WHITE PAPER

Reduce Labeling Content, QC & Tracking Challenges

For companies, product labeling is a highly regulated and complex process that is an integral part of the overall quality system. Labeling errors, mix-ups and misbranding are among the most prevalent labeling errors that can lead to product recalls. The results can be damaging to an organization in terms of loss of revenue and market share, as well as negative publicity that can severely tarnish a company's image including fines.

Most of this is a known story for labeling teams. Labeling leadership should move towards digital & automation and away from "same-old document" world. COVID showed all companies the overall possibilities, opportunities and risks as well. So labeling teams should not aim to go back to "normal" status-quo when it comes to labeling.

A product with a wide geographical footprint requires labels in each country/region to comply with the requirements of local agencies. This increases the risk of having inconsistent information across labels of the same product. As per latest market reports 33% of product recalls are due to labeling documents.

Some content challenges include:

Labeling Content related issues:
• Significant delays to submit safety changes
• Delay in updating patient information documents
• Delay in available of superseded versions of labels and patient information
• Data updating from core data sheets to national labels
• Label change request review and approval
• Health Authority comments updating
• Timely updating of label text (safety information)
• Priority issues between global & local RA teams

For most organizations, the primary processes involved in developing a product labels are manual, labor intensive, and prone to mistakes and additional (sometimes in the name of Oversight) QC layers. Moreover, the processes are time consuming, with multiple stakeholders such as medical, regulatory, legal, manufacturing, and quality specialists need to be involved in each label update. This increases overall costs and additional time for any company.

Benefits of Labeling Automation & Digitization tool

Label Content Management & Life Cycle Automation

In order to find and implement text in different formats and languages, organizations utilize key resources to first make a side-by-side comparison of the documents, and then update the local label. This is both labor-intensive and error-prone. By using technology, differences are automatically highlighted between the labels, significantly reducing operational costs, and improving quality and time-to-market due to the steep reduction of human intervention. Labeling software should generate country specific labels "automatically" to save time for authors and minimize QC

CCDS Management

System need to have provision for template design for various labeling processes. Certain business rules need to be generated and implemented internally. System shall have the provision to create, update/edit and review the CCDS, and more importantly should allow to generate automatically various regional labeling documents. Based on data updated in CCDS, version management should also be maintained for updates.

Compliance Check

Tool should have built-in country regulations (Regulatory Intelligence) & local requirements of multiple regulatory agencies. This will help finding deviations and label violations easily and timely without having to do a large manual reconciliation projects.

Reports Generation

Tool should generate various reports for labeling change documents such as format/administrative changes, safety changes, version changes, compliance issues, HA updates, and so on. This is crucial during the marketing in multi geographical areas to capture or knowing the required information.

Multi Format Document & Comparison (Internal/External)

Tool should have the provision for document comparison (document level & section level, internal & external) in either format of word, pdf and excel. The observation can be found in both color indications and document mode (download).

QC Review Process

System should allow to reduce QC time by at least 75%

Publishing and Format Checks

Since each HA having its own requirements for labeling, document formatting is also one of the critical and key aspects during the label publishing and submission. For example the formatting requirements in final published labels are different from FDA to EMA, thus the final labels of (USPI & SmPC) must be in line with the given standards of Health authorities. Systems should generate these automatically and minimize below mentioned labeling specific formatting issues.

Labeling Formatting related issues:
• Inconsistency during label updating
• System compatibility (alignment)
• Style guide checks (regional/local requirements)
• Manual format updates
• Cross references & bookmarks
• Style guide specific checks (text size, font, style, line space, bold, …)

Each formatting mistake may cause errors that result both in publishing and submission issues. In addition, more chances to get deficiency letters from health authorities because of these. This causes additional rework for any company in terms of time, resource and cost. To overcome this manual and time process, tool should generate these formats automatically.

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