Key process elements to achieve successful artwork

Nooru Raju, Artwork - Senior Manager, Freyr Software Solutions, explains and addresses some of the pressing critical artwork challenges and the implementation of key process elements to produce error-free artworks consistently with minimal effort

Pharma and life sciences companies are governed by the global Health Authorities with stringent quality norms. With years spent on innovating new drugs the life sciences organisations, due to tight timelines, sufficient time may not be available for artwork design processes, which may result in an incompliant product presence. In such scenarios, a company's well-defined artwork management system plays a key role in curtailing the possible compliance setbacks. With defined regulatory artwork processes, organisations can sustain such critical situations, especially in time-bound pressures.

Introduction

Being an intrinsic part of the pharma product supply, the Artwork process always goes through constant pressure to deliver accurate output in a compressed time frame. Even minuscule errors (such as misplacement of a decimal point) can be costly, damaging, and puts companies at risk owing to the threat of product recalls, health authority warnings, and fines. According to the data by the US Food and Drug Administration (USFDA) over a six-month period, there were a total of 455 recall notices, of which 51 per cent were attributed to mislabelling and 13 per cent to faulty packaging, which sometimes root back to Artwork inefficiencies.

Due to tough regulatory requirements and heavy investments in innovative or generic products, pharmaceutical and life sciences companies across the world must have established and defined artwork processes in place that guarantee zero errors and secures timely approvals for quick market entry of the products. These can truly be possible by implementing technology-driven robust processes that help to efficiently integrate the areas of repository management, data management, label regulatory control, authoring, and design control.

Artwork process challenges

It is quite evident that when it comes to Artwork management there are certain challenges. If these challenges are not timely addressed, there is a risk of regulatory fines and recall, increased time-to-market, loss of competitive position, and damaged brand equity. Here are a few of them:

1. **Compliance burdens:** Artwork and labelling compliance is probably the biggest challenge for pharma companies of any size. From keeping abreast with the ever-evolving local or regional regulatory authority updates to adapting to the new market requirements is a huge and complex task. For a company, whose core focus is to innovate medicinal products, it is challenging to track the regulatory updates.
2. **Recall risks:** Product recall is a terrible experience for a manufacturer. As per research, it is believed that more than 50 per cent of product recalls are due to labelling or artwork packaging, and more than 60 per cent of all recalls are caused by human errors. The consequences of product recalls are dire. Also, such errors may cause serious risks to patient safety, which may result in fines, reputational damage, and even job losses.
3. **Multiple artwork revisions:** Reworks can be costly, time-consuming and ultimately cause delays in the artwork review and approval process. When a job card is initiated without much information on the drug, there will be delays and errors, resulting in rework. Also, reactive and poor communication are the major reasons that cause unnecessary revision cycles that consume resources bandwidth and delay the artwork design output.
4. **Poor tracking of the process:** The artwork process flows across many facilities and regions globally making it difficult to track. Hence, it is challenging to track accurate information and report and measure performance. It calls for a necessity for process centralisation, to enable visibility throughout the product lifecycle for identifying any bottlenecks and process inefficiencies.
5. **Difficulty integrating with partners:** Integrating with partners and global expansion will be highly difficult to achieve without a standardised artwork workflow. Also, improper communication with the partners results in more reworks that delays the entire process, which in turn may cost much to a partner.
6. **Delayed time-to-market:** Poor stakeholder visibility, inefficient processes, and difficulty in ensuring the completion of mission-critical tasks along with all the challenges mentioned above can put the artwork creation and approval process at a source of risk resulting in delayed market entry. The consequences of delays can be significant and costly.

An ideal artwork process workflow

To secure a compliant marketplace manufacturers must follow an ideal workflow for artwork. It can be like:

Implementation of key process elements for successful artwork

Pharma artwork is a complicated and lengthy process as developing the product itself. Implementation of standardised process elements and automation can protect organisations from vulnerabilities and accelerate their existing workflows. Here we discuss some of the key elements to achieve successful artwork.

Aligning unstructured data: Many pharma and life sciences companies are still using traditional methods such as spreadsheets to manage their artwork and approval processes. It necessitates routing of printed documents, which host a lot of risks and inefficiencies, through emails and folders. These documents can easily be lost, damaged, or misplaced, costing valuable time and resources. Also, therein such cases, it becomes difficult to find out which document copy is the most recent. Without a proper version, it is never clear that your spreadsheet has been routed to the right parties for approval.

A well-established document management system working in a closed-loop can save the day. It helps to keep track of all the required documents and provide the required right version at the right time with proper electronic signatures validated and drives a higher level of accountability.

Streamline artwork process: Pharma must have an ideal artwork process to come up with error-free artwork with quick time-to-market. Therefore, organisations must move towards standardising and harmonising the existing processes. It helps in creating and developing artworks under a common platform in a standard way.

Standard Operating Procedures (SOPs) also play an important role in regulating and operating processes and workflows. Creating result-driven SOPs can outweigh the challenges, monitor the entire lifecycle, improve overall performance and provide right-first-time artwork.

Transform to automated/digital artwork management: The traditional Artwork management process has been cumbersome. There are still many companies using the old manual processes for Artwork management. Incorporating an automated artwork approval process into your product lifecycle can help you deliver on-time, quality work consistently. Automation acts as an aid for manual work. An automated tool can help teams to apply their attention to moving the projects forward and speeding up time-to-market.

From original documents to graphics and design layouts to finished materials, automation can quickly verify the diverse components. Text verification tools can ensure error-free documents. Such automated solutions are readily available and easily leveraged to transform productivity and optimise outputs.

Enable regulatory compliance: There are various regional compliance standards, language differences, and consumer needs that make the artwork process increasingly difficult. It is crucial to keep track of the ever-changing regulations with an audit trail of all projects with the help of a digital tool to ensure compliance with regulations such as ISO certifications and 21 CFR Part 11. Hence, the tool should maintain a permanent record of the entire project, including all approval points, status, dates, and users involved in any critical route. It helps users to monitor output and streamline processes within their divisions, as well as with their supply chain partners and consumers.

Conclusion

In a nutshell, product artwork and packaging play a critical role in the market entry of medicinal products. With quick time-to-market, a product's influence on consumers and brand recognition can be maximised. It indeed is highly recommended to implement the process elements in a best-structured way.