015 Quality management systems - Requirements
- ISO 9004:2009 Managing for the sustained success of an organization - A quality management approach
- ISO 19011:2011 Guidelines for auditing management systems



ISO 13485 represents the requirements for comprehensive quality management in the design and manufacture of medical devices. Although ISO 13485 is a modified version of ISO 9001, it does not have the same emphasis on continuous improvement. The terminology used in ISO 13485 is also relevant to the medical devices industry.

About memoQ

memoQ Translation Technologies is the developer of memoQ, one of the world’s most advanced translation environments. Used by hundreds of enterprises and translation companies all over the world, memoQ is the #1 solution to automate and optimize the entire localization process and manage translation and localization projects in a time and cost-efficient manner.

Contact us

Take your life sciences localization processes to the next level. Let our localization professionals help establish or optimize a workflow for you.

Get in touch with us at sales@memoQ.com

Further Reading

Medical Device regulation
in Multilingual FEB/MARCH 2018

Localizing Medical Software – Global UX consideration for medical devices (Multilingual FEB/MARCH 2018)

MT application to localization of life sciences
https://multilingual.com/all-articles/?art_id=2456

Linguistic quality assurance in localization
https://multilingual.com/all-articles/?art_id=2460