Ink and Identity: The role of Labelling in Branding Success

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ABSTRACT
Labelling and printing play a vital role in pharmaceutical industry. Labelling and printing are part of pharmaceutical industry from ages, labels provide various information to the consumer such as instructions, manufacturing date, expiry date, directions to use, storage conditions, manufacturer information. There are various types of labels. Labels can be applied in various methods hot melts, semi-automatic, fully automatic. Now a days there an enhancement in the pharmaceutical labelling and printing such as barcode, QR code. Labelling and printing should follow various regulations and guidelines according to GMP for better outcome of product.

Keywords: Labelling, Branding, Section 21 CFR 820.80(b), 21 CFR 820.70(f), 21 CFR 820.120, 21 CFR 820.30, QR labelling

Introduction

PHARAMCEUTICAL PRODUCT LABELING AND PRINTING

Pharmaceutical product labeling plays a vital role in product labeling in pharmaceutical industry. Label may be the only source of instruction on the product consumption, pharmaceutical labels usually require perfect and fine details and printed on certified substrate. The pharmaceutical labels contain contents of the product, directions to use the product and safety features, products identity, strength, quality, purity. Labels help in identify the product and describe them, they help in proper handling and storage of product.

FIG 1: PHARMACEUTICAL PRODUCT LABEL
Medication Labels 101: Categories, Regulations, and Best Practices - Caresfield Blog

IMPORTANCE OF LABELING

The labeling process is one of the critical and vital part of pharmaceutical manufactured products. Label acts as a unique identifier to ensure authenticity of health care professionals. Labeling is a printed information that provides identifications of product and detailed information of the product, labeling helps branding of a product. Label gives information about official product name, active and inactive ingredients with quantity, use, warnings and allergic reactions which makes it convenient for use of product.

HISTORY OF PHARMACEUTICAL PRODUCT LABELING AND PRINTING

It started in early 20th century where very basic labels were printed manually and attached to the containers, as time passed technology advanced printing methods got evolved which included offset later letter press and it got advanced in which digital printing got introduced. The advancement of these technologies allowed more detailed and standardized labeling which included drugs name, dosage, usage instructions and varies parameters of the product.

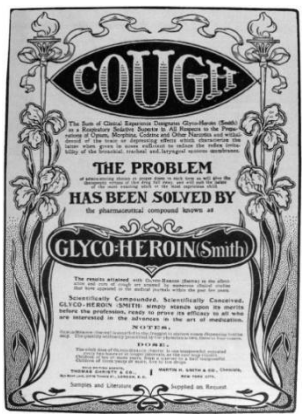

FIG 2: LABELS DURING 20TH CENTURY

In mid-20th century Food and Drug Administration regulatory bodies required more comprehensive and standardized labeling and pharmaceutical product, this made improvement and development in labeling guidelines, labeling content and format. Later in 1980's was an era in which the introduction of barcoding technology such as UPC (University product code) was introduced, which made better tracking and inventory management of pharmaceutical product. This technology helped in patient safety by reducing medication error.

In late 20th century and early 21th century there was rise of digital technology, this brought about integration of electronic labeling and printing systems which allows more customized and

Source detailed labelling. This technology paved way for the inclusion of QR codes and Radio frequency identification technology for better product information.

HERE ARE SOME OF THE GUIDELINES WHICH NEEDS TO BE FOLLOWED IN PHARMACEUTICAL LABELING AND PRINTING

Pharmaceutical industries should follow Quality Assurance program in various elements to meet the demand of GMP required in quality system regulation such as adhesion, legibility etc. QA program make sures that labeling is under controlled system so that proper labels are printed and used.

Various sections of Quality system regulations on labeling have a huge impact such as:

- Section 21 CFR 820.80(b) - inspection and testing of materials which includes labeling.
- Section 21 CFR 820.70(f) – for maintaining proper design and sufficient space for labeling operations.
- Section 21 CFR 820.120 – it is for the specific requirements of labelling control, it applies to inspection, handling, storage and distribution of labelling. If these requirements are not met then FDA considers a device to be adulterated.
- Section 21 CFR 820.30 – this is designed history file, specification are required in design history file for the physical design and content parameter of labelling.

SPECIFIC REQUIREMENTS FOR LABELING

- Receipt and Inspection – In receipts of all kinds of packaging and labeling materials which includes preprinted container should be examined and acceptance activity must be performed. Designated individual(s) are allotted to proofread labeling samples. The acceptance activity should be recorded in device history record as per 21 CFR 820.80(e) and 21 CFR 820.120 to present that inspection and proofreading were performed.
- Label Integrity – Designs and application of labels to the devices and containers should remain in place and legible during conditions like distributions, storage, use, user instructions.
- Storage – All required labelling materials including preprinted packaging materials, preprinted containers and labels should be stored in a manner such that it doesn't mix up (21 CFR 820.120). Labels should be segregated and identified to prevent the mixing up of similar looking labels.
- Changes – Changes to labelling should be made according to formal change control system similar to the specification21 CFR 820.30(i). Before implying the labels must be formally rechecked and authorized. While changes are done to the per primary aspects and documentation, the review group should check if any secondary things like labels or instructions are affected.

TYPES OF LABELS

Labels appear in a bottle or product, which gives best information about the product. Various materials like paper, fabric, plastic and foil are used for labels. Choices of the labels will depend on the need of the economy, some of the labels can directly printed on the containers of the product by silk screen or hot transfer process. Different kinds of labels –

- Paper labeling – Many labels are printed on papers because it is most economical method, but in case of paper labeling there is a limit to the colors and technique which can be used.

FIG 3: Paper label of a pharmaceutical product
pharmaceutical-paper-labels.jpg (500×500) (imimg.com)

- Foil labels – It is necessary to laminate foil with paper so that labels work properly in labeling machine, for best results the paper and foil should be together with measure 0.0025 to 0.003 inch.

FIG 4: Foil label of a pharmaceutical product
3-250x250.jpg (250×250) (imimg.com)

- Transfer labels – Many processes are present for transferring heat sensitive inks from preprinted strips to the container.

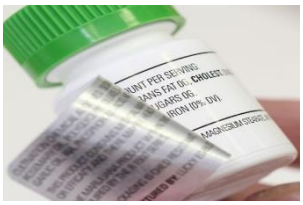

FIG 5: Transfer label of a pharmaceutical product
Peel-Labels-PTM-Label.jpg (440×400) (ptmlabels.com)

- Sleeve labels – They help in product protection and product identification; they have combination of designed prints usually metallic or surface prints for eye catching graphics. Sleeve labels virtually complexes the curves of any product shape. There are two types of sleeve labels – stretch band and shrink tubing

FIG 6: Sleeve labeled pharmaceutical product
http://tauruspackaging.com/market/pharmaceutical/

PHARMACEUTICAL LABEL PRINTING

Every label is not similar, different kinds of application need different digital technology and this is the reason printing is one of the vital reasons around the world. In pharmaceutical labels

printing is done on certified substrates and need a specified attention for anti- counterfeiting and even for brand protection. For the protection of brands label converters needs to have an additional measure to protect their brand by micro texting images and so on. Pharmaceutical labeling needs fine detailing and description and one of the recommended digital technologies is *Dry toner technology*. Major things which need to be considered in label printing: –

- Image quality on the pharmaceutical label – In the pharmaceutical product, labels should be legibly seen, even the smallest words and numbers should be clearly visible which requires a high-resolution printing technology.
- Brand Protection – In order to protect the brand label converters and brand owners combine different technologies to have an affective protection, they try to make unique labels which helps in easy identification and differentiation.
- Certified Substrates – In most of the cases brand owners certify the substrates in the pharmaceutical industry. Requalification is due to the alteration done to the compositions, which have a huge impact to the owners and as well as printers.

METHODS OF APPLYING LABELS

I. Hot melts – In this method glue is applied on the board, on the brush and the labels are placed up on the glue, later they are removed manually and stuck on the container, this is very simple method to apply a label.

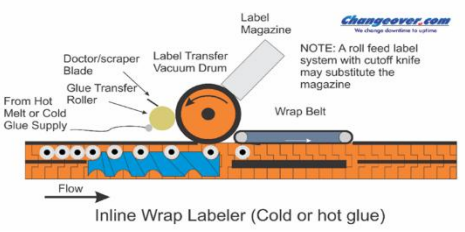

FIG 9: Hot melt method of applying label
5-31-19-Whitepaper-Cold-glue-labelers.pdf.

II. Semi-automatic labeling – In this method container is placed in position and the machine applies the label. Speed of the operation is based on how fast the operator can remove the old product and place the new one.

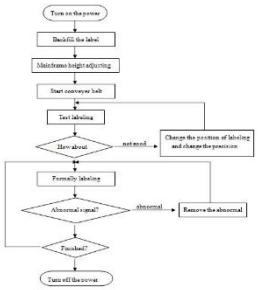

FIG 7: Semi-automatic method of applying label
HTB1zo0sIpXXXXbvXFXXq6xXFXXXp.jpg (503×552) (alicdn.com)

III. Fully automatic labeling – Fully automatic labeling machine is useful to place the label in round shape around the product. Products of different diameters can be placed in the same machine. The vital feature of machine is if diameter of the body changes, then machine also operates conveniently.

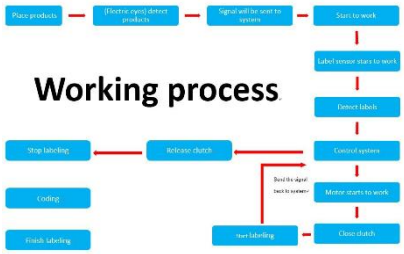

FIG 8: Fully automatic method of applying labels
The working principle of automatic labeling machine - Xinxing Label

CURRENT TRENDS IN PHARMACEUTICAL LABELING

Pharmaceutical labeling plays a role in pharmaceutical packing industry, pharmaceutical labeling has evolved to accommodate a new demand in pharmaceutical industry. Here is some of the latest trend of pharmaceutical labeling: -

- Stringent Quality Certification – For quality control we see lot of certifications and automated inspections to prevent errors and eliminate the poor pharmaceutical labeling. Drug errors and medical errors which lead to fatalities are due to mislabeling and print defects, due to these pharmaceutical industries should follow ISO, cGMPs, 100% inspections and full automation in printing labels for pharmaceutical products to avoid labeling errors.
- Counterfeiting Protection - Pharmaceutical industries are bringing adding convert images, descriptions and verifications strategies for labels to prevent from counterfeit protections.
- Accessibility – Pharmaceutical labeling should have information which is necessary such as usage instructions, disposal instructions, allergy warning, emergency care contact information and expiry date due to rise in self-medication by patients. The printed information must be clear legible to the patients, this information makes the product patient friendly.

QR CODES THE TREND SETTER

QR codes also known as Quick Response Codes are 2D barcodes that are printed on labels of product which contain information about the product. The QR codes can be scanned at any point to get the information digitally. QR codes on the pharmaceutical labels are effective, simple and gives significant impact in making the pharma industry more secure.

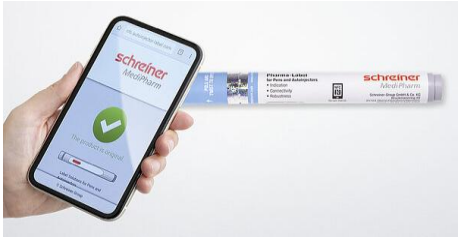

FIG 3: Paper label of a pharmaceutical product
Source

QR code on label in each level of packaging stores data or information which is readable with software applications and also fascinates tracking and trading. The stored data or information should have:

➢ Unique product identification code	➢ Name and address of manufacturer
➢ Name of API	➢ Batch Number
➢ Batch size	➢ Brand name
➢ Date of manufacturing	➢ Date of expiry.
➢ Manufacturing license number	➢ Serial shipping container code.

Why should pharmaceutical companies include QR code on medicine or drug packaging-

- ➢ QR codes adds additional information of product details on the product labeling.
- ➢ QR codes on label of the product when scanned shows video information about the product.
- ➢ QR codes on label encourage the patients to ask questions.
- ➢ Verifying product authentication can be done using QR codes on labels.
- ➢ For over-the-counter drugs QR codes can be used to inform the patients about the product information.

WHY DID GOVERNMENT MANDATE QR CODES-

On 18th January 2022, the Gazette notification was issued by the Ministry of Health & Family Welfare, which says that “Every active pharmaceutical ingredient manufactured or imported in Idia should have a QR code on its label on each and every kind of packaging which contains data or information about the product with a software to facilitate their tracking and tracing”. Scan the QR code to get the label on your devices:

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