

# Language Technology

## for Life Science Industries



### Process and data security during the localization of complex content

On the one hand, life science industries such as pharmaceuticals and medical technology are positioned around the world and they market their products internationally. On the other hand, these industries are especially subject to regulatory specifications, also with respect to their product and corporate communication. In order to generate foreign language versions of clinical studies to package inserts on through to marketing, sales, and training documents efficiently and so that they are compliance-conforming, structured processes and central repositories are required across all language variants.

#### Across language technology can help you

- » fulfill the regulatory specifications with maximum process stability
- » bring new products onto the market faster in foreign countries
- » incorporate language service providers into a seamless “linguistic supply chain”
- » integrate the localization of all relevant content directly into your corporate processes

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# MULTILINGUAL CONTENT IN LIFE SCIENCE INDUSTRIES

The products of the pharmaceutical and other life science industries are usually marketed internationally. The adaptation of complex product-related documentation for foreign language versions poses special challenges for these industries.

Technologies for the central administration of language resources and for the central management of translation processes are thus indispensable components of the IT system environment of pharmaceutical and life science companies, also and precisely in case of a partial or complete outsourcing of translation services.



## REGULATORY REQUIREMENTS

In hardly any other industry are the regulations for the creation of product information so extensive and restrictive. These are dictated, for example, by the US Food and Drug Administration (FDA), the European Medicines Agency (EMA), and the Japanese Ministry of Health, Labour and Welfare (MHLW). The International Conference on Harmonization (ICH) strives towards a harmonization.

The standards and requirements to be observed for the international marketing of pharmaceutical products range from project handling according to GAMP/GxP to the CFR 21 Part 11 compliance on through to the guidelines for electronic Common Technical Documents (eCTD) and Structured Product Labeling (SPL) as well as the conventions of the Clinical Data Interchange Standards Consortium (CDISC).

## COMPLEX CONTENT

During the product life cycle, a multitude of product information arises, from the clinical study and treatment protocols to the statistical process control (SPC) and the package insert (PI) on through to the labeling and the marketing, sales, and training documents.

All of this content must be stringent with respect to content, it must use uniform terminology and always reflect the latest state of the information. And this across all languages, document types, and publication channels. Structured product information management (PIM) based on XML technologies lays the groundwork for this and is at the beginning of the linguistic supply chain.

## STRUCTURED PROCESSES

The use of language technology is indispensable for exploiting the entire approval period and being able to put pharmaceutical products on the market in timely fashion despite distributed processing by mother-tongue translators, short update cycles, and time-consuming validation and review processes.

Across Systems is one of the leading suppliers in this sector worldwide. Across solutions help

- » re-use multilingual content consistently
- » manage and automate translation and release processes continuously
- » assure compliance-conforming content
- » integrate upstream and downstream processes seamlessly
- » guarantee a quick time-to-market and maximum process stability in the result

## CONSISTENT LANGUAGE RESOURCES ACROSS ALL PROCESS STEPS

The Across Language Server is the central platform for all corporate language resources and translation management. A translation memory acts as a learning system so that existing formulations can be reused. This recycling increases the consistency and quality of your texts and reduces translation costs by up to 80%.

The integrated terminology system also helps assure maximum consistency across all content. This is all the more true as every unwanted variant is multiplied by the number of target languages.



### **“LINGUISTIC SUPPLY CHAIN” FOR MAXIMUM PROCESS STABILITY**

The Across Language Server oversees the entire process, including translation-oriented composition of source texts, workflow control, as well as translation, correction, and release of content. Regardless of which jobs (if any) are passed on to service providers, the customer is at the beginning and end of the supply chain. Thus, you retain control over your projects and related costs, and over your language resources, which grow with each new translation.

This is especially true of complex processes such as document versioning, relay translation of dependent languages, and follow-up on source-text updates in the translations. Optionally, recurring processes for certain content, document types, or language combinations can be automated.

### **SEAMLESS INCORPORATION OF TRANSLATORS AND EDITORS**

Translatable document formats range from XML/HTML to MS Word and Adobe FrameMaker to layout formats such as Adobe InDesign and resource files for software user interfaces. A multiple-format editor allows translators to concentrate on their core task.

Regardless of whether you work with in-house staff, with translation agencies or directly with freelance translators, Across combines everybody involved into a continuous process and ensures the consistent usage of uniform formulations on the basis of data stored centrally.

### **QUALITY MANAGEMENT ANCHORED PERMANENTLY IN THE WORKFLOW**

While the translation mainly requires linguistic expertise, the review and release depend more heavily on functional expertise. The Across Language Server enables systematic verification of translations and seamless inclusion of the various departments and other authorized parties in the overall process. In this way, translators benefit from automatic checks, e.g. for the spelling and completeness of the target text and reviewers from their review clients optimized for their tasks. There are also appropriate components available for rule-based quality assurance and system-supported adherence to corporate or product-specific formulation rules.

### **MULTILINGUALISM AS AN INTEGRAL COMPONENT OF CORPORATE PROCESSES**

No matter whether you simply want to exchange the data to be translated directly with your editorial or content management system, whether you want to make defined terminology available in the entire company or receive translation jobs via an internal Web portal: open interfaces enable seamless integration in your enterprise IT and the direct incorporation of corresponding processes. There are highly-integrated interfaces from the Across Language Server to a multitude of third-party products, e.g. for data exchange with SAP ERP or for the machine pre-translation of particular content.

## TO EACH HIS OWN ACROSS

### Across Language Server

The Across Language Server is the basic product of Across that is configured and scaled according to customer and application needs.

You can use the Across Language Server

- » as a purchased license for use in your company
- » as a hosted service according to the ASP or SaaS model
- » as a basic technology for corporate language portals

### Across Professional Services

With a competent team of specialists, the Across Professional Services division supports you in making the most of Across technology for your individual needs.

With our services related to consulting, training, implementation, and system integration, we support you through your Across projects, from the planning and introduction, through the implementation.

An extensive network of authorized partners is also available to assist you.

### Additional Information

Visit [www.across.net](http://www.across.net) for testimonials on practical aspects of use, an overview of available partner solutions, and much more.

Please call us for further information, to make arrangements for an online presentation, or to schedule an in-person appointment with Across at your office.



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