

Essential Checklist for Artwork Compliance



Content Accuracy

Product Information

Verify that the product name, active ingredients, strength, and dosage form are correct.

Indications and Usage

Ensure that the intended use or indication aligns with approved claims.

Legal Statements and Warnings

Check for required safety warnings, contraindications, and precautionary statements

Instructions for Use

Confirm clarity and accuracy of dosage instructions and any administration details.

Expiration Date and Batch Number

Ensure placement and readability of expiration dates, batch numbers, and other traceability information.



Regulatory Compliance

Labeling Requirements

Confirm that all mandatory labeling requirements for the target market are met.

Local Language Requirements

Verify that the artwork includes approved translations for all languages required in each market.

Font and Style Conformity

Ensure compliance with specified font sizes, styles, and legibility standards, especially for critical information.

Country-Specific Regulatory Symbols and Logos

Check for the correct use of regulatory symbols (e.g., CE mark for the EU, FDA for the U.S.) as needed.



Artwork Integrity

Document Comparison

Use document comparison tools (e.g., [TVT](#)) to detect deviations from the approved text and artwork.

Image and Graphical Elements

Confirm that images, logos, and other visual elements meet quality standards, are in the correct format, and align with brand guidelines.

Barcode Verification

Validate that all barcodes, including QR codes, DataBars, and GS1 barcodes, are correct and functional for traceability and anti-counterfeiting purposes.



Brand and Design Consistency

Brand Guidelines

Ensure adherence to brand guidelines, including logo placement, color schemes, and fonts.

Consistency Across SKUs

Check that design elements, layout, and information presentation are consistent across all SKUs, as applicable.

Graphic Sensitivity Settings

Ensure that the software sensitivity settings for artwork comparison are set to detect subtle differences in colors or graphics (use high-sensitivity levels as needed).



Technical and Quality Control

File Format and Resolution

Confirm that artwork files meet print-ready specifications, including file format (e.g., PDF) and resolution requirements.

Final Proof Review

Conduct a final proof review, ensuring that all edits have been applied accurately without introducing new errors.

Compliance with Printing Standards

Ensure compliance with printing standards for colors, bleed, and cut lines.



Approval Documentation

Record of Approval Signatures

Maintain documentation of all required signatures and approvals in compliance with regulatory standards.

Version Control

Ensure that the latest approved version of artwork is clearly marked and documented.

Audit Trail and Change Log

Keep a log of all changes made to the artwork, with an audit trail to ensure traceability for regulatory audits.



Post-Approval Verification

Pre-Market Label Check

Before printing, conduct a final check of pre-market labels to catch any remaining deviations or errors.

Post-Market Surveillance

Plan for ongoing monitoring and feedback collection to catch any artwork issues that may arise after release

Compliance Confirmation

Verify that packaging artwork remains compliant with new regulations or changes in regulatory requirements across target markets.

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