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Tracking and implementing label changes are crucial to the lifecycle of a marketed drug product.

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Safety and efficacy data of a drug hold a key position in the entire drug lifecycle. Handling labels for vast product portfolios, regularly tracking label data and changes, and meticulously implementing changes at both artwork and supply-chain levels can be challenging. But, despite the risks involved, many companies are tracking their label data through local trackers and legacy tools rather than using modern technology. This article discusses some of the problems that can occur and some best practices for labeling workflows.

For a marketed product, the change triggers received from disparate sources tend to increase over time owing to the product's momentum in the specific market. These triggers, despite their source, are crucial because their impact could extend to local labels and corresponding artwork. It is important for marketing authorization holders (MAHs) to track all of these triggers, regardless of their execution/implementation. Going further, the significant task for MAHs can be:

- scrutinizing and categorizing the triggers as per the safety- and non-safety related parameters,
- assessing the safety and non-safety related changes,
- identifying the potential labeling processes that could be impacted, and
- implementing the changes within the timelines.

Change assessment

A critical safety-related change could potentially impact all the downstream labeling processes (i.e., core, local product documents [LPD], and artwork). Hence, it's important to track these triggers and to assess how critically they may impact the other areas of labeling. Inefficiency in doing so can lead to compliance issues as submission timelines may be exceeded, leading to further repercussions. In the current industry practices, companies track their data

manually in local trackers, which could be helpful to an extent. However, this practice is risky if the frequency of triggers is high and if the product portfolio is large. In such a scenario, it's advisable for companies to use a centralized system to track all the variations/triggers, assess their criticality in real-time, and identify the processes they may impact, if implemented.

It is also important to assess the documents that could be impacted at each functional level (i.e., core and local/regional labels). At the core label level, changes can be applied to company core data sheet (CCDS), and company cores safety information (CCSI) documents, and at the local/regional label level, changes can be applied to product information, promotional material, the inserts, and so on. Some changes may also be extended to the artwork.

Functional-level linking

At each functional level, a link must be established between the trigger and safety- or non-safety related change and the impacted areas of the label. If the change extends to all the downstream processes, then there must be a consistent link between the core labels, local labels, artwork components, printing, and the non-printing components (i.e., supply-chain items). Depending on the linkage and its robust incorporation, there is a possibility of tracking the supply-chain items even after they've been dispatched from the warehouse. This process might, in fact, enable the possibility of reverse tracking of finer items back to the upstream processes. **Figure 1** shows an ideal workflow for labeling processes, to ensure end-to-end tracking at all levels.

Figure 1. Ideal workflow. Images courtesy of the author.

Notifications

Current industry practices, however, are too conventional to achieve this level of granularity in tracking for several reasons. One reason is outsourcing of downstream activities (e.g., artwork and supply chain). In such cases, even if the inflow of data is managed efficiently, there is a possibility that the link between the changes and their subsequent processes could be lost. Moreover, if the notifications sent out to the stakeholders are manual, there could be a delay in aligning with timelines, leading to compliance issues. Right from the time a trigger is received to the time it is implemented in the core documents and distributed, all the stakeholders (global, local, artwork, and supply-chain teams) must always be notified on the procedural progress. Without a robust system in place, notifying all the stakeholders in real-time could be hard to achieve.

Deviations

Another dimension to efficient tracking is to be able to manage deviations. Both content deviations and timeline deviations have their own significance and must be tracked, regardless of their approval/disapproval status. It is important to maintain a record of health authority correspondence linked to these deviations. This aspect is critical for tracking and it has timeframes fixed to it for on-time submission of local documents to the health authorities.

Solution

Companies should integrate sophisticated technology solutions in their labeling operations, using a system that can accommodate and track the data from the time a variation is received to the time it is incorporated into the labels and onto the artwork. This level of tracking can be achieved if the product registrations are linked to pack sets and pack sets to printable/non-printable components, which in turn are linked to the finished products. This linking would ensure comprehensive label traceability.

About the author

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