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### **JODI S. CASTRO,**

President and CEO of  
ABC Translation Service,  
talks to *Future Pharmaceuticals*  
about translation services as a  
key factor in the increasing global  
pharmaceutical industry

# SPANNING THE GLOBE

The world of clinical trials is expanding with many patient participants being engaged from sites around the globe. This calls for a clear translation — that is the translation of the study must be contextual and factual in whatever language it is being read. For pharmaceutical companies that do not have this specific expertise, the translation industry can be a link to clear communication.

**Future Pharmaceuticals** What is the role of the translation industry and why is it so critical to the globalization of the pharmaceutical industry?

**Jodi Castro** In clinical trials, the need to find patient participants outside of the U.S. has become increasingly important. With this need comes the requirement for clear and open communication of the study, however, this expertise is rarely a core competency in a pharmaceutical company or clinical research organization (CRO). This is where the translation industry fits into the equation — global communication is the core expertise of the translation industry with specialized communications critical to the successful clinical trial environment.

Additionally, translation services provide solutions to the issues the pharmaceutical industry faces in communicating with world populations. Clinical trial translations are filled with industry-specific terms and specializations which must be understood within the context of the end-user culture prior to the translation. The translation agency offers expertise and insight regarding cultural nuances among each ethnicity and specifically to key disciplines — including scientific, medical, and legal professionals within native-speaking communities. A translation partner navigates the issues related to properly communicating industry-specific language to native-speaking end-users and eliminates costly delays and errors.

**FP** What are the most important aspects/characteristics of a translation service partner to the pharmaceutical industry?

**JC** Choosing the proper language partner is critical to the successful outcome of a clinical trial. First and foremost, it is important that the language partner can provide translations into virtually any language, and has access to a global network of professional linguists. These linguists must be certified specialists in the target market having a complete knowledge and full understanding of

the culture where the clinical trial is taking place. This will play a vital role when recruiting patients and developing proper communications; ensuring consistency, accuracy and reducing the risk for error. An effective language partner must also provide: dedicated project management and key personnel; administrative and standard operational procedures which meet regulatory requirements; and key product deliverables — from patient-enrollment outreach materials and diaries to medical product inserts and labels.

Beyond the ability to fulfill standard business requirements, a true translation partner shares client goals and assumes an ownership for the achievement of these goals throughout the lifecycle of the project. As with any partnership, effective communication from the beginning is crucial to a productive relationship. Having confidence in a translation agency that provides the best possible client service and strategic approach can prove to be an invaluable long-term resource.

ABC Translation Services (ABC) provides the best of all worlds: it has the depth and resources to handle projects of any size, targeting any culture or language in the world, yet it is small enough to provide unparalleled customer service and support, as it has done for over 20 years. ABC has sustained long-term relationships, which inevitably provide work flow efficiencies and cost savings over time.

**FP** How can the translation partner ensure success throughout the clinical trial process?

**JC** Regardless of whether the translation partnership is with a pharmaceutical company or a CRO, early selection and integration at the beginning of the process is the key to long-term success. The translation partner has the expertise and insight, which can help companies avoid potential issues that can adversely affect schedules and costs. Therefore, it is advisable to begin the translation process early during the developmental stage, as this will enhance the outcome and eliminate any delays. The sooner this working relationship can be established, the sooner

the synergy of the partnership can be applied toward the success of the project.

In order to ensure the highest level of accuracy in each and every translated document throughout all phases of the project, it is recommended that the author of the source is accessible “as needed.” This prevents potential delays and even the recall of materials due to misinterpretation, particularly with time-sensitive translations.

On-time delivery of accurate translations is paramount to keeping a clinical trial on schedule and within budget. If one product is delivered off-schedule this will impose an entire project imbalance, as many of the deliverables are incremental. For its part, ABC has the ability to meet accuracy and delivery demands through its extensive global network of several hundred certified linguists translating over 150 languages. It can also maximize efficiency related to time-sensitive material by taking full advantage of global time, which affords 24-hours a day/five day per week up-time in some cases.

The most effective means of mitigating error is to employ stringent Quality Assurance/Quality Control (QA/QC) standards to the translation methodology. ABC uses structured QA/QC protocols throughout the translation process providing a check and balance system designed to ensure that the highest quality translation is delivered. It is recommended that the language partner includes a backward translation performed by their own team of professional linguists before delivering the translation to the client.

In order to ensure success throughout the clinical trial process it is crucial to follow a structured methodology from start to finish during the translation process. The first step we take is to fully assess the entire project and determine the key concepts. We encourage the author to be available to communicate with us throughout the length of the project.

We assign a Project Manager who is responsible for assembling the best teams of specialized linguists. For projects involving the pharmaceutical industry, the translation linguists must also be highly



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trained in very specific areas, such as cardiology, immunology, infectious disease, and oncology.

All of our professional linguists must meet our standards, which are some of the highest in the industry. Linguists are required to be certified, and have at least five to 10 years experience translating material of the required expertise. Each linguist goes through a very strict evaluation; and must have full knowledge and understanding of two cultures and the source and target languages, and may be required to translate a written sample, if requested by the Project Manager or client. Once approved for a project assignment each certified linguist is regularly critiqued on his or her job performance. In order to remain in our active global network of resources, each professional linguist must maintain a perfect track record in overall performance that meets the highest standards as measured by metrics including delivery time, accuracy, and customer/peer service.

The translation begins with a team of three linguists. The first translator will translate the source text into the target language. This will follow with the second linguist who will edit to match the source text, convey the proper meaning of the source document and use proper nuances. The final proofreading will then be done by the third linguist.

Then a second team of three linguists does a backward translation. This step should only be done just before the translation is delivered, as it can cause complications and create errors if a separate team not associated with ABC performs this task independently. The second team will follow the same suit as the first, but they will convert the translated text back into the source language.

When the backward translation is completed, a

third team of linguists compares it with the forward translation, and then the source document. They then make any corrections needed to deliver a high quality translation. They also make notations of these corrections and give explanations for the changes.

The next step is the cognitive debriefing, which allows the final translation to be tested by the target population or audience for comprehension. This “focus group” testing determines if the end-user or patient is able to grasp the concepts appropriately and interpret the proper meaning.

In the final step the project is given to a team of professional linguists who are completely unfamiliar with the project, to edit and proofread objectively on unbiased terms before delivering the final translation to the client.

## **FP** What are some of the tools available to the translation industry to assist in meeting the increasing needs of the pharmaceutical industry and when are they most beneficial to implement?

**JC** It is very important to realize the difference between ‘memory software’ and ‘translation software.’ Memory software — for example, the CAT tool Trados — can be defined as a linguistic database that continually grows and “learns” from the actual translator. All of the previous translations are accumulated, including the source and target text; they are then reused so the same sentence is never translated twice. As this memory builds, the time saved for the linguist increases, which in turn will accelerate the delivery of the project.

The translator utilizes the software by opening the source file; the software extracts the exact

matches and similar — or “fuzzy” — matches and inserts them into the target file. As the translator works through the source file the matches can either be accepted or overridden with the chosen preference of the translator. If the translation unit is manually updated it is stored in the memory for the repetitions in the current text, and also stored in the database for future purposes. This enables the translation to be consistent and saves a lot of time.

There is a difference between translation memory software and machine translations — ABC does not use machine translations. Machine translation automatically translates without human input. These translations are fast, but they are very poor quality. A machine translation does not have the capability to understand subtleties or contexts of texts. Machine translation is also quite limited in the number of languages it can read.

SDL 2007 translation memory software supports almost all languages and the actual translation is done by a professional linguist. The translation memory assists the linguist by providing exact and fuzzy matches from the legacy translation database allowing the translator to work with greater efficiency, consistency and quality. SDL memory translations can be worked on almost all file formats including Microsoft Office 2007, Windows XP, OpenOffice, QuarkXpress, XML and Adobe InDesign.

So, SDL translation memory can be of great benefit to the clinical trial translation, by accelerating the project turnaround, and improving the consistency and overall quality of the project. Translation memory makes the difference when time and quality are the key factors to guarantee a successful clinical trial. **FP**



**JODI S. CASTRO** is the President, CEO and Founder of ABC Translation Services, a full-service woman-owned translation agency located in the Washington D.C. metro area. Her agency began 20 years ago, then called Midwestern Translators. The company relocated to the Washington D.C. area in 1992 and changed its moniker to ABC Translation Services. Ms. Castro has travelled the world extensively becoming fully educated and gaining knowledge of several cultures. Her determination to bring the world together through communication continues to lead to success and gratification. The aim of ABC is to bridge the worldwide language gap — connecting people, businesses, and nations.

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