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Short communication

Optimization of packaging artwork management within the Pharmaceutical Quality System

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Introduction

In the highly regulated pharmaceutical industry, the management of packaging standards and artwork documentation represents a critical element of the quality system (World Health Organization, 2002). These documents directly affect regulatory compliance, patient safety, and product integrity throughout the product lifecycle. The preparation and approval of artwork documentation involve multiple activities and requires close collaboration among several departments, including Regulatory Affairs, Quality Control, Procurement, Quality Assurance, and qualified packaging material suppliers (printing houses). Due to the complexity of the process and the large volume of data transferred between multiple documents and stakeholders, there is an increased risk of administrative errors, version inconsistencies, and discrepancies in packaging material text.

The aim of this paper was to analyze the existing system for managing standards and artwork documentation, as well as to identify opportunities for process optimization to increase efficiency, improve data control, and reduce the risk of errors arising from manual data entry. Special attention was given to the review of packaging standards and to the management of data repeatedly transferred from approved artwork documents through different stages of the process.

Process analysis and identified challenges and improvements

Packaging artwork and labelling encompass the visual presentation and organization of product information on pharmaceutical packaging materials. These include primary and secondary packaging. A systematic artwork approval process is essential for ensuring labelling compliance within the pharmaceutical industry. Artwork change control is a critical element of the pharmaceutical quality system. A structured change control framework ensures that all updates are intentional, validated, and compliant with international standards (EFPIA, 2025).

The artwork change control framework includes the following stages:

1. Initiation: Submission of standardized change request, QA review.
2. Impact Assessment: Risk evaluation (FMEA), Regulatory analysis.
3. Approval: Controlled authorization with full documentation.
4. Implementation: Artwork update with strict version control.

The process of artwork design and approval consists of the following steps:

1. Product requirements and regulatory needs are defined, and approved source content (SmPC, PIL, Labelling) is collected.
2. Packaging layouts are created in accordance with the text approved by the National Agency for

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Medicines and Medical Devices (ALIMS) as reqired by Ministry of Health of the Republic of Serbia (2011, 2018, 2023).

3. Pre-approval review of artwork is conducted by Regulatory Affairs and QA. The text is compared with the version approved by ALIMS
4. Final approval of artwork
5. Preparation and approval of Packaging Material Standard - controlled document based on approved artwork and packaging specifications.
6. Approved artwork and Standard are stored with complete audit trail, version control, and compliance documentation.

Approved artwork is compared with print proofs to ensure the absence of deviations prior to production. The artwork approval process in Alkaloid d.o.o. is performed manually, which may lead to delays and errors identified during the final stages of production. Since the text is approved by ALIMS, such errors may result in batch recalls, repackaging activities, and additional costs for the company.

Vemuri and Gupta (2013) have shown that several factors can contribute to these errors, including: insufficient personnel training, multitasking and workload pressure, inadequate decision-making, ambiguity in communication and human errors during manual data transfer.

During the analysis, the steps of preparation, review, approval, implementation, and archiving of artwork documentation were considered, as well as communication between the relevant organizational units involved. Challenges related to data duplication across multiple documents, version control, change management, and consistency between approved artwork, standards, and the final printed packaging material delivered by the approved supplier (printing house) were analyzed. Additionally, the impact of manually transferring data from artwork documentation into packaging standards and other supporting documents was evaluated regarding the potential for human error and increased administrative workload. Process analysis identified final approval as the critical stage most vulnerable to errors caused by repetitive manual data handling. Therefore, a detailed verification checklist was implemented prior to final QA approval. The checklist ensures thorough verification of both visual and technical elements, including product name, packaging material code, revision code, dimensions, grammage, paper fiber direction, PIL folding method, labels, typography, printing colors, EAN code, Pharma code, batch number, expiry date, blue box requirements, Braille lettering, and print markers. In addition, the checklist verifies compliance of the packaging text with the version approved by ALIMS. Completed checklists containing all essential information serve as the basis for the preparation of packaging material standards.

Conclusion

The analysis of packaging artwork management within the pharmaceutical quality system demonstrated that manual workflows are highly susceptible to errors, delays, and inconsistencies that may compromise regulatory compliance and patient safety. Recent technological advances enable automation of critical activities such as version control, change management, and approval workflows.

Manual artwork management processes can be significantly improved through automation and implementation of Packaging Artwork Management (PAM) systems. Integration of AI-based technologies, including natural language processing for text verification, computer vision for layout and color inspection, and predictive analytics for risk assessment, can reduce human error, accelerate approval timelines, and strengthen regulatory compliance. Such technological improvements enhance efficiency, traceability, and overall quality of packaging artwork management while reducing the risk of costly recalls and supporting patient safety.

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