

Artwork Creation & Control of Printed Packaging Components

processes used for the creation, approval and version control of labelling text, graphics and artworks, and for supply of these to the appropriate packaging sites.

These procedures should address the responsibilities for change control and maintenance of document archives and databases for labeling text, graphics, artworks and approvals thereof. The role and responsibilities of contractors should be included, together with the responsibilities within the company for interfacing with the contractors.

5.3 Graphics and Artworks Created by a Packaging Site/Contractor on behalf of a Marketing Company

When the Graphics Unit involved is not part of the Marketing Company, written agreements should be in place to describe the responsibilities of the Marketing Company and the Graphics Unit involved. These should address the responsibilities for change control and maintenance of document archives and databases for labelling text, graphics, artworks.

When the Graphics Unit involved is part of the Marketing Company, the above agreements may be replaced by written procedures approved by the departments involved - see Section 5.2.

Each Graphics Unit should have written procedures in place to describe the processes used for the creation, approval and version control of graphics and artworks (based on market approved labeling text).

5.4 Interface with the Printers, Quality Assurance and Release of Printed Components for Packaging Operations

Packaging sites should have written procedures in place that describe the processes and responsibilities for:

- the receipt of approved artworks (from a Marketing Company or from the sites own Graphics Unit)
- the supply of artworks to printers
- the receipt and quality assurance of printed components
- the release of printed components for packaging operations
- the correctness and quality of text and graphics that may be printed during the packaging process.

These should include change control procedures to manage securely the replacement of superseded versions of artworks, printed components and associated packed stock with new approved versions, in a timely and regulatory compliant manner, together with the destruction of obsolete printing plates, stocks of printed components, etc.

The procedures should also address the processes and responsibilities for the printing, quarantine and supply of samples of new or revised printed components that may have to be produced to obtain approval from regulatory authorities/agencies before they can be used in finished products.