Packaging and Labelling – Artwork Core, Interfacing and Supporting processes

by Stephen McIndoe and Andrew Love

Whilst there will always be many ways to reach the same result, and artwork creation is no exception, a high level process is presented here as a basis for discussion. This process is based on experience working with a number of different companies, and if you are involved in artwork processes we are sure you will recognise many elements of it.

Artwork-related processes can be divided into three distinct areas. The three areas are:

Core Processes: The primary activities involved in defining and executing individual artwork changes.

Interfacing Processes: Those business processes that interact directly with the core process, will have an influence on the core process and may be modified as a result of this interaction.

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

High level core process steps

At its highest level, creating artwork is no more complex than defining what is required, creating a work product such as an artwork and then verifying that this output meets the requirement initially defined. This is a very familiar process to anyone involved in quality systems.

For the purposes of this discussion, our model high level process consists of five fundamental, or level 1 steps. Each of these steps is defined briefly below.

1. Create Local Language Text

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

In this part of the process you are typically taking the company's source product text (perhaps a Company Core Data Sheet), performing local translations and engaging with country and regional Regulatory Agencies to gain approval for the proposed labelling for the product

2. Define Change

In this step what is required to be created or modified as part of this change is defined. There needs to be a concise statement about what it is that is changing and why, written in a way that all stakeholders will be able to understand. In most companies this is a controlled manual or electronic form that details the requirements and is sometimes called the 'brief'.

In this step you would also undertake the impact assessment of the changes and prepare a marked up copy of the artwork.

Creating correct artwork is an activity that requires many groups to act together in an orchestrated way to deliver a successful result, on time. In this, the third paper in the series on artwork control, we examine the way of ensuring that these people act together in a co-ordinated way is to define a set of processes that everyone adheres too.

3. Produce Artwork

The artwork operator would produce a new or revised artwork that complies with the requirements defined in the Define Change step. This would be subject to proof-read, checking the text, graphical and technical elements of the artwork. It would then be approved by the local market and any other relevant approvers in the company and, depending on local Regulatory rules, perhaps by the external Regulator.

4. Produce Printer Proof

In order to print the component, the print supplier needs to prepare a modified artwork file that can be used in the packaging component printing process. This file differs from the artwork produced in step 3 in that it is modified to include all features that will allow it to be successfully printed via a specific printing route. In order to ensure these modifications have not introduced error to the artwork, a printer proof can be requested to be checked against the artwork master before the print run is undertaken.

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

5. Implement

One the component is printed and supplied to the packaging facility, the component needs to be checked to allow it to be introduced to production. Typically undertaken in the QC labs, sample components need to be checked against the master artwork to ensure the print process has been successful. This is often done using electronic comparator tools. The component can then be released through the site's material control systems.

Critical control points

It is worth pausing at this point and briefly discussing process critical control points. Given that this process produces information that, if incorrect, can have a significant and potentially fatal impact on patients, it is critical that there are defined control points in the process to ensure that the

quality of the output of the process is to the highest standard practically achievable.

To achieve this, companies have found it useful to define critical control points in the artwork process to ensure that all necessary tasks have been completed to a high quality before moving to the next phase. Each control point would normally include a quality check for accuracy as well as a formal approval by key individuals to proceed. In addition, some control points will provide an approval of a master document which will form a part of a master record source for GxP information.

Triggers for change

There are a number of events within or external to a company which can trigger the need for the development of new or modified artwork. One of the challenges for any organisation is to put in place mechanisms that funnel these triggers to initiate the appropriate artwork creation or changes.

Typically, triggers include:

1. *The requirement to change the Company Core Data Sheet (CCDS)*
   Where there is an identification to change information held within the CCDS that is relevant to patient-critical information contained within packaging artwork.
2. *The requirement to change the core regulatory text*
   Where there is an identification to change regulatory core text, either regionally or locally, which does not impact the CCDS.
3. *The requirement to change other information on an artwork*
   Where a requirement is identified to change non-core text, i.e. that which is not on the core text document. Examples of this might include: address changes; trademark changes; barcode changes.
4. *The requirement to change the brand image of the product or pack*
   Where the brand image of a product or pack is required to be changed, this will drive a change in one or more artworks.
5. *The requirement to change the physical design or dimensions of an artwork*
   If the physical structure or size of a pack are identified as requiring a change.

Capturing the process

It is important not just to design your process, but also to capture and document the content. There are several objectives in defining and capturing the business process:

- Ensuring everyone knows how to play their role in the process.
- Ensuring critical work is done in a complete and standard way.
- Ensuring there is a "corporate knowledge" capture on which future improvement can be based.

There are many different specific ways to describe processes and each has its merits, but we typically observe a framework based on levels of detail as follows:

- Level 1: Policy – laying out the highest level of requirement for the management of artwork creation and change in an organisation and is normally managed under the company quality management system. It would not normally define how artwork management would be done, just that it needs to be done.
- Level 2: Standard operating procedures, work instructions and checklists – the core documents that define the activities which people have to perform in order to carry out the process and, again, would normally be managed under the company quality management system.
- Level 3: Guidelines and work aids – define a level of instruction or advice which may be helpful to operators, but is not necessarily mandatory. Guidelines and work aids might instruct the operator on the way to use IT systems and tools for particular activities, or they may provide guidance in decision-making during certain steps of the process. Whatever they are used for, we would always recommend that they are considered an integral part of the overall process definition documentation set and be formally managed as such, even if they are outside of the company's formal quality management system.

Interfacing Processes

The artwork process does not operate in isolation. It is a process which relies on information and activity in many other processes in order to operate successfully. Furthermore, some of these processes are owned and operated by organisations external to the company who owns the core process. Some typical examples of these interfacing processes include:

- Change control process;
- Production planning;
- ERP data management process;
- Physical packaging development process;
- Company core datasheet development;
- Component code management.

The design of the artwork process must clearly take account of each of these interfacing processes. For each process it should be clear at which point the interface(s) occur,

what information is interchanged between the processes and in what format.

When designing the artwork process, it is highly unlikely that all of the interfacing processes will provide exactly the right information in the ideal format to support the new artwork process. Consequently, analysis will have to be done in each case to decide the best way forward. In some cases it will be necessary to modify the interfacing process to meet the ideal needs of the artwork process. In other cases it will be necessary to modify the design of the artwork process to accommodate the constraints of the interfacing process. In many cases a compromise solution will result. In some cases it may be necessary to phase the implementation of the new process, initially implementing a less optimal solution which can later be optimised when the corresponding interfacing process can be modified.

Supporting Processes

Whilst the core processes defines how individual labelling and artwork changes will be carried out, it is not sufficient in itself to provide a complete capability. A number of support processes need to be in place to achieve this. These include:

- Governance;
- Performance Management;
- Issue Management & Resolution;
- Process Lifecycle Management;
- Education, Training & Competence Management;
- Information Technology Support;
- Service Provider Management;
- Project & Programme Management;
- Forecasting & Budgeting;
- Business Continuity Management.

Many organisations will find that they already have one or more of these supporting processes in place that can be adapted or extended in scope to include the necessary artwork process areas. In many instances, this approach is to be recommended, as the artwork capability does not necessarily need its own unique iteration of a supporting process.

There are a number of questions that need to be considered in making the choice about incorporating artwork into an existing supporting process or creating a separate artwork-specific iteration. These include:

- Does a robust supporting process already exist elsewhere in the organisation which has a close fit to the supporting process requirements for artwork?
- Is the existing process owned and managed by a part of the organisation heavily involved in the artwork process?
- Would the owners of the current process consider artwork an appropriate extension of their scope?
- Is the existing process governed by an appropriate steering team that will take fair account of the needs of the artwork process when considering changes to their process?
- Is the artwork capability sufficiently small in scale to be successfully managed within another support process?

If the answer to any of the above questions is no, then careful consideration should be given to creating an artwork-specific support process rather than trying to force fit artwork into an existing process capability.

Summary

Defining a clear process with structured, mandatory control points, effective supporting documentation and clear interfaces to other company processes is a fundamental enabler to establishing a capable labelling and artwork service in your organisation. As discussed, failure to do so is a significant risk to product quality and the safety of the patient.

The next article in this series will look at some of the underpinning capabilities that support these processes, particularly organisation, technology and outsourcing.

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