Auditing artwork processes and services: Tips 6 to 10

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 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.

This article covers Tips 6 to 10 and forthcoming articles will cover the other tips in this series.

Tip 6 – Adequate process and task definition

Is the overall process and are individuals' tasks defined to ensure complete and consistent working?

Discussion

It is important to ensure that the end-to-end process is formally documented and managed in the relevant quality management system (see Tip 1).

Given the detailed nature of the artwork process and the fact that it often involves many individuals from all over the world doing the same tasks, it is important to ensure that the description of tasks are sufficiently detailed to ensure work is carried out consistently, completely and correctly.

To achieve this, it is normally necessary to employ a number of different process documentation tools, which may include the following.

- Policies.
- Standard operating procedures (SOPs).
- Checklists.
- Work instructions, guidelines, job aids.

Too often, we find that the process is only documented in SOPs at a very high level and individuals have little idea of how they need to carry out the tasks asked of them.

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. As we continue in 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 7 – Clear roles and responsibilities

Are roles and responsibilities clearly defined, including at key approval points?

Discussion

Ensuring that the roles and responsibilities are clear for the artwork process is important for a number of reasons.

Firstly, it is critical that, where an individual needs to carry out tasks in the process, they are clear which tasks they are expected to complete.

Secondly, for the end-to-end process to be robust, it is imperative that all the relevant stakeholders are involved in each step of the process, particularly the review and approval stages.

An easy shortcut that is often taken is to only involve a subset of the necessary stakeholders in the process, particularly when under time pressures. This can lead to errors and omissions not being identified, with the consequent risks to patient safety.

Tip 8 – Adequate artwork quality checks

Are there adequate quality checks of all text and graphics at every document revision?

Discussion

It is important that the artwork quality checks that are performed are adequate. These can be categorised into the following three areas.

- All text, characters and symbols are present, correct and, where appropriate, consistent with source text documents.
- All graphical elements are present and correct.

- All technical requirements have been met, e.g. barcodes, size, varnish finish, etc.

Clearly, in order to verify the above, the individuals performing the checks need to have access to the appropriate reference information. This is one of the reasons we would recommend the preparation and formal approval of a change requirement, or brief, to be included in the artwork process.

Furthermore, it is important that checks are carried out to verify that changes have been performed correctly and that no unintentional changes have been made by mistake. For this latter reason, we would recommend carrying out full checks at all verification steps, regardless of the scope of the change that was intended to be made.

Tip 9 – Audit trail

Is an audit trail created and held for an acceptable period?

Discussion

An adequate audit trail should be created and maintained to ensure that it can be demonstrated that the artwork process was carried out completely and correctly. Furthermore, it may also be beneficial to record additional information in the audit trail to assist with continuous improvement activities. The audit trail could include the following.

- All approved documents.
- Signature records from all approving stakeholders.
- The results of all critical quality checks.

The company needs to have a mechanism in place to ensure that the audit trail is maintained for the minimum period as required by local regulations and as defined in their corporate records retention policy.

All audit trail records need to be kept in a manner that will prevent their loss in the event of occurrences such as fire or theft.

Tip 10 – Document version management

Is there effective document version management in place?

Discussion

As with all document management activities, it is essential that everyone is clear which iteration of a document needs to be used at any particular time in the process. Many errors have occurred because this has not been clear. For example, necessary changes have been accidentally omitted because a previous iteration of a document was carried forward in the process.

Alternatively, approvals can be incorrectly given if the wrong iteration of a document is used by the approver. One solution to this problem is to ensure that there is a robust document revision numbering system put in place which ensures the following.

- Each iteration of a document is given a unique revision or version number.
- Each and every time a document is modified in any way, its revision or version number is changed.

In this way, there will be a high degree of confidence that all iterations of a document can be clearly identified to everyone concerned.

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 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 second article of five tips in this series on artwork auditing; in our third article we will discuss Tips 11 to 15.

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