Auditing artwork processes and services: Tips 11 to 15

by Stephen McIndoe and Andrew Love

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 companies 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.

This article covers Tips 11 to 15 and a forthcoming article will cover the final tips in this series.

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 paper we continue this series of four articles on auditing of artwork processes and services. The series takes the format of 20 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.

Tip 11 – Are there methods in place to ensure different forms of each document are the same?

We live in a world where we constantly deal with documents in different interchangeable formats. Rarely are the documents we deal with today created on paper; normally they are created electronically and shared using a number of different electronic and paper formats. These hybrid systems are common and difficult to manage, and artwork and its associated documents are no different.

It must be recognised that different documents may need to be prepared using different software tools, e.g. MS Word for source text documents, Adobe Illustrator for artwork, etc. It is often not practical or desirable to share these "native" documents using their creation tools. Therefore, facsimiles of these native documents are created and shared (see Tip 16). This immediately creates different forms of the same document.

Also, electronic documents may need to be printed, signed, scanned and submitted into an electronic records system. This again creates other forms of the same document.

What must be ensured in the process of dealing with these various forms of a document is that everyone is seeing the same thing when they should be.

When auditing artwork capabilities look for procedural evidence that the methods by which users view documents, particularly during review and approval are defined. This will typically be on screen or via printout.

From an information technology (IT) perspective, look for evidence that the risks of errors being introduced in rendering artwork images and printouts have been considered and that the appropriate risk mitigations have been put in place.

Tip 12 – Is everyone using the correct version of a document?

We discussed the issue of ensuring that the evolution of a document is identified and managed robustly in Tip 10 – Document version management. Having uniquely identified different versions of a document, the next thing to ensure is that everyone in the process is using the right version of a document at the right time.

Many errors have occurred in document management processes because individuals carried out their tasks correctly, but using the wrong version of a document.

The end-to-end artwork process and the supporting document repositories need to ensure that, at each stage of the process, individuals have access to and use the correct version of the documents. This may be through ensuring they are sent the right documents or, more ideally in our opinion, they have ready access to a secure document repository where they can confidently access the right version of the document.

When auditing artwork capabilities, ask how the process ensures that individuals use the correct version of a document at each stage of the process.

Tip 13 – Is ongoing education, training and competency assessment in place?

Many of the tasks that need to be performed in the end-to-end artwork process rely heavily on the skill and competence of the operators. Particular examples of this would be artwork operators, proof readers and other document reviewers.

Some operators are regularly involved in the process, whilst others are not. For example, many local market representatives may only deal with the artwork process a small number of times a year, whilst proof readers may execute the process many times each day.

Therefore, the education, training and competence assessment of individuals performing roles in the end-to-end artwork process needs to be carefully designed to ensure everyone will carry out their tasks completely, correctly and competently.

When auditing artwork capabilities, look for evidence that the competency requirements of all roles have been assessed and that the appropriate education, training and competence assessment has been put in place to ensure the following.

- Users are competent when they start their role.
- Users are competent to execute any changes to the process.
- Users undergo periodic refresher training and competence re-assessment.

Furthermore, look for evidence in individual training records that the above steps are being carried out.

Tip 14 – Are service providers formally managed under a quality management system and subject to routine audits?

Service providers, such as external artwork studios and printers, are often used by a company to make up their full artwork capability. Where third parties are used to carry out patient and product safety related activity in the end-to-end process, a company needs to ensure that any tasks that are delegated to the third party are managed acceptably. Typically, the following measures would be put in place.

- Formal third party assessment and selection process managed under the company's quality management system.
- Formal contracts established covering the full scope of the third party's activity.
- Critical aspects of their activity defined and agreed in some form of formal technical agreement.
- Critical quality standards they must adhere to defined and agreed in some form of formal quality agreement.
- Formal mechanism to identify and mutually agree any changes to the above.
- Formal periodic reviews of the performance of both parties in executing their duties.
- Periodic audits of the third party.

All of the above points are essential to ensuring the quality of the artwork remains constant when using third part service providers.

Tip 15 – Are critical IT tools managed under a quality management system?

Many IT tools are often used to support a typical end-to-end artwork process. Examples would include the following.

- Artwork creation desktop.
- Electronic proof-reading tools.
- Document management and electronic signature systems.
- Workflow tools.
- Barcode creation.
- Verification tools.

As with any IT tools used to support a patient or product safety related process, an assessment of the risks that the tools present must be performed and the relevant quality management system used to ensure that those risks are managed effectively. Typically, this risk assessment will result in most tools discussed above being considered critical and requiring management in a formal IT quality management system.

Anyone who has dealt with IT quality management systems will understand that this is a complex area and we would recommend the reader consults experts in this field.

For each of the IT tools, look for evidence that a risk assessment has been carried out to identify those systems which must be managed under a quality management system. Where required, ensure that the systems have been validated and that they continue to be managed under an appropriate IT quality management system.

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 the third article of five tips in this series on artwork auditing; in our fourth and final article we will discuss Tips 16 to 20.

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