Globalisation and the Importance of End-to-end Translation Management

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Most manufacturers are now global in their outlook, as it has become easier than ever for pharmaceutical and medical device companies to market their products all over the world. But global and local regulatory requirements can be complex and varied. Adhering to these is a significant task when registration requires translation of dossier content for each local authority. AMPLEXOR Life Sciences' Nancy Pollini maps out her vision for what an end-to-end translation programme looks like for an international life sciences firm in 2018.

In terms of international trade, the world has never been smaller. Major life sciences companies are taking their products all over the world, from Africa and Asia to Latin America and Eastern Europe – there are few markets left untapped. Such emerging markets present a wealth of business growth potential – as long as organisations can enter each country quickly, cost-efficiently, and at low risk. This means ensuring that registration dossiers and other documentation, including patient-facing materials, are precisely, consistently and accurately translated for each new market in line with the current local requirements.

Some markets are more challenging than others. China requires that all content included in product registration dossiers is translated into standard, simplified Chinese. The translation workloads involved for China alone are immense and speed is often of the essence. It is not unusual to be expected to turn around certified translations for these dossiers within as short a timeframe as two to three months.

Tread Carefully with Local Language Support

A life science firm will typically devolve responsibility for individual market translations of registration documents, as well as patient-facing labels and information leaflets, to local teams, to manage with the help of local translation agencies. This comes with a fair amount of risk, though – significant variation in quality, differences in the look and feel of translated content – which can translate to rising expense and delays.

The first main issue is that these satellite operations primarily comprise sales and marketing staff. Although tasked with growing the business, these people ordinarily will not have the capacity or project management skills to organise and keep on top of regulatory content translations and at the same time, monitor evolving regulatory requirements and their bearing on translations for the local market.

The Ever-increasing Complexity of Regulation AND Language

Even in the more established market of Europe, the demands are so substantial and in such a constant state of flux, that dedicated personnel with the right experience and skills are needed to maintain compliance. Brexit has shown that EU membership isn't set in stone, and such changes in membership could have implications for the dominance of the English language in regulatory administration, once the European Medicines Agency has reoriented itself on the mainland.

Currently there are 24 languages to cater for, for the EU's centralised authorisation procedure. Broadening out to Europe as a whole, including eastern Europe, increases the regional translation burden to more than 30 different languages. When you add in the multitude of languages in Asia, Africa and Latin America, the scale of the challenge becomes clear – whether it be local dialects that must be reflected in patient-facing materials, or variants of French, Spanish or Portuguese required by local health authorities for submissions. Where the translation workload also includes clinical activities, additional considerations will need to be applied to where studies are taking place.

Why Centralised Translation Matters

With such a rapidly expanding translation requirement, an organisation's best hope of keeping its growth strategy on track is to have a holistic, end-to-end approach and system for tracking evolving international regulatory requirements, and for delivering timely and accurate local translations for each target market.

All of this points to the merits of a centralised, systematic approach to the coordination and execution of translation projects. On the one hand, this will enable greater consistency, cost-efficiency and a clear line of sight across workloads and upcoming demands. On the other, it paves the way for additional efficiencies – such as those enabled through the strategic application of technology for helping to process translations.

Improving Time to Market AND Quality

Managed regulatory translation service providers which specialise in life sciences content will have pools of resources, skills and experience that companies can count on and draw on as needed. Moreover, they will also have found ways to accelerate delivery – for example by harnessing translation memory technology: software that can automatically draw on specialist, agreed phrasing and terminology in the target language, from previous use cases.

The longer an organisation continues to use the same provider to manage translations, the faster the output. Over a period of five years, one major life sciences brand saw the rate of leverage (acceleration of output using repeated terms and phrasing) grow from 20 to 60 per cent on translations for Chinese submissions. Apply this kind of efficiency to dossiers running to two million words, and it's easy to see how local registration timescales and translation costs could be reduced so that tight deadlines of 2–3 months can be met with a small, dedicated expert team.

Translation memories belong to the client and are specific to each company, to ensure complete data security and privacy. But, as well as including each firm's specific terminology and references (e.g. excerpts from previous translations for the company), they benefit from regional and country-specific templates and glossaries of standard terms and phrasing. Specialist tools are becoming more and more sophisticated all the time, too – now even including automated formatting checks to meet authorities' respective standards for international submissions. All of which helps to expedite the delivery of high-quality output to ensure prompt, smooth authorisation.

Although widespread, next-generation automation using artificial intelligence and machine learning for medical content is still some way off, given the sensitivity of the content and the 'life-or-death' requirement for accuracy, such capabilities are advancing all the time and, in due course, are likely to add significant value to automated translation opportunities for life sciences. A good translation partner will have this kind of technology built into its technology automation roadmap, for when tools are deemed mature and robust enough to meet the acutely sensitive needs of life sciences/medical content.

Translation and Growth Go Hand-in-hand

Ultimately, regulatory translation activities can be seen either as a cost/necessary evil, or as a gateway to new global market opportunities. With so much at stake – timely access to new revenue streams vs the risk of costly delays or worse (risk to patients) caused by registration hold-ups – it is well worth companies' while taking a strategic position on regulatory translations, and developing a robust, centralised global capability. In reality, quality assurance depends on having ready, uninterrupted access to the right expertise, consistency and capacity; reliable, technology-enabled automation; and confidence-inspiring certification.

As the current decade matures, and as companies' global ambitions expand to encompass substantial emerging markets, life sciences firms are likely to find that they already have too much on their plates to contemplate tracking, project-managing and quality-assuring international regulatory translations and submissions, despite their importance. It is for these reasons that the business case for seeking qualified, co-ordinated worldwide help has never been more compelling.

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