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Review Article

# A REVIEW ON ELECTRONIC ART WORK MANAGEMENT

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**ABSTRACT**

Packaging material design plays a pivotal role in pharmaceutical companies. Investments on packaging increases day by day in the industry. Art work management plays a crucial role in packaging process. This process includes designing of lay outs, form filings and approvals. These all tasks run through a manual process which leads to defects and delays which results in huge losses. Errors in printed packaging material is one of the major consequence for product recall and complaints. Facing these consequences, replacing the affected products and handling the associated litigation runs in millions. Export of pharmaceutical products into different countries takes place in large scenario. Each of these countries have their own specifications and requirements regarding packaging. Manual process cannot satisfy all the requirements also cannot keep up with such variations. Any errors in package work flow causes hindrance in validation process. Human errors and insufficient data regarding packaging process result in recalls which further cause hindrance to the growth of pharmaceutical companies. In order to cope up these challenges an automated art work process should be incorporated by them. This aims at automating the entire process from design to print. It overcomes the tedious and lengthy artwork procedure and provides accurate data by eliminating defects. With electronic form fillings, global online approvals and version controls, the process of art work becomes faster and better.

**Keywords**: Art work, Automated art work, Electronic form fillings, Global online approvals and Version controls.

## INTRODUCTION

It has been anticipated that the costs associated with pharmaceutical packaging can represent up to 70% of the cost of the finished product. In addition upon assessment it is found that about 35 to 40 percent of all pharmaceutical product recalls are endorsed to packaging and labeling errors and omissions. Currently report by AMR Research showed that in a six-month phase last year, the Food and Drug Administration data contain 455 product recall notices, 51 percent of which were as of mislabeling, and 13 percent were because of faulty packaging.

By the above statistical data it can be clearly understood that packaging plays a very crucial in launching of drug products into market. The Artwork Creation Process is a decisive part of the product introduction or relaunch of existing products. Without packaging a new product could not be sold, and devoid of changed packaging a relaunched product would not create any consideration. Therefore the packaging artwork design must not be underestimated since a cool product won't sell with poor packaging [1-4].

## DISCUSSION

### Art work management

Artwork and Packaging Management is the process of managing packaging changes as per customer brief and adapting artwork from their source language to create artwork in different languages. Creating correct artwork is an activity that requires many groups to act collectively in a schematic way to deliver a victorious result, on time.

Artwork-related processes are conversed under three distinct areas, in an attempt to make things clearer.

The three areas include:

**Core Process**: The primary activities concerned in defining and accomplishing individual artwork changes.

**Interfacing Processes**: Those business processes that relate directly with the core process, and will have a control on the core process and may be adapted as a result of this interaction.

**Supporting Processes**: The business processes that are requisite to support the core process and other artwork capabilities.

**High level core process steps:** Art work process is a very decipherable process to anyone involved in quality systems.

**1. Create Local Language Text**

Create and grant local language source text document(s) for each of the packaging components to be produced or modified.

**2. Define Change**

Define exactly what is essential to be created or modified as part of this change.

**3. Produce Artwork**

Produce a new or revised artwork that obeys with the requirements defined in the Define Change step.

**4. Produce Printer Proof**

Produce a modified artwork file that can be used openly in the packaging component printing process. This file differs from the artwork created in step 3 in that it is modified to include all features that will permit it to be successfully printed via a specific printing route.

It is likely to eliminate this step through the use of a print ready process.

**5. Implement**

Ensuring that, at minimum, the first time a new or changed artwork is used to create packaging components for use in the manufacture of real product, that they are correct [7-9].

This process of artwork approval is frequently handled manually, leading to delays and defects found at the ultimate stage of production. The approval through emails, spread sheets, or FTP also has significant precincts. Many errors occur due to this manual art work process and due to this many recalls occur and in the Life Sciences industry, drug recalls encompass a big impact on cost and brand image for various organizations.

Various causes are responsible for this errors and some of them include:

- Lack of competence.
- Lack of quality time.
- In appropriate decision making.
- Ambiguity.
- Errors in source information.
- Human error.

**Lack of competence:** When the operators do not have any necessary skills, knowledge or instructions required to perform the business process assigned to them, then it leads to errors in the content of art work.

**Lack of quality time:** Sometimes it does not matter how competent people are but if they have no enough quality time to perform the required task then they are likely to perform errors in the form of one or another.

**In appropriate decision making:** People will make inappropriate decisions during the implementation of the business process which lead to errors in the resulting artwork.

**Ambiguity:** The artwork process involves many individuals providing complete instructions to other individuals in the process, which results in opportunity for ambiguity in these instructions to lead to errors in the artwork. Deficit of templates or instructions on how to pass on information and instructions in an unambiguous way can be examples of this type of issue.

**Errors in source information:** If erroneous source information is used in the process then it is highly likely to cause errors in the resulting artwork.

**Human error:** A typical artwork process consists of many steps where people are directly responsible for carrying out activities such as: transcribing information from one source to another; performing multiple complex or repetitive tasks. So many mistakes may occur due to natural tendency of human to make mistakes.

To ensure the correct artwork version with all necessary approval, the process of approval must be automated, without leaving any chance for mistakes. . Leading companies use packaging artwork management (PAM) software systems to significantly reduce or eliminate these errors while ensuring that packaging artwork development keeps pace with product development [5-8].

When comparative analysis is done regarding manual work flow and email work flow, electronic art work management , automated one has advantages in many aspects as depicted in the below chart1 and table1.

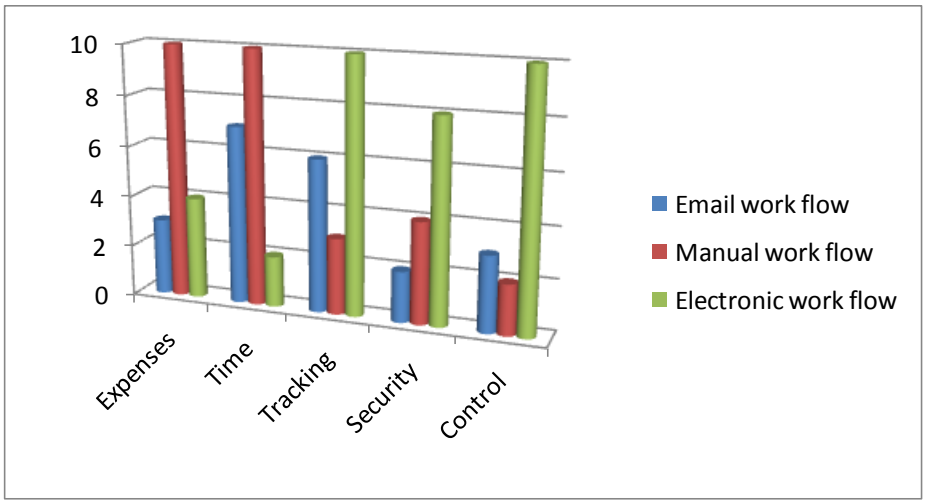


**Chart 1: comparative analysis of email, manual and electronic work flow" [8]**

**Table 1: Benefits of electronic work flow [7]**

| Expenses | Time | Tracking | Security | Control |
|---|---|---|---|---|
| Low operational costs. | Instant approval & collaboration. | Easy to track and trace | Secured data and communication | Supreme control on entire work flow. |

**Electronic art work system**

This web based system is used to handle the approval process of Artworks for companies dealing with many brands and product categories. It is built to be a customizable, robust system with features like User management, Master data inputs, Work order initiation, Artwork review and commenting, Collaboration between approvers, Managing artwork versions, Send approved artwork and source files for print production, Archiving of artworks, Reports in detail, Status notifications, Deadline reminders etc.,

**Art Work Life Cycle Work Flow**


**Fig. 1: Art work life cycle work flow [8]**

**As depicted in the Figure-1 the art work life cycle flow comprises of the following sequences of steps:**

**Change management:** With the Change Management module in AMS it is achievable to get an improved overview of the artwork process from start to end. With the registration of a Change Request and links to allied artworks, the User will from one page in the system easy see the current status.

**Work files:** Artwork work files can emerge in many different formats. General file types are PDF and Word used for documents, drawings, labels, leaflets, etc. The AMS system however can hold work files of any kind. Each and every file is imported into the system and marked as the starting point, (manuscript) for a new artwork.

**Review proof:** Somewhere in the organization, or even externally if outsourced, a graphical department is designing or amending an artwork, creating a "Review Proof" of the new artwork to be. This proof is then assessed by one or more users through the AMS system where any required changes are described and attached as annotations. All these annotations are archived & attached to each proof, the system can retain an audit track of all requested changes. For each new assessment round, new annotations can be added and previous annotations can be copied from the previous proof. All annotations are also marked with date and time of when created and with User ID for an entire trace to the reviewer.

**Content control:** AMS system uses the Content Control method which is an electronic proofreading utility. As a new proof has been amended the reviewer has the option of using an automated comparison tool to evaluate the content of the file with any previous proof or version. The comparison tool can also be used to read and compare the text from the annotations with the text on the customized artwork. This to authenticate that the artwork has been changed according to reviewer's notes. The result of the comparison is displayed both graphically on screen and within a printable report including the artwork file image viewing the exact location of all deviations.

**Version management:** A primary feature of the Artwork Management System is the version handling which keeps track of all created drafts and versions of an artwork file. The version management also regulates all approvals and authorizations of new artworks.

**Work flow:** The life cycle for artwork such as labels and leaflets can be complex. There are many instances involved in the process; marketing, regulatory, quality assurance, to mention a few. The traditional timeline from change request to printed material can be time-consuming, especially in global companies serving many markets with the implementation of an Artwork Management

System, the workflow configuration utility, will help you define unique business processes to manage different requirements from markets, customers, regulatory authorities, etc.

**Delivery inspection - receipt control:** As an ultimate measure and to assure correct delivery of the printed artwork, an automated inspection can be carried out by scanning a sample of the printed material and comparing it to the Authorized Version stored in the electronic archive [8-14].

**Key features**

The electronic art work system is built to be a customizable robust system with the key features such as Digital asset management, Digital briefing process, Virtual package design, Electronic color management, Copy certification and translation, Automatic art work generation, collaborative art work management, On demand visualization etc,.

**Digital asset management:** Many companies face a great number of challenges in their efforts to manage brand assets globally and this occurs largely because Companies lack visibility into their brand asset portfolio, Brand consistency is difficult to enforce across the supply chain and there is no proper repository for capturing brand assets, product information and work flows. Automated art work flow faces all these challenges by gaining control over all brands by creating centrally managed repository of all brands and it gives more visibility into their entire portfolio and greater control over its execution.

**Digital briefing:** The briefing process is basic to achieve the goal of "right-first-time" implementation of packaging and artwork. Companies face considerable barrier to streamline the briefing process due to incomplete and inconsistent information, insufficient coordination between creative and technical requirements, inability to re-use existing briefs, specifications and work product from previous projects. Leading companies are implementing automated process to optimize the briefing process and to unite their creative and technical strengths over the life of a product and also include the creative and technical information required for "right-first-time" execution in a single brief that links to all disciplines concerned in packaging and artwork development, including legal, marketing and product development teams

**Virtual package design:** Package design is an increasingly vital component in consumer product innovation. Most packaging design projects struggle to meet deadlines and recurrently exceed their budgets. But companies using automated process can manage the package development process more efficiently. Using automated wizards, they can create a master pack structure that specifies all the required elements for any package or package family. These templates simplify the process of creating new packaging while ensuring that all designs are fit for purpose. Digital prototypes can be routed for comment and approval using CAD-neutral 3D visualization tools that dramatically decrease design cycle time and cost by eliminating the need for physical prototypes.

**Electronic color management:** These tools remove the complexities of managing colors that are complex to constantly produce and maintain by providing accurate color standards that are accessible by design groups, packaging development, quality assurance and printers.

**Copy certification and translation:** Errors in translation are a general cause of delays. Copy certification systems give packaging label designers an automated workflow combined with stored common phrases. These tools help lessen copy development time associated with translations.

**Automatic artwork generation:** In situations where packaging artwork teams are forced to produce a final product very quickly, they can turn to artwork generation tools that can produce error-free artwork through standardized label design templates and certified copy. While automatic artwork generation is not suitable in all cases, companies can significantly reduce time and costs by automatically generating art files.

**Collaborative artwork management:** For most companies, artwork review and approval is a prolonged process and study conducted shows that just the artwork approval process can consume more than three weeks. Companies can efficiently manage the growing volume and complexity of artwork by establishing a web based that provides collaboration, information management and workflow capabilities. It electronically links all artwork and labeling to the product brief and pack structure – both of which are dynamically linked with all brand assets, product formulation, regulatory requirements and production constraints. Desktop collaboration tools and virtual work spaces based on standard technology make it possible to perform virtual label reviews. Digital workflow streamlines the approval process by alerting reviewers when artwork is ready for review and instructing them on which aspects of the artwork they need to endorse. Electronic sign-off and a full audit history make sure the transparency and accountability throughout the process. By leveraging technology, companies can dramatically reduce costs and decrease pack development time while increasing quality of the finished product [6, 9, 15-16].

**Integrated artwork management for printed packaging material**

Package artwork development is also a critical part of the product development and commercialization process. Many problems occur during art work management and we often listen the problems such as that company is waiting for artwork to manufacture the product or still they haven't received art work approval so that they can't launch the product. As companies speed up the product development engine with the use of product life cycle management (PLM) systems, packaging artwork development process has also to be improved a lot. PLM helps strengthen the product development machine but often does not sufficiently deliver on improving the development of packaging and artwork. Leading companies work out this problem through the use of specialized PAM systems that complement their PLM system.

PLM's strengths are traditionally in project portfolio management, product data management, and the integration of authoring and design tools as described in the figure 2. Since specialized packaging

artwork development capabilities are not always a competitive strength for PLM systems, a significant capabilities gap exists. The graphic below illustrates how a PAM solution can fit within a PLM platform and provide specialized functionality that supports the needs of a firm's packaging artwork development process [17-18].

The implementation of an Artwork Management System supports the complete artwork process, from change request and development to print, combining the strength of a standardized platform with powerful tools for review, version control, automated proof-reading functions, structured filing and user access [19].

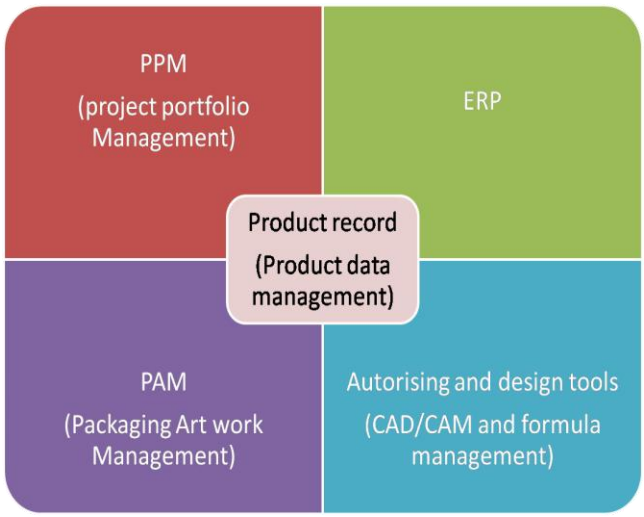


**Fig. 2: PLM Tools [18]**

**Benefits of art work management**

Packaging often is the most important part of a product, often more important than the product itself. The package is what the consumer first sees, touches and sometimes even smells. Packaging is what makes a consumer pick your product up off the shelf. Companies need to have systems in place that distribute perfect packaging on time, all the time.ARM satisfies all the challenges faced during packaging. Regarding the aspects of efficiency, costs, quality and display of reports ARM has its own benefits.

**Efficiencies**

- Earlier approval process and reduction in artwork lead times.
- Increased speed to market and ensured timely product launches.
- Out of stocks (due to artwork issues) abolished.

**Quality**

- Reduced the risk of asset misuse (wrong versions, errors, reprints).
- Digital file comparison.

**Costs**

- Costs were reduced through improved efficiencies
- Enabled better forecasting of print volume for vendors.
- Delivered capability to send artwork samples to multiple suppliers for quotation.

**Reporting**

- Capability to automatically create PDF reports for customers on request.
- Functionality to run reports for outstanding artwork approvals.
- Capability to generate review reports for all artwork pieces in production [6-8, 17, 20-21].

Additionally packaging art work management system can reduce painful blunders that occur during packaging. Producing artwork too slowly will delay the product launch and cost them their jobs. Yet, producing artwork too quickly can result in packaging artwork errors such as erroneous language translations or a wrong number prints that results in an entire product recall. These errors are also potentially career ending. So leading companies use packaging artwork management (PAM) software systems to considerably reduce or eliminate these painful blunders while ensuring that packaging artwork development keeps pace with product development.

Clinical trials are a crucial endeavor for the pharmaceutical company. If things go well, it will mean approval of the drug and potential revenue for the firm. However slight errors have the potential to cause delays in the trial, wasting time and resources. And this Artwork management is one of the required underpinning processes for a clinical trial and there are number of criteria to be followed for a successful clinical trail. In the clinical trial, information will be continually changing as the trial evolves. This will be driven by various internal and external factors. Therefore the artwork process needs to be adequately flexible to cater for this volume of change. Volumes for clinical trials can be small and often supplied using local or on-line printing capabilities. The artwork process can therefore be required to supply artwork files in formats other than traditional PDF, with specific required additional features, to support the local printing technology. As well as using the active product and placebo for trials, comparative studies against other marketed products from other companies can be undertaken. This requires repackaging or over-labelling and can drive a significant range of required artwork profiles. The range of suppliers involved in the trial (contract clinical trials providers, internal or contract packaging facilities, packaging component suppliers) creates a complex network of internal and external stakeholders who all need to be integrated into the artwork change process. Through execution of the trial, the product safety profile and instructions for use are being detailed and defined. This has considerable impact on the final commercial product, so the artwork process needs to support effective decision making from appropriate impacted stakeholders. Finally the process must ensure accurate and repeatable artwork is provided to support a successful trial.

Ability to develop, launch and maintain new products and variants in many different markets as rapidly as possible, while at the same time ensuring that all regulatory requirements are demonstrably met. It would be suggested that this can only be achieved if a company puts in place an effective packaging labeling and artwork management ability [19, 23].

**Main high lights of art work management [18-19]**

- Secure Online Access
- Configurable Workflows
- Online Approval
- Online Digital Artwork Comparison
- Complete audit trail of the users annotations
- Compliant with FDA guidelines (CFR21/11)
- Faster approval process times
- Reduction in artwork turnaround times
- Increased speed to market
- Automatic email alert

**CONCLUSION**

Most consumer products companies confess the existence of barriers to effective packaging and artwork management performance, including insufficient control over brand assets and their manifestation across products, variants and markets, Incomplete or inconsistent briefing materials, delays ensuing from inefficient, redundant processes at all stages of design and production and inability of design and production teams to work collaboratively across the supply chain and with product development. The only solution to these challenges is use of electronic art work management system. This system is used to achieve a sustainable business performance and it can be supported by statistical data such as Reduced artwork time by 30 to 50 percent, reduced package design time by more than 80 percent, increased productivity overall by 30 to 50 percent and reduced costs in the

packaging and artwork development process by 25 percent. Thus it enables consumer products companies to drive brand value in the market through better alignment of people, processes and brand assets in a way that

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