Schlafender Hase®

A SCHLAFENDER HASE WHITEPAPER

Reduce Errors and Costs

Proven ROI with TVT, the document comparison software for life sciences

Intensifying regulatory requirements leave no room for error when putting goods into the hands of patients and consumers. Yet in life sciences, one of the most strictly controlled industries due to implications for public safety, more than 50% of product recalls are caused by packaging errors.

A typical recall event costs a business a minimum of US$1 million and can easily top US$100 million. As goods are recalled, firms risk not only paying the price of lost sales, of corrections and of redistribution, but also of losing market confidence.

50%

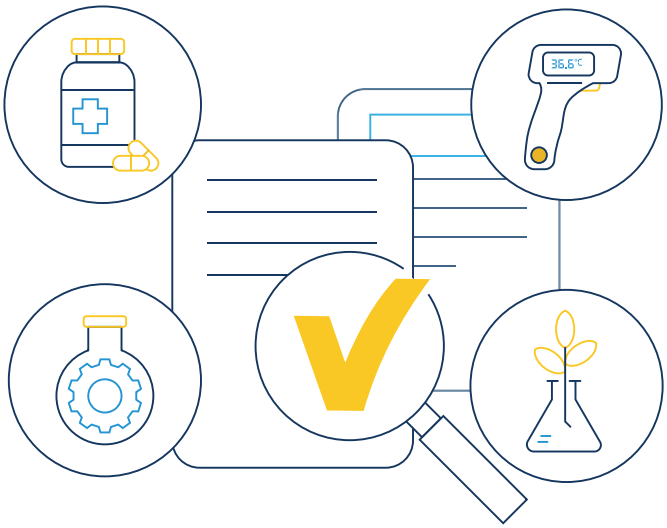
of product recalls are caused by packaging errors

$1m → $100m+

cost of lost sales from a typical recall

Schlafender Hase's document comparison software, TVT, was built for Regulatory Affairs and is the industry standard for life sciences, which has the biggest need for precision and zero tolerance of errors in content.

Having set the standard for proofreading in highly regulated industries, TVT provides a valuable 'best practice' reference point for other industries which now face tightening requirements – including chemical, crop science and cosmetics.



The Dangers of Manual Proofreading

Exposure to error

Humans make mistakes. Even with two or three sets of eyes on a document, proofreaders can develop blind spots, either because they've looked at the same content for too long, or because the task is so repetitive and unstimulating that the brain becomes distracted[1]. Yet even the smallest editing or artwork oversight can have serious consequences. In life sciences, the difference between "store this product at **2-8°C**" and "store this product at **28°C**"; "take **1-2** a day" and "take **12** a day"; or "do **not** chew and swallow" and "do **not not** chew and swallow" could be a matter of life and death.

Exposure to recalls and reprints

A last-minute rework because of a mistake identified late in the process takes time and could delay production, with substantial financial ramifications. It could result in a change in production lines, even being out of stock for several days. For each day that a product is not on store shelves, sales are being lost and competitors have the advantage. In the event of a product recall, costs can range up to and beyond US$100 million, especially if a huge damage limitation exercise by marketing is required.

Hidden costs

Proofreading is a required and crucial part of Regulatory Affairs work; however, manual proofreading (typically performed by one person reading a document out loud while another marks it) is an inefficient use of a professional's time. For example, it can easily take a professional proofreader several days to spot all the differences between two versions of a multilingual IFU (with an estimated 250,000 words), with no guarantee that all differences will be spotted.

The cost per hour of work from the employee doing the proofreading doesn't just include their salary, but also taxes, benefits, insurance, holidays, office space, training, recruitment costs and so on, which can more than double the gross salary.

Language limitations

Markets are becoming ever more global, and it isn't just Europe that presents a range of disparate languages and regulatory requirements; Asia and Africa bring additional demands.

While obviously a native speaker skilled in the local language will be required to verify the accuracy of the language in an original master document, each manual revision of packaging-related documents (e.g. an artwork file in PDF) requires rereading the entire document to ensure that no new errors have been introduced. This adds steps and takes up precious time.

Multiple correction cycles

If a mistake is not identified early in the review process, to multiple correction cycles might be needed. Each correction cycle involves multiple stakeholders and takes time away from other projects.

This is a situation we have heard about one too many times: Things start off great, everything is on time, then a mistake is noticed during the 3rd revision. This is where the pressure starts to escalate, since a mistake identified at this stage is enough to have major implications on a product's release date. When it comes to getting a product out to market on time, there is no room for delays; it must get done. This creates an environment in which Regulatory Affairs professionals are having to work harder. Many work overtime with no additional compensation. This creates a cycle of stress and constantly playing catch up on projects that had to get pushed back.

Workplace realities

A professional responsible for proofreading is expected to review and catch any mistakes in text, graphics, tables, barcodes etc. This is a very detailed job, one that requires expertise, time, patience and uninterrupted concentration. As a busy Regulatory Affairs professional, proofreading is only one aspect of the job and therefore interruptions are inevitable.

According to a study conducted by Berkley University, the recovery time after being interrupted from a complex task is about 25 minutes. If you are interrupted (ex: colleague asking a question, checking your email, eating a snack) just 3 times while reviewing a leaflet, this can easily add 75 minutes to the already long review time.

How TVT Helps With Proofreading

Using a document comparison software like TVT is meant to complement and support the work of Regulatory Affairs professionals by eliminating the risk of human error. It does not replace the need for the professional but allows users to quickly identify errors and inconsistencies in their documentation, labeling, packaging and other materials that can lead to mistakes, misprints and recalls.

Increases Accuracy of Content

One of the main goals of Regulatory Affairs is to ensure accuracy of product information, whereas the main goal of TVT is to find and highlight differences before content gets published or printed. This sounds like a perfect match; once a Regulatory Affairs professional has created a perfect main document, TVT can find the slightest changes and differences between this document and any other text, table, graphic, barcode, whatever the text formatting (bold, italic, font etc.), reading order, and in whichever language, ensuring document consistency across departments.

Typical uses for TVT include reviewing leaflets, labels, cartons, inserts, packaging, submissions, CCDS, SPC/SmPC, SPL, SPM, QRD, IFU/DFU/Manuals, Printer's Proofs, SOPs, comparing translations, Marketing Materials, amongst others.

Reduces the time spent on proofreading

In the regulated life sciences industry, proofreading packaging and labelling is often just one part of a person's job. The time spent proofreading manually is time that highly qualified professionals can spend on other tasks.

Using TVT also saves significant time when reviewing multilingual documents. Anyone (native speaker or not) can run a comparison between different file versions and if any language deviations are identified, then the native speaker can be consulted; if not, the review process can continue.

When a major pharmaceutical company was ordered by the European Medicines Agency (EMA) to check all of the Summary of Product Characteristics (SmPCs) for all of its products, it had a choice. It could hire an army of temporary native speakers for each of its target markets to perform the manual proofreading, a task estimated to take **25-30 people 2-3 months**. Using TVT, the firm accomplished the project in **just three days**, without the need for additional resource or special language skills.

TVT can run any comparisons in just a few minutes. It is then the responsibility of the professional responsible for proofreading to review all the differences found to decide whether they are mistakes or not. This is essential, as TVT cannot make these crucial decisions.

Ensures accountability and transparency

Proofreaders in life sciences occupy a high-risk job. Even the most highly trained and skilled professional reaches his or her limits during a workday. It's simply not possible for one person to find every difference each time.

TVT finds all differences while documenting everything you do. After comparing documents and marking up changes, you can create an annotated PDF of the document showing all annotations and corrections, then save (or print) a project report that outlines everything you and your team have done. This creates more accountability and transparency through a proofreading "audit trail".

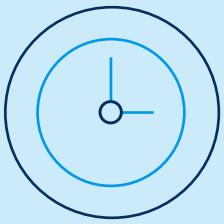
Shortens Review Times

The average number of correction cycles for manual proofreading is 3-4 per submission, but with TVT, you can adopt the right–first time approach. The solution is simple: run a new comparison, and any differences will be highlighted and visible at a glance. You can see whether a mistake have been corrected, and whether new ones have crept in. You won't need to proofread the whole document again manually.

What is TVT's Return On Investment?

With TVT, a typical like-for-like document comparison will take a matter of minutes, versus 3-4 hours if done manually by a human. A customer survey we conducted found that 74% of TVT users save a minimum of **1.5 hours** per comparison.

Based on the usage figures in the survey, companies are saving on average **5 hours per week** versus manual proofreading. Comparing this against the average salary of a Specialist Regulatory Affairs employee with about 5 years of experience (estimated at US$133,796 or €114.069 according to RAPS[2]), this works out to a **yearly saving/productivity increase of US$16,275 or €14.250 per user.**



74%
of TVT users save
1.5 hrs
per comparison

Companies save
on average
5 hrs
per week

Average yearly saving of
$16,275
or
€ 14,250
per user

If you would like to figure out a more specific ROI for your company, please visit our ROI calculator and insert your details: What is my ROI with TVT

At the end of the day, proofreading with a document comparison software is simply more cost effective than manual proofreading, as it mitigates risk by finding mistakes commonly overlooked by humans, and allows resources to be used more meaningfully by saving time and decreasing repetition – all while increasing accuracy and safety by reducing risk.

Sources

1 January 2016: Pharmaceutical Packaging: What You're Doing Wrong - Xtalks

2 RAPS - 2024 Global Compensation and Scope of Practice Report for the Regulatory Profession

Connect with us

linkedin.com/company/schlafender-hase

@schlafender_hase

@schlafenderhase275

facebook.com/SchlafenderHase

www.schlafenderhase.com

Contact us

SCHLAFENDER HASE GMBH

St Martin Tower,
Franklinstr. 61–63,
60486 Frankfurt am Main,
Germany

Phone: +49 69 244 481 0

Email: TVT@sh-p.com

SCHLAFENDER HASE INC.

245 First Street Suite 1800 – 103,
Cambridge, MA 02142–1292,
USA

Phone: +1 617 607 4900

Email: us@sh-p.com