

Auditing artwork processes and services: Tips 16 to 20

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Developing and sustaining excellent packaging, labelling and artwork processes and the supporting capabilities is vital to ensuring regulatory compliance, reducing risk to patients and your business and operating 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.

The first paper in this series (published in *GMP Review* Vol. 14 No.1 April 2015) covered Tips 1 to 5, which addressed the following.

- Tip 1:** Management of artwork capability under a formal quality management system.
- Tip 2:** Scope of the artwork management capability.
- Tip 3:** Triggers for change resulting in all relevant artworks being changed.
- Tip 4:** Adequate definition of critical control points.
- Tip 5:** Creation and approval of a complete version of the artwork.

The second paper (published in *GMP Review* Vol.14 No.2 July 2015) covered Tips 6 to 10, which addressed the following.

- Tip 6:** Adequate process and task definition.
- Tip 7:** Clear roles and responsibilities.
- Tip 8:** Adequate artwork quality checks.
- Tip 9:** Audit trail.
- Tip 10:** Document version management.

The third paper (published in *GMP Review* Vol.14 No.3 October 2015) covered Tips 11 to 15, which addressed the following.

- Tip 11:** Are there methods in place to ensure different forms of each document are the same?
- Tip 12:** Is everyone using the correct version of a document?
- Tip 13:** Is ongoing education, training and competency assessment in place?
- Tip 14:** Are service providers formally managed under a quality management system and subject to routine audits?
- Tip 15:** Are critical IT [information technology] tools managed under a quality management system?

This final article in the series covers Tips 16 to 20.

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. In this, the fourth paper, we conclude our series on auditing of artwork processes and services by outlining Tips 16 to 20. Across the four papers, we have provided 20 tips that cover all the different aspects of an artwork service and outline the issues you should consider when preparing for conducting and reporting an audit of artwork processes and services.

Tip 16 – Do all IT tools used during review and approval ensure the correct image is displayed?

As we discussed in Tip 11, documents are likely to exist in a number of different formats and different individuals may need to deal with these different formats in different ways, e.g. images on screen, or printouts.

It is essential that everyone viewing a document, in whatever format, is presented with an accurate rendition of the original document. Unfortunately, given the many software and hardware tools required to create and present these images, there are many opportunities for errors in the images to be introduced.

In the electronic space, standards such as Portable Document Format (PDF) were created to help address this issue. PDF is often used as an electronic mechanism by which documents in an artwork process are shared and the tools that are used to view PDF files can ensure accurate rendition when managed effectively.

When auditing artwork capabilities, look for evidence of IT risk assessments having been performed for the various document visualisation methods used. For those risks identified, check to see that appropriate mitigating actions have been carried out.

The types of solutions that are often seen as a result of this sort of risk assessment include the use of specific tested and controlled printing routes and the use of controlled virtual desktop technology.

Tip 17 – Is work planning and adequate resource level management in place?

A significant cause of error in artwork processes is a lack of adequate planning and resource level management.

To be successful, many individuals from many different locations, functions and often companies need to play their

part in the artwork process at the right time. Furthermore, there is often a significant safety or business imperative to do this work in a relatively tight timescale.

In today's business world, nobody is sitting around waiting for work to arrive, we are all very busy. If adequate mechanisms are not in place to ensure that individuals know when they will need to carry out their tasks, then the resulting "surprise" will often result in either a delayed process, or rushed work with the resulting error risk.

Furthermore, there should be mechanisms in place to ensure that, on an ongoing basis, there are sufficient levels of competent resource available to carry out the workload. If not, then more often than not, individuals will resort to cutting corners in order to meet the required timeline, which clearly leads directly to a significant error risk.

When auditing artwork capabilities, look for the following.

- Evidence of a planning methodology.
- Definition of critical milestones.
- How the organisation ensures that people have sufficient time to do their tasks.
- Evidence that the workload of individuals is managed to ensure they are not constantly over stretched.

Tip 18 – Do individuals have an appropriate working environment?

Many of the tasks involved in the end-to-end artwork process require a great deal of focus and attention to detail on the part of the individuals performing them. Some tasks also require specific tools to be able to complete them correctly. Consideration should be given to the requirements of each task and measures taken to ensure that the appropriate environment is put in place to allow the individuals to do their tasks effectively and efficiently.

All individuals responsible for creating or reviewing artwork documents should be provided with a working environment that allows them to focus in the activity without undue distraction. Where dealing with large artwork documents, such as multi-language leaflets, they should also have the physical space to deal with the paper documents, or large screens to deal with them effectively electronically.

Where individuals are doing specific tasks, such as proof reading, requiring frequent long periods of intense concentration and attention to extreme detail, consideration should be given to providing purpose designed office space for the task: distraction free; well lit; adequate surface area; comfortable seating, etc.

When auditing artwork capabilities, review a sample of the

working environments of people carrying out tasks in the process to ensure good housekeeping. Pay particular attention to proof-reading environments to ensure they are acceptable for the activities that need to be carried out.

Tip 19 – Is there an issue management and continuous improvement process in place?

An artwork capability is a complex interaction of different tasks, people, functions, and organisations that must come together to produce a result which is correct in minute detail. The process has to do this in an environment of constantly evolving regulatory requirements and business pressures. Therefore, there are going to be issues which arise or changes that need to be made to the process.

It is critical that a robust and formal issue management and continuous improvement process is in place. This process should be managed under the company's quality management system and include the following aspects.

- Key performance indicators, including non-conformance.
- Short-term user alerting of issues.
- Robust root cause analysis.
- Corrective and preventive actions approval by appropriate cross-functional groups.
- Implementation management and tracking.

When auditing artwork capabilities, one should look for the following.

- Evidence that issues are captured and dealt with appropriately.
- Evidence of a development improvement plan.
- Evidence that change control is used to manage changes to the capability.

Tip 20 – Is there adequate cross-functional/organisation governance in place?

All processes need governance to ensure they operate effectively within and across companies. Due to the potential significant impact of errors created by the artwork process on patients and the company, it would seem appropriate for the governance of the process to be at a relatively senior level in the business.

The end-to-end artwork process operates across functional and potentially organisational boundaries and, therefore, any governance should include senior representation from all of

the impacted stakeholder groups. Without this, there is a significant danger that the process will not be managed or executed successfully and will fail.

The governance team would normally ensure the following.

- A strategy for the end-to-end artwork capability is developed and communicated.
- Change to the capability is managed effectively.
- Ongoing operations are managed effectively.

The governance team would not normally be responsible for the day-to-day management of the capability. When auditing artwork capabilities, look for the following.

- Evidence that the end-to-end artwork process is governed by a team including representation from all the impacted functions.
- Evidence that the governance team meet regularly and that the agenda covers the topics discussed above.

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 IT tools. This requires a good understanding of the risks and the performance of existing artwork management processes and management. 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 this series on artwork auditing.

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