Auditing artwork processes and services: Tips 1 to 5

by Stephen McIndoe and Andrew Love

Developing and sustaining excellent packaging labelling and artwork processes and the supporting capabilities is vital for regulatory compliance, reducing risk to patients and ensuring your business operates in a cost-effective manner. However, the management and control of artwork is a critical and difficult activity involving many functions and it is one that is often forgotten in a company's auditing programme.

We all know the complexity of the challenge but it is worthwhile asking yourself and your organisation these three simple questions.

- Does our auditing/self-inspection schedule include a regular assessment of our artwork processes, internal and external?
- Do our auditors have the skills and training in how to audit the complete artwork control system?
- Are senior management aware of the risks in artwork control and are they actively engaged in managing them?

If the answer to any of these three questions is no, or if you are even unsure of the answer, then it is likely that you would benefit from a hard look at your artwork processes and overall system of control.

Every company is unique and its artwork management processes will be different, so to help you in this task we have developed a series of 20 tips that you can customise into questions to be asked in any audit or self-inspection of artwork processes and performance.

As in any effective auditing process, beware that you don't stop when you see an appropriate procedure. You must dig deep by looking for evidence that the processes are not just defined in procedures, but that the procedures are actually implemented fully and that data is available to show that the processes work, in other words, they achieve what they are meant to.

In this article, we will address the first five tips by looking at the overall artwork management capability and scope of the artwork processes, the triggers and the critical control points in the processes.

Tip 1 – Is the end-to-end artwork capability managed under a formal quality management system?

The packaging labelling and artwork management process in the healthcare industry creates an output which, if incorrect, can have serious implication on patient safety. Therefore, I would suggest that the artwork process must be managed under one or more formal quality management systems (QMSs).

Artwork errors and the underlying deficiencies in the artwork processes and system of control have traditionally been a major cause of product recalls from the market. This is the first in a new series of four articles on auditing of artwork processes and services. The series takes the format of twenty tips to cover different aspects of an artwork service and outlines some of the issues you should consider when preparing for undertaking and reporting an audit. This article covers Tips 1 to 5 and forthcoming articles will cover the other tips in this series.

Furthermore, the QMS that the artwork capability is managed under should, in some way, link to the company's corporate level QMS.

Where third party service providers are used to provide all or part of the overall artwork capability, these operations should also be covered by an appropriate QMS, which is again linked back to the company's corporate level QMS.

Therefore, when auditing artwork capabilities, evidence of operating QMS(s) should be obtained. Within the relevant QMS(s), there should be policies and procedures which dictate how artwork will be managed. It should be possible to trace the link between all relevant QMSs through the relevant policies and procedures.

Tip 2 – Does the scope of the artwork management capability cover all labelling and artwork creation?

Once the existence of a QMS is established, the next thing to verify is that all artwork changes are managed within this framework. We have come across several situations where there was a good artwork capability in place, but, unfortunately, it was not used to manage the creation or changes to all packaging artwork for the business.

Typically, it is the products which fall outside of the mainstream of activity for a company that find themselves with no adequate packaging artwork management process. Product areas to look out for include subsidiary company products; recently purchased products; products produced locally for local or regional use and products produced by third parties.

When auditing artwork capabilities, look for these types of products and then seek evidence that their pack changes are being managed under a QMS which meets the standards discussed in Tip 1.

Tip 3 – Does a trigger for change result in all relevant artworks being changed?

One of the most basic causes of artwork error is not carrying out every change that is necessary as a result of a change trigger. For example, if a local regulator introduces a new packaging regulation requirement, one of the first questions that needs to be answered is: which markets, products, packs, components and, therefore, artwork is impacted?

For this reason, it is critical that there is a robust process in place to assess the impact of any trigger for change and ensure all the existing and new packaging components which are impacted are identified. For each component that is impacted, there needs to be a robust mechanism to ensure the required changes actually occur.

This is often achieved by formally triggering an artwork change process at this point. For changes such as critical safety changes, it may also be necessary for a company to be able to report on the successful completion of the resulting pack changes to some external regulators. When auditing artwork processes, we suggest you look for evidence of the following.

- Change triggers are documented in a formal change control process.
- An effective impact assessment is carried out to identify ALL impacted markets, products, packs, components and, therefore, artworks.
- The artwork change process is triggered for all artworks identified in the impact assessment.
- The original change control is not closed until successful completion of all impacted artwork changes.
- There is a management mechanism in place to address artwork changes that were identified as necessary in an impact assessment, but have either not been triggered or completed on time.

Tip 4 – Are critical control points adequately defined?

We have observed many artwork errors occurring because the artwork process has continued despite the fact that a previous stage of the process has not been fully completed.

A typical artwork change management process will divide the development of new or changed artwork, and its subsequent implementation, into a number of logical steps. Ensuring that there are clear control points in the process that must be fully completed before proceeding is a useful way to minimise this risk. Typical control points might include the following.

- Approval of the definition of the change requirement.
- Approval of the artwork.
- Approval of any printer proofs.
- Approval of packaging components for use.
- Batch release to ensure correct version of artwork is used.

Look for evidence of clear control points in the process when auditing artwork capabilities. We would suggest that these control points should include the requirement for the appropriate group of stakeholders to sign that they are happy to proceed.

Tip 5 – Is a complete version of the artwork created and approved?

We have encountered a number of occasions where errors occurred because the artwork that is initially developed and approved by the relevant stakeholders is not complete. Subsequent additions to the artwork, say to add product barcodes, create errors which are then not caught in any subsequent quality control steps.

For this reason, we would recommend that, when approved by the necessary cross-functional stakeholder group, the artwork is complete with respect to all information that will be presented to the prescribers and patients.

Furthermore, any information on the artwork which is used to identify it throughout its subsequent development or use should also be present at this time. This helps avoid gross errors caused by the wrong artwork/packaging component being used. In addressing this last point, it will often be necessary to understand how any third party service providers identify artworks and packaging components in their processes.

Summary

In summary, delivering a compliant performance in artwork control requires the management of a complex interaction of business processes: people in many different functions, organisations and countries using many, often validated, information technology tools. This requires a good understanding of the risks and the performance of existing artwork management processes. Consequently, it is vital that your auditing/self-inspection processes and skills are developed and implemented effectively if significant compliance risks are to be avoided.

This completes the first article of five tips in this series on artwork auditing; in our second article, we will discuss Tips 6 to 10.

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