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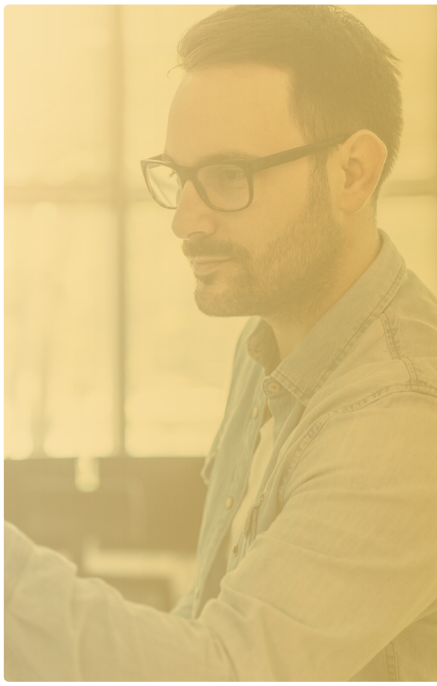
Case Study

Identifying local label deviations and ensuring global and local compliance for pharmaceutical companies

A Fortune 100 pharmaceutical company approached Acolad Life Sciences for help in resolving a critically important compliance issue related to deviations in local labeling of its products in various languages around the world.

The Challenge

Maintaining compliance at both the global level and local level is a tough challenge facing most drug makers. The creation of local labeling is a process where errors can be easily introduced. For example, local translators or authors might misinterpret what is stated in the companies' prime reference document, often the Company Core Data Sheet (CCDS). In addition, occasionally, extra elements are added because local health authorities require country-specific data to be included in the local label. This can often happen in a decentralized model where local operating companies/division are in control of the local labeling. It's a common hurdle for global regulatory teams to jump. How do you know if your local labeling is compliant with both minimum company requirements and local health authority requirements?



In this case, our customer realized they had lost sight of the state of the local labeling of its products in various locations and did not know what was being submitted to local health authorities. This situation created the possibility that labels carried different information or instructions to patients.

Before approaching Acolad Life Sciences, our customer conducted field tests and gathered a significant collection of local labels for evaluation. During their review, our customer discovered a discrepancy between their CCDS and the local label. This disparity caused our customers to realize they needed additional assistance to research and rectify any labeling discrepancies.

Acolad Life Sciences was tasked with creating a solution to identify instances of non-compliance in local labeling and correct any discrepancies in order to achieve regulatory compliance in all current markets.

The project scope was extensive as it encompassed the company's entire global drug portfolio, including approximately 100 countries and 50 different language combinations. It also required identifying all discrepant information and correcting all issues classified as significant or critical by the relevant health authorities in each jurisdiction. The timeline for this project was 18 months.

The Solution

The experts at Acolad Life Sciences studied the challenges to determine the best course of action to fit within the required 18-month timeframe. Like most pharmaceutical companies, the customer went through a traditional labeling process:

- Creation of the drug product's CCDS and listing all information about the drug, ranging from dosage instructions to clinical trial results.
- Distribution of the approved CCDS, in English, to the regional regulatory groups.
- Then each regulatory group takes elements from the datasheet and creates the local labeling, in the relevant language, to ship with the product.

Acolad Life Sciences quickly realized the process needed to address this customer's requirements did not currently exist and required to be created. Acolad divided the new process into three distinct areas:

1. Retranslate

Translate all local labeling back into English. In order to accomplish this task, Acolad Life Sciences brought in 400 linguists to translate almost 3,500 files or labeling, and more than 13 million words from 44 separate language combinations, translated into English.

2. Linguistic review

Review of all translated Prescriber Information and Patient Information Leaflets to assess compliance with Reference Safety Information documents. Any issues with local labeling were reported to the customer. This review consisted of 1,370 files and almost 13 million words in 35 language combinations.

3. Labeling assessment

Pull all current active artwork – defined as anything that ships with the drug such as Patient Information Leaflets, Prescriber Information, bottle labels, cartons, blister packs, pre-filled syringes, packaging, and pouches – to identify errors in labeling. Acolad Life Sciences developed a 20-hour training course that required the linguistic assessors to methodically check each piece of artwork against a very detailed assessment template. This process allowed the customer's medical risk assessors to review the findings, determine the risk of any identified deviations, and identify artwork that needed to be updated or corrected.

Acolad Life Sciences partnered with the customer to establish minimum content requirements for all artwork. After the artwork assessment was complete, Acolad Life Sciences provided the customer with the findings and recommended revisions needed for the artwork to be compliant with local health authorities. After Acolad Life Sciences provided the customer with the results, the customer performed an internal audit to determine the severity of the deviation. Acolad Life Sciences used 200 assessors to review 21,000 pieces of artwork from 95 countries in 47 language combinations. The labeling assessment constituted more than half of the overall project.

The Results

At the end of the 18-month project, the customer passed its Health Authority inspection with praise from the inspector. The customer also saw significant financial savings – more than $500,000 in translation memory savings and almost $750,000 in volume and process refinement savings solely due to Acolad's innovative thinking and creative problem-solving.

$500k

translation memory savings

$750k

volume and process refinement savings

Acolad Life Sciences continues to provide ongoing services to maintain compliance, such as interim labeling checks. A quality assurance check can be performed even if the artwork or labeling is still being developed in-country, thus allowing our customer's Global Regulatory Affairs department to maintain visibility of the state of the local labeling at the time of labeling implementation.

The Acolad Life Sciences Difference

Our customers faced a potentially severe compliance issue with inaccurate or incorrect local labeling for their products, with possible fines and loss of revenue and/or margin. Acolad Life Sciences strategically partnered with this customer to offer process insights, improving the overall workflow from creation and approval to translations and production. By combining lessons learned from the initial labeling audit with Acolad's unique service offerings, we created a new centralized labeling process to avoid this potential compliance issue. The process removed managing label translation control from local countries and returned control to the company's Global Regulatory Affairs; thus, ensuring visibility throughout the process and allowing products to meet local requirements while maintaining global compliance. Transitioning to a centralized process offers pharmaceutical companies efficiency gains in quality, timelines, and short- and long-term costs.

Since the initial project's conclusion, Acolad Life Sciences and the customer are working together to implement this new workflow process throughout the company so that they can maintain visibility and control in the future.

In addition, Acolad Life Sciences is supporting their customer to research, collect, and categorize country-specific requirements for labeling components. This comprehensive data does not exist in one single place anywhere in the industry. The data collected will also be used as the basis for the future implementation of structured content authoring and management of regulatory and local requirements, which Acolad Life Sciences can also support through their Life Sciences Solution Suite.

For pharmaceutical companies facing this kind of challenge in their regulatory affairs and supply chain, Acolad Life Sciences brings **a unique blend of services and software that allows us to offer an end-to-end solution.**

Discover more about how Acolad can support your unique translation needs!

Reach out to us today →

acolad.

hello@acolad.com

www.acolad.com