Reed Tech, Schlafender Hase® and TVT®

Working Together to Provide World Class Solutions

Reed Tech and Schlafender Hase are leaders in the Life Sciences industry working together to ensure that pharmaceutical companies and their products are compliant with global regulatory standards. These companies work closely together to create a fast, efficient and, most importantly, accurate process for their customers by understanding industry challenges and regulations and creating responsive solutions.

LexisNexis® Reed Tech®

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INDUSTRY CHALLENGES

Pharmaceutical companies operate in a highly regulated industry with countless regulations, mandates and deadlines that require fast turnaround time and, above all, accuracy. Both Reed Tech and Schlafender Hase have become known in the industry for continuously meeting theses high standards.

Industry Requirement

Structured Product Labeling (SPL)) is a Health Level Seven (HL7) international standard for regulatory guidance documents as a method for communicating product and facility information. Accepted by the Food and Drug Administration (FDA), SPL enhances the cohesiveness and honesty of product information because it requires reliable structure and standardized terminology. SPL documents consist of not only the content of labeling (text, figures and tables) but also information about the product (drug listing data elements) that is readable by machines.

The SPL specification was created to assure that there was a consistent way to develop labeling content. By using an established method for product labeling, enhancements and improvements can be attained throughout every step of the process, from the creation to the distribution of labeling content by industry and health authorities. The labeling of products is a crucial part of product life cycle management.

Hurdles of this process?

- **Complicated.** The procedure of product labeling is detailed, complicated and closely monitored. The content that the product label contains is very precise, especially regarding its safety data and adverse effects. With so many parties within the healthcare system relying on accurate information, it is problematic for one party to misinterpret another's message. SPL solves for clear communication with regulated classifications. Many FDA divisions have required SPL since June 2009, including Center for Biologics and Research (CBER), Center for Veterinary Medicine (CVM), Office of Nonprescription Products (ONP), and Center for Devices and Radiological Health (Medical Devices, CDHR). Other divisions, like the Center for Drug Evaluation and Research (CDER), have followed the requirement since October 2005.

- **Cumbersome.** In order to bring a product to market, all files and artwork need to be thoroughly examined not only for mistakes but also to make sure that they include only approved information and that information is in all required formats. This is certainly a grueling process when done manually and can be riddled with costly human error. In fact, when Reed Tech started offering their services, well before structured labeling content conversion, their team completed at least one year of manual proofreading. Due to the rigorous attention to detail, the necessary proofreading required after the conversion of PDF to XML was quickly identified as a bottleneck. They recognized a need for software that would reduce proofreading time and guarantee accuracy. It was also important for Reed Tech to find a company already in the Pharmaceutical industry who had built a solution designed for drug product labels.

REED TECH SOLUTIONS

Reed Tech has created a centrally managed tool for FDA human prescription, over the counter and animal drug product submissions data in Structured Product Labeling (SPL) format.

SingleSource™ for Drug Products is a web-based application developed to 21 CFR Part 11 compliant standards that allows drug product manufacturers and distributors to collect and store their global product listing, establishment facility and labeler company data in an easy-to-use master submission data library.

SCHLAFENDER HASE SOLUTIONS

Schlafender Hase has created TVT®, the Text Verification Tool®, a software that verifies text, spelling, barcodes and artwork. This tool, originally developed in 2003, helps prevent misprints by inspecting files with different layouts and file formats to catch deviations early in the process. Schlafender Hase also allows TVT to be integrated into existing workflows at Reed Tech to ensure that only approved content is printed or published. TVT is designed to be compliant with FDA and EMA by supporting SPL and QRD templates. TVT ensures compliant, error-free and consistent packaging.

THEIR PARTNERSHIP

As a best-in-class solutions provider, it was important to Reed Tech to establish data quality processes using the very best available software tools. The team therefore tested several software programs that claimed to automatically compare Word to PDF and PDF to XML. At the end of the testing phase, the results from TVT, along with its reputation as the best proofreading tool on the market, led Reed Tech to select it from among its competitors as the tool of choice.

The team was impressed with how specific TVT was. They felt as if the software was customized for them and therefore the relationship quickly became more of a partnership. “We are in this world with file conversions and find a company that understands and has the experience within the Pharma industry, so they know they must bring that standard into their product,” said John Lorenc, Sr. Product Manager at Reed Tech. They have been able to grow their business because of positive business relationships like the one they have with Schlafender Hase. Rachel Finley, Supervisor, Life Sciences Services at Reed Tech adds: “If we didn’t have TVT, we wouldn’t be able to include proofreading as part of our services because we could not make the time commitment to complete manual proofreads.”

One of the reasons Reed Tech is successful are the high standards they have for themselves and for the businesses they work with.

REED TECH

Reed Tech offers product and service solutions to help Life Sciences professionals gain control over their own and their industry's data. Our offerings smooth the collection, transformation, submission and analysis of regulatory data for manufacturers and distributors of medical device and drug products and for those who support them in consulting and IT roles. Reed Tech believes that when people and organizations are enabled with technologies that help them achieve regulatory compliance, manage product data and gain insights backed by analytics, the potential to positively impact patient outcomes is unlimited.

For over 13 years, they have been a leader in providing Structured Product Labeling (SPL) solutions and services to Rx, Biologic and OTC professionals to help facilitate the collection, analysis, transformation and submission of data to regulatory agencies.

LexisNexis® Reed Tech®

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SCHLAFENDER HASE

Since Schlafender Hase® introduced TVT®, the Text Verification Tool®, this software has taken the lead in providing intelligent, automated text and graphic proofreading solutions for the most highly regulated industries. Its customers include the world's leading pharmaceutical and medical device companies. Schlafender Hase is currently expanding its focus to bring the same time-saving and increased productivity benefits gained by this sector to pre-media, consumer packaged goods (CPG) and fast-moving consumer goods (FMCG) customers. Schlafender Hase is proud to be known for product quality, service excellence and customer success. Founded in 2001, the company is headquartered in Frankfurt, Germany with a North American division in Cambridge, Massachusetts.

More at **www.schlafenderhase.com**

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