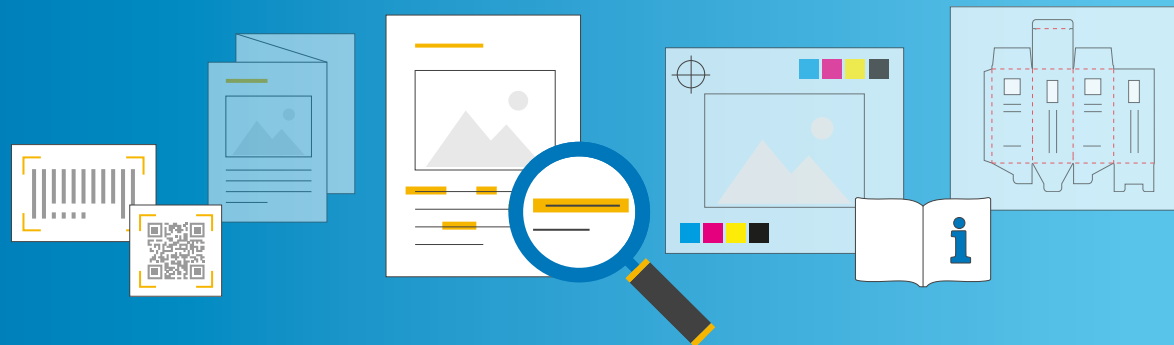


QUANTITY AND QUALITY

Reliable, efficient content verification: The best insurance policy for compliant labeling – in any market, any language, any layout.



Intensifying regulatory requirements leave no room for error when putting goods into patients and consumers' hands. Yet in life sciences, one of the most strictly controlled industries because of the 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 \$1 million, and can easily top \$100 million. On top of the cost of lost sales, correction and redistribution, firms risk losing market confidence and market share as goods are recalled.

It is surprising, then, that critical processes such as the proofing of labels and customer literature are still left to chance today. Relying on manual processes is inefficient and error-prone¹, yet the practice is still commonplace for checking and comparing essential customer information as this content evolves and is adapted for international markets.

At a time when all regulatory hands need to be on deck to cope with wider issues there is a further challenge: companies cannot spare the time spent by highly qualified professional staff on proofing new and revised materials.²

It isn't exclusively the heavily regulated industries of pharmaceuticals, biopharmaceutical and medical devices that demand robust labeling. Food and nutrition³, and consumer goods more broadly⁴, are also under pressure to tighten their labeling to meet increasingly stringent regulatory criteria. This is not only to meet consumer safety targets (e.g. allergens), but in response to growing public consciousness on a range of issues – from the nutritional values of food, to a product's origins.

Until now the options for automating the proofing of label and packaging have not been sufficiently complete and robust to help shoulder the workload. TVT, Schlafender Hase's Text Verification Tool, changes all that. The following white paper explains how TVT differs from alternative approaches, and sets out a detailed business case demonstrating the return on investment that can be expected from the tool which can be deployed in a range of different ways to suit every circumstance and budget.

THE BURDEN OF ACCURACY

Globalization and growing customer consciousness are just two of the drivers causing regulators to increase their demands on product labeling. There is no excuse for compromising public safety through carelessness. Consumers expect transparency too, forcing regulators to respond with new targets for product labeling with additional detail about contents, origins and processes.



More rules, more products

The more rules there are, and the more frequently they change, the greater the scope for error. Similarly, the more products, variants and markets a company is dealing with, and the shorter the release cycles, the bigger the chance that something could go awry with the labeling. Media archives are laden with examples of big names that have fallen foul of regulations, by simply failing to spot a misprint until it's too late, or neglecting to meet new guidelines in a particular market. From children's cough medicines to dietary supplements, the simplest error in how consumers should store or take the product could result in illness, harmful side-effects or even death.

Not all mistakes result in costly recalls, though these are still alarmingly common⁵ and potentially devastating to the affected companies⁶. But even where misprints are spotted before a product has gone to market, there are the cost and delay incurred by redesigning and reprinting the content. If the product is a cough syrup due to catch the winter flu season, a delay getting product onto pharmacy shelves can result in substantial lost sales as customers switch to an alternative brand.



Maintaining quality when outsourcing

Quality assurance pressures have also increased due to a higher reliance on international markets for supply and for outsourced services such as graphic design⁷. Risks include counterfeit products entering the market, or substandard labeling, potentially compromising patient safety and leaving the company open to penalties and loss of face.

Globalization may open up new market opportunities to firms, but it also introduces new commercial pressures. Competition is fierce and as blockbuster drugs can no longer be relied upon for guaranteed revenue streams⁸, all companies are under pressure to keep costs under control to protect dwindling margins.

From a regulatory and quality assurance perspective, this presents a dilemma about how to manage local, in-country operations. Which operations should be centralized, and if affiliates are the chosen route to a market how can companies maintain control over standards and mitigate risk? Although the affiliate may take responsibility for translating labeling and meeting the regulatory requirements in the local market, liability and reputation management remain with the manufacturer/brand owner.

Rather than leave themselves vulnerable, companies should try to retain control of their own proofreading. In many cases they use temp agencies to recruit native speakers in each target language at great expense.

As long as firms rely on manual proofreading for accurate consumer labeling, there will always be the possibility of error.

THE DANGERS OF MANUAL PROOFREADING



Exposure to error

Humans make mistakes. Even with two 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 has become distracted. 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.



People are expensive

Manual tasks such as proofreading are unrewarding, demotivating and a poor use of qualified professionals' time. Yet pharmaceutical companies often employ highly qualified and educated Regulatory Affairs professionals. In addition to their regulatory duties, they are frequently expected to perform the unrewarded job of proofreading. This is quite expensive and an inefficient use of their time.

The cost per hour of work from the employee doing the proofreading doesn't just include the salary, but also tax, benefits, insurance, holidays, office space, training, recruitment costs and so on, which can more than double the gross salary. In the case of graphic designers, there may be additional fees for re-work if the resource is external.

When budgets are tight, and skills in Regulatory Affairs and Quality Assurance at a premium¹⁰, it isn't very astute to be using experts to do menial tasks, however vital the outcome. In the worst cases, people who feel un-challenged or under pressure to do extensive manual tasks on top of already demanding workloads, will leave the organization, and studies suggest that losing a salaried employee can cost as much as twice their annual salary¹¹, especially for a high-earner. Adding to employee's faltering morale is the stress caused by being at fault for an error – errors that are very easy to make, yet equally easy to avoid.



Time is money

A last-minute re-work because of a mistake identified late in the process takes time and could delay the 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 the store shelves, sales are being lost and competitors have the advantage. In the event of a product recall (because the mistake hasn't been picked up in time), costs can range up to and beyond \$100 million; the wider implications are a huge damage limitation exercise by marketing.



Lack of flexibility

Manual proofreading isn't especially flexible. It requires specialist knowledge, native language experts and dedicated, uninterrupted time. It can tie talented people to their desks, and detract from more impactful work.

WHERE AUTOMATION HAS TRADITIONALLY FALLEN SHORT

In the past, attempts to automate proofreading and document comparison – to relieve experts from repetitive, menial tasks – have fallen short. This was due to technology limitations, language restrictions, and insufficient accuracy to fit the purpose.



Document conversion problems

Traditional text comparison tools have clear limitations. They covert files to PDF format and then compare them visually. This option is inadequate for heavily regulated markets. Converting from one format to another is far from ideal: it can introduce anomalies, and the process doesn't allow teams to work from original documents. In addition, document conversion for the purposes of comparison is a violation of GMP processes and can lead regulators to question the validity of comparisons, and the entire packaging review process.



Content corruption

Graphic designers often take the blame for errors caused by conversion errors, because of the different software packages they have to work with. Typically designers will take a Word file, import it into InDesign/QuarkXPress/Illustrator, work on it and then convert it back to a PDF file. The problem is that the various software systems originate from different companies (e.g. Microsoft/Quark/Adobe). The fonts they use may have different names, and even change certain characters (a classic one in pharma is “µg” being changed to “mg” by certain artwork creation software).



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.

Relying on software to read and interpret a human language has traditionally been a challenge, despite advances in technology. The issues are similar to those associated with performing the original translation. As specialist agencies note, “MT [machine translation] is not the way to go. Yes, it's cheap and there's minimal effort required on your part, but at the end of the day do you really want to lower the value of the high quality content you've created for your home market?”¹²



Inadequate levels of accuracy

Where file conversion is taking place, or comparisons rely on certain fonts, language or specialist content knowledge, accuracy starts to suffer. And when teams can't depend on automation for the highest levels of accuracy, their confidence in technology diminishes until they stop using the software, undermining any return on investment. For those users whose necks are on the line, it's better to play safe.¹³



Complexity & cost

Costs and long deployment cycles have also proved prohibitive. Inflexible licenses can drain capital budgets, while the typical software procurement and implementation cycle is 9-18 months.

HOW SCHLAFENDER HASE'S TVT, TEXT VERIFICATION TOOL, IS DIFFERENT

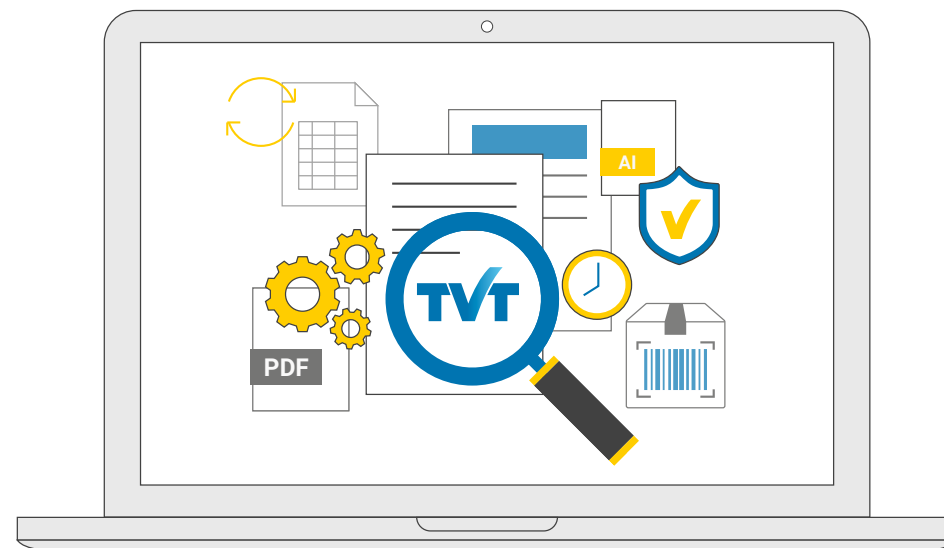
Scope

TVT, a unique software tool from Schlafender Hase, takes a different approach to text comparison. It does not work on the basis of language at all, but rather compares the underlying universal code ('Unicode') – i.e. the international standard agreed across the software industry. This means that, regardless of the format, font or operating system, the software understands what it represents. When it makes document comparisons, it is comparing the code behind the characters – allowing it to compare two files in any language.

Unicode allows data to be retrievable with a simple keyword search in a database or document management system, and allows documents to be transferred to other applications without risk of the content changing or being corrupted.

This offers unprecedented levels of accuracy, and incredible speed. TVT is able to find the slightest changes and deviations, so that these can be addressed swiftly without the need to painstakingly go through entire documents manually.

TVT can handle images too, allowing RA and QA teams to compare logos, charts, chemical formulae, etc., and highlight the tiniest discrepancies.



“ By reducing the correction cycles, MERIAL has gained a faster time-to-market. ”

Hélène Cerutti, Manager Regulatory Packaging Merial, France

Accuracy & speed

Whereas it would take a professional proofreader a week to spot all the differences between two versions of the novel Huckleberry Finn (with an estimated 500,000 words), with no guarantee that all deviations will be spotted, TVT takes just 3 minutes to reliably pinpoint every tiny variation.

When a major pharmaceutical company was ordered by the European Medicines Agency to check all of the Summary of Product Characteristics (SmPCs) for all of its products, it faced hiring 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 from Schlafender Hase, the firm accomplished the project in just three days, without the need for additional resource or special language skills.

“ TVT has the potential to revolutionize how we work in regulatory affairs, dramatically reducing ‘dead’ proofreading time so it can be spent on more value-adding activities. I wish I’d known about this proofreading solution years ago! ”

Jillian Stewart, Regulatory Affairs Manager, Teva, Ireland

Increased productivity

A typical like-for-like document comparison will take a matter of seconds, versus 3-4 hours done manually by a human, even if the language is unfamiliar. This frees up experts’ time for higher-level verification/decision-making and frontline regulatory/quality assurance work. A customer survey conducted by Schlafender Hase found that 74% of TVT users save a minimum of 1.5 hours per comparison.

For example, a company that needs to proofread labels can expect to save on average at least 1 hour per label. In the case of multiple countries and languages, a day per product. Overall time savings exceed 80%.

Based on the usage figures in the survey, companies are saving on average 5 hours per week versus manual proofreading/text verification. Extrapolating this against the average salary of a specialist Regulatory Affairs employee with about 5 years of experience (estimated at \$114,117USD or €71.777), this works out at a yearly saving/productivity increase of \$14,500USD or €9.000 per RA user.

“ Purchasing TVT was a very wise business decision. The software has been an enormous asset to our department. It has cut down on the time it takes to proofread, allowing us to accomplish our goals more quickly and efficiently. The accuracy of this software is amazing. We have found that it catches errors that are impossible to see with the naked eye. The software is very user-friendly, and the support is fantastic. ”

Erika Galiatsos, Corporation Manager, Labeling, Regulatory Affairs, Interchem, Paramus, New Jersey, USA

Flexibility & affordability

TVT is available in a number of deployment options. In addition to traditional user-based and server-based licenses, there is a cloud-based option. This enables companies to procure TVT as a service – an operational expense, with flexible scalability and remote access. For small biotech startups, or companies with a geographically diverse global workforce, TVTaaS offers an optimum solution.

Server and corporate licenses, meanwhile, offer complete control for organizations to internally extend TVT's capabilities for the benefit of other departments, beyond RA/QA, Labeling, Packaging and Graphic Design. Legal, Marketing and Communications teams have their own pressures to ensure content is absolutely accurate, so can also benefit from TVT.

The ability to choose and switch between the different software delivery options may be particularly useful in the case of international roll outs, or to support merger and acquisition activities. TVT can be easily integrated into any Document, Regulatory Affairs or Artwork Management Systems, which provides flexibility and accuracy at any stage of your document review process.

“ TVT is an essential tool for us to ensure our pharma packaging and labeling is fully compliant with our marketing licenses. We started with just a few local user licensees and moved to a fully hosted server model when our global colleagues wanted to share in the benefits and ease of use of this tool. ”

Nick Hill, Senior Director, Regulatory & Quality, EAME Allergan, UK

A heritage in highly regulated industries

Schlafender Hase's software is well established in the pharmaceutical and medical device industry, which has the biggest need for regulatory precision and the lowest tolerance of errors in content. TVT set the standard for proofreading in highly regulated industries, therefore TVT provides a valuable 'best practice' reference point for other industries which now face tightening requirements – including chemical, crop science and cosmetics.

“ TVT's user-friendliness, attention to detail and overall specification to our business played a key role in the decision. ”

Dr. Klaus Menges, Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM), German Health Authority

A PROVEN TRACK RECORD

Once companies witness a demo of TVT, they find the tool speaks for itself. Below is some further client feedback about the tool and its impact across a range of life sciences businesses as they simultaneously address risk, performance and costs challenges:

“ We use TVT daily. We are both a translation and print company and the work this does for our quality assurance in the DTP/formatting process is indispensable. ”

Erica Manning, Project Manager Imperial ClinicaLingua, Grand Rapids, Michigan, USA

“ I’ve been extremely impressed with Schlafender Hase and their Text Verification Tool software. TVT works faster than our previous option and greatly improved our workflow. Schlafender Hase is very responsive and working with them feels like a true partnership. I wouldn’t hesitate to recommend this product and company to anyone. ”

Ross Copp Manager, Product Packaging Janssen, Toronto, Canada

“ TVT is used throughout the global Regulatory department at Gilead. It allows our users to be able to use a standard tool to compare documents quickly and effortlessly. ”

Wendy Diederich, Senior Regulatory Operations Associate Gilead Sciences,
Foster City, California, USA

“ We have been testing and evaluating all known applications for text comparison and electronic proofreading for 3 months. In the end all users and managers decided that TVT from Schlafender Hase is the best software to compare text. It’s robust, reliable, 100% accurate and extremely user-friendly. The service and the support from the Schlafender Hase team is outstanding. ”

Metin Yilmaz, Regulatory Affairs/ Regulatory Operations specialist, CSL Behring, Germany

“ TVT is particularly useful when comparing labelling content across the many European languages. We appreciate having this functionality, as well as the very competent product knowledge and support we receive. Our processes are now much more effective and efficient using this solid and flawless software. Also, the degree of customer support displayed by Schlafender Hase truly created an environment of comfort and a ‘team’ atmosphere. ”

Francisco Fernandez Peñaranda, Head of Section, Parallel Distribution and Certificates,
European Medicines Agency (EMA)

LOGO

LOGO

LOGO

LOGO

LOGO

FOOD FOR THOUGHT

All too often it isn't until the event of a damaging product recall that organizations have recognized the danger of relying on manual proofreading to verify labeling for each of their markets. The fact that companies are leaving themselves vulnerable in this way should be a cause for concern.

Reducing reliance on manual proofreading processes isn't just a risk avoidance or insurance strategy. In life sciences, the rise in merger and acquisition activity and the growing trend of smaller batch numbers and increased drug personalization means label demands are soaring and becoming more complex to manage.

At the same time, the more the public becomes safety, socially and environmentally conscious, the greater the pressure for firms to be transparent and more detailed in their labeling and collateral. Each new demand, each new regulation multiplies the burden on Regulatory Affairs, Quality Assurance and Marketing to be responsive, accurate and thorough. From a business perspective, these new demands cannot drive up costs or slow time to market, leaving companies with no option but to tighten processes and streamline workflow.

TVT from Schlafender Hase meets all of the needs and more – in a range of flexible delivery options that support both companies' existing needs, and their requirements as they might evolve in the future – whether that's towards increased centralization or a greater reliance on outsourcing.

To find out more about TVT's capabilities or deployment options, please write us: [Let's Talk About Your Proofreading Needs | Schlafender Hase](#)

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