Trusted Healthcare Experts
Transforming Supply Chains

Welcome to our Be4ward newsletter, our opportunity to share with you our most recent articles, along with our company and wider industry news.

In this issue we share our company news, including an April webinar watch-back **One Year After EU FMD Compliance: What Issues Need to be Addressed?** along with an introduction to our Be4ward brochure, which we invite you to download, have a read of and learn more about who we are and how we work with our clients.

As always, we share our consultant's thoughts and knowledge via a series of articles from the VP blogs, with the second part to Grant Courtney's blog on **FMD Alerts in 2020** and continuing our look at **Excellent Packaging Artwork Capabilities.** From Andrew Love's blog we bring you the next two parts in the **Ensuring Effective Translations** series. You can find these in our Featured Blog Post section below, available for you to read on or off-line.

We're pleased to share with you our Executive Briefing for this issue: **Top 20 Artwork Auditor Tips** an online reference guide with twenty top tips for a first rate artwork capability.

One topic continues to dominate the industry headlines right now. In our Top News Picks we focus on the race for the Covid-19 vaccine and the supply chain implications, sharing a few articles from the industry that we think are worth a read.

We appreciate you taking the time to enjoy sharing our news and updates. As always we welcome your thoughts and comment. If you and your business require advice or assistance in any of these areas, please do not hesitate to get in touch.

Kind regards,

The team at Be4ward

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Be4ward Company News

One Year After EU FMD Compliance: What Issues Need to be Addressed?

WEBINAR WATCH-BACK

Be4ward | Optel | Jennason

60 min

It's been one year since the European Union (EU) adopted the Falsified Medicines Directive (FMD) as a means of combatting counterfeiting in the pharmaceutical industry. How effective has the EU FMD been and how secure is the supply chain now?

In this webinar, OPTEL and Be4ward consultants Grant Courtney and Scott Pugh, both traceability experts, weigh in on the issues that still need to be addressed, including the EU FMD's bookend approach that creates a race between authentic and counterfeit medicines in reaching the patient first.

The solution can be found in aggregation and multilayer protection such as serialization, tamper evidence and digital watermarks, which are technologies that OPTEL has been developing and perfecting for decades.

Join our watch back to learn about:

- Overview and rationale of the EU FMD
- How the EU FMD is working so far
- What the EU FMD has improved or solved
- How the Jennason alert manager can help
- What issues the EU FMD hasn't solved
- How OPTEL can solve these remaining issues

* please note, as this is a watch-back the interactive chat and Q&A function is not available

About Be4ward

"We are an international team of subject matter experts and implementation specialists dedicated to improving and enhancing healthcare product lifecycles, from packaging through to patient. "

Find out who we are, how we support our clients, how we work with our clients and why you should work with us in our company introduction brochure.

Download the Be4ward brochure

Industry News

Momentum for GSI global barcode standard grows with new Digital Link upgrade

EVRYTHNG, an AIPIA member providing digital identities for global consumer products, has announced its support for GS1 Digital Link 1.1, released earlier in 2020.

Read the AIPIA article

Featured Blog Posts

By Stephen McIndoe

FMD ALERTS IN 2020 – WHERE WE ARE A YEAR INTO LEGISLATION: PART 2

Associate blog post from Grant Courtney, Principle Consultant

It's been 15 months since EU FMD came into force and after initial problems bedding in the new systems, false alerts remain a problem preventing the realisation of the full benefits of the directive. With many grace periods now coming to an end, where are manufacturers on the EU FMD journey and what are the real consequences of unresolved alerts moving forward?

In part two of the FMD Alerts in 2020 series, Grant Courtney Principle Consultant at Be4ward, looks at the process that happens when an alert is triggered, what manufacturers should be doing and what's coming next in the EU FMD journey.

Read it online

EXCELLENT PACKAGING ARTWORK CAPABILITIES PART 3 – CORE AND INTERFACING ARTWOK PROCESSES

In part two of my blog series on how to create excellent packaging artwork capabilities, I looked at some of the main causes of artwork error and the importance of creating a service culture. Here in part three I introduce three important artwork processes and look in greater detail at the core and interfacing artwork processes. I highlight the 5 fundamental core process steps and examine some typical interfacing processes and their interaction with the artwork process.

Read it online

Featured Blog Posts

by Andrew Love

ENSURING EFFECTIVE TRANSLATIONS – INITIATE YOUR PROJECT

As we continue this series of posts expanding the topic of *Ensuring Effective*

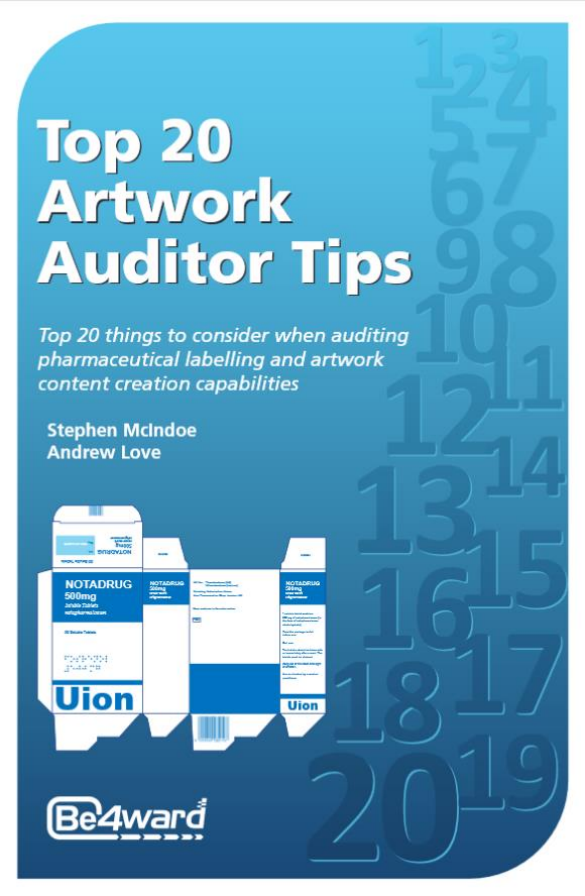
Translations to help you establish your translation capability, we move to the next set of tips, based around step 2 – *Initiate your project.*

Read it online

ENSURING EFFECTIVE TRANSLATIONS – PREPARING TEXT FOR TRANSLATION

As we continue this series of posts expanding the topic of *Ensuring Effective Translations* to help you establish your translation capability, we move to the next set of tips, based around step 3 to help you make sure that the text you are supplying for translation is prepared in way that allows for a high quality translation.

Read it online



Top 20 Artwork Auditor Tips Executive Briefing

Stephen McIndoe
Andrew Love

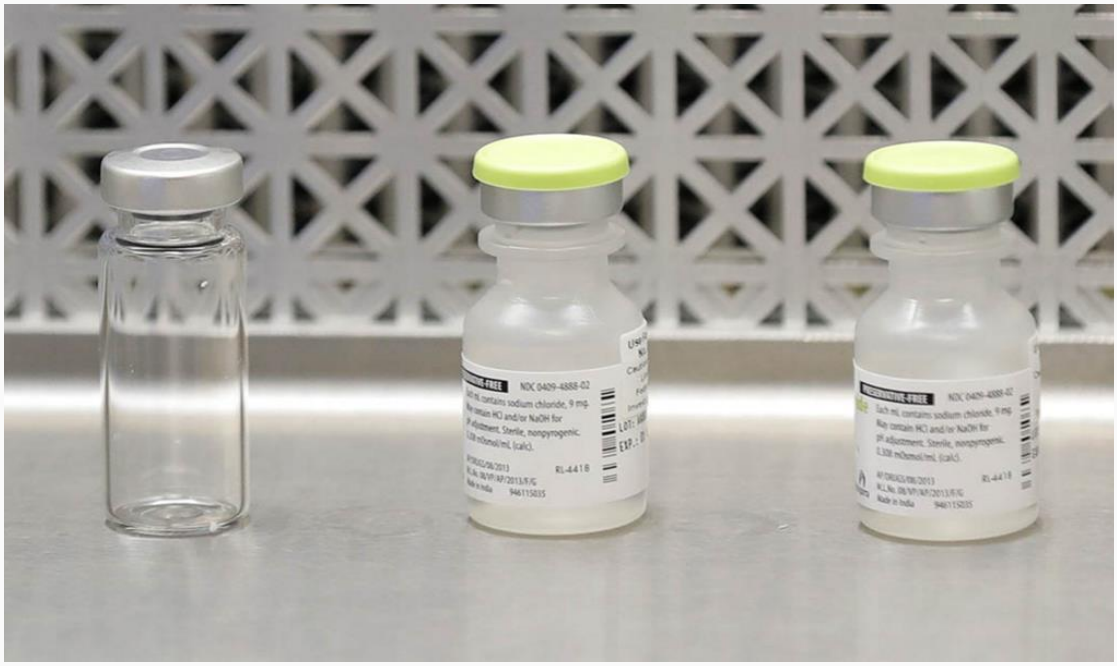
This Executive Briefing is designed to help professionals involved in pharmaceutical packaging labelling and artwork activities to develop improved auditing techniques. In itself, this book does not attempt to create a guideline or structure for auditing such capabilities.

The Executive Briefing takes the popular Top 20 Tips format to describe key features of an artwork capability in an easy to digest format.

Read the Executive Briefing to learn more

Top 3 News Picks

We share some of the latest worldwide news picks, on topics related to Serialisation, Artwork, Proofreading, Packaging and Supply Chain Optimisation. Here are three links from the many recently shared articles in the industry that we think are worth your time.



The ‘biggest challenge’ won’t come until after a coronavirus vaccine is found

By Sarah Owermohle for *Politico*

The nation’s supply chain isn’t anywhere close to ready.

Meeting the overwhelming demand for a successful coronavirus vaccine will require a historic amount of coordination by scientists, drugmakers and the government.

Click here to read the article

Why vaccine ‘nationalism’ could slow coronavirus fight

By Richard Milne in Oslo and David Crow in New York
for *Financial Times*
Health experts fear US-China tensions could hamper global co-operation and limit poorer nations’ access to a treatment

Click here to read the article

Why we might not get a coronavirus vaccine

By Ian Sample Science editor for *The Guardian*

Politicians have become more cautious about immunisation prospects. They are right to be.

It would be hard to overstate the importance of developing a vaccine to Sars-CoV-2 – it's seen as the fast track to a return to normal life. That's why the health secretary, Matt Hancock, said the UK was "throwing everything at it".

Click here to read the article

Executive Briefing: read offline

Top 20 Artwork Auditor Tips

Introduction

This Executive Briefing is designed to help professionals involved in pharmaceutical packaging labelling and artwork activities to develop improved auditing techniques. In itself, this book does not attempt to create a guideline or structure for auditing such capabilities.

The Executive Briefing takes the popular Top 20 Tips format to describe key features of an artwork capability in an easy to digest format. .

Tip 1 – Quality Management System

Is the end-to-end artwork capability managed under a formal Quality Management System?

Discussion

It almost goes without saying that the artwork management process creates an output which, if incorrect, can have serious implication on patient safety. Therefore, the artwork process must be managed under one or more formal Quality Management Systems.

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

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

Tip 2 – End-to-end Coverage

Does the scope of the end-to-end capability cover all labelling and artwork creation?

Discussion

Once the existence of a Quality Management System(s) is established, the next thing to verify is that all artwork changes are managed within this framework. The following checklist may help establish this:

- All subsidiary companies
- Recent acquisitions
- All products
- All markets and regions
- All components
- 3rd party or contract packaging operations

- Products produced locally for local or regional use
- Repackaging and over-labelling activities

We have come across several situations where there was an acceptable artwork capability in place to manage the majority of the company's packaging artwork, however, there were significant gaps in the scope of the coverage of this capability.

Tip 3 – Effective Impact Assessment

Does a trigger for change result in all the relevant artworks being created or changed?

Discussion

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 is also necessary for a company to be able to report on the successful completion of the resulting pack changes to some external regulators.

Tip 4 – Critical Control Points

Are critical control points defined?

Discussion

A typical artwork change management process will divide the development of new or changed artwork and it's subsequent implementation into a number of logical steps or stages.

Many errors have occurred because the process has continued despite the fact that the previous stage has not been fully completed.

Therefore, ensuring that there are clear control points in the process that must be fully completed before proceeding is a useful way to minimise this particular risk.

Control points may include:

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

The acceptable completion of a control point should be recorded by the signature of the appropriate individuals. It is critical that all the appropriate cross functional individuals are included in this approval step.

Tip 5 – Complete Artwork

Is a complete version of the artwork created and approved?

Discussion

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 it's subsequent development or use should also be present at this time. This avoids 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 3rd party service providers identify artworks and packaging components in their processes to ensure that this risk is adequately covered.

Tip 6 – Adequate Process & 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:

- Policies.
- Standard operating procedures (SOP).
- 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.

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 sub-set 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 that each iteration of a document is given a unique revision or version number.
- Each and every time a document is modified in any way, that it's 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.

Tip 11 – Document Form Consistency

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

Discussion

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. Artwork and it's 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.

Tip 12 – Correct Document Use

Is everyone using the correct version of a document?

Discussion

We discussed the issue of ensuring that the evolution of a document is identified robustly in Tip 10. 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 too 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.

Tip 13 – Education, Training and Competency

Is ongoing education, training and competency assessment in place?

Discussion

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 operator. 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 competently.

There should be 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 that:

- 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.

Tip 14 – Service Provider Management

Are service providers formally managed under a Quality Management System and subject to routine audits?

Discussion

Service providers such as external artwork studios and printers are often used by a company to make up their full artwork capability. Where 3rd 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 3rd party are managed acceptably.

Typically, the following measures would be put in place:

- Formal 3rd party assessment and selection process managed under the company's Quality Management System.
- Formal contracts established covering the full scope of the 3rd 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 3rd party.

Tip 15 – IT Tools Management

Are critical Information Technology tools managed under a Quality Management System?

Discussion

Many Information Technology (IT) tools are often used to support a typical end-to-end artwork process. Examples would include: artwork creation desktop; electronic proof reading tools; document management and electronic signature systems; workflow tools; barcode creation and 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 systems Quality Management Systems will

understand that this is a complex area and we would recommend the reader consults experts in this field.

Tip 16 – Ensuring What You See Is What You Get

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

Discussion

As we discuss 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, e.g. images on screen, printouts etc.

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, technology such as Adobe's Portable Document Format (PDF) was created to help address this issue. PDF is often used as the 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.

The risks introduced by document display and printing methods need to be identified and appropriate mitigations put in place.

Tip 17 – Effective Planning

Is work planning and adequate resource level management in place?

Discussion

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 is 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.

Tip 18 – Working Environment

Do individuals have an appropriate working environment?

Discussion

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 do 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 a 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.

Tip 19 – Continuous Improvement

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

Discussion

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 such aspects as:

- Key Performance Indicators, including non-conformances.
- Short term user alerting of issues.
- Robust root cause analysis.
- Corrective action approval by appropriate cross-functional groups.
- Implementation management and tracking.

Tip 20 - Governance

Is there adequate cross functional / organisation governance in place?

Discussion

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:

- 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.

About Be4ward

Be4ward helps Pharmaceutical, Biotech and other Healthcare companies and their supply base to improve patient safety and drive additional value from their product range. They do this through a range of products and consulting services.

Visit us at www.be4ward.com or contact us at enquiries@be4ward.com.

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Featured Blog Posts : read offline

FMD Alerts in 2020 – Where we are a year into legislation: Part 2

Associate blog post from Grant Courtney, Principle Consultant

It's been 15 months since EU FMD came into force and after initial problems bedding in the new systems, false alerts remain a problem preventing the realisation of the full benefits of the directive. With many grace periods now coming to an end, where are manufacturers on the EU FMD journey and what are the real consequences of unresolved alerts moving forward? In part two of the FMD Alerts in 2020 series, Grant Courtney Principle Consultant at Be4ward, looks at the process that happens when an alert is triggered, what manufacturers should be doing and what's coming next in the EU FMD journey.

With false alerts still in play, if an alert is triggered it is necessary to establish if it is due to a technical or procedural error or if in fact it is due to a suspected falsified product. The need to investigate and resolve alerts is stated as a requirement within the Delegated Regulation and the organisation operating the National Medicines Verification System should provide for the immediate investigation of all potential incidents of falsification (Art 37(d)). Moreover, the EU Q&A document makes specific reference that the National Medicines Verification Organisations should ensure the National Competent Authorities (NCA) are informed as soon as it is clear that the alert cannot be explained by a technical or procedural issue.

The MAH has a role to play in this and must check if they have caused the alert by not uploading the serialisation data or if the data has errors. The expectation is that this resolution should happen quickly, within just a few days, and the relevant NMVO is made aware of the outcome of this investigation. In addition, authorities are starting to introduce specific reporting requirements and systems which could vary from country to country.

The common goal remains that we must reach the point at which an alert prevents a pharmacist from dispensing the medicine to the patient, as

dictated by the legislation, and with this in mind, ten member states have now ended their stabilisation period.

The resolution of alert errors heralds a new phase in the EU FMD journey, where the target is for investigation and resolution of alerts to happen quickly, with the results documented and shared with the NMVOs and authorities. If alerts are caused by technical or procedural issues within the MAH then Corrective and Preventative Actions (CAPAs) need to be executed in alignment with quality procedures and the data uploaded or corrected to resolve the issue before many more alerts are triggered for the same batch. The consequence of not addressing these false alerts is that the flow of goods will stop and product returns could increase.

So a year after the EU FMD compliance deadline, what should manufacturers be doing and what is coming next?

If manufacturers have not already started, processes and systems must now be put in place to receive, analyse and investigate alerts. The backlog of any alerts that have not been addressed should be cleared and any technical or procedural issues identified and resolved. The regulatory environment should be carefully monitored so that the emerging requirements on alert reporting are captured and built into internal procedures. Regulators are starting to include aspects of the EU FMD within audits and alert management will feature as a topic within these moving forward.

Companies also need to consider how they are going to manage this on an ongoing basis. Tools that have worked for tracking alerts up to now, such as spreadsheets, will reach their technical limit as over time the historical volume of alerts grows. Systems will also have to output to external alert reporting systems operated by the NMVOs and authorities requiring new functionality and potential interfaces.

It is perhaps not surprising that legislation as ambitious as the EU FMD will take some time to achieve its original goal of preventing falsified products from entering the pharmaceutical supply chain. A tremendous start has been made and it is now time to build on this significant foundation and ensure that necessary alert management steps are put in place to allow falsified packs to be correctly identified, only then will the benefits of EU FMD by fully realised.

Should you have any questions about this or any other of my blogs, or would simply like to request a copy of any of our publications, please don't hesitate to contact me directly on my email: stephen.mcindoe@be4ward.com

For more information on serialisation strategy and implementation, go to our free download section.

Read it online

Excellent Packaging Artwork Capabilities part 3 – Core and Interfacing Artwork Processes

By Stephen McIndoe - VP of Be4ward

In part two of my blog series on how to create excellent packaging artwork capabilities, I looked at some of the main causes of artwork error and the importance of creating a service culture. Here in part three I introduce three important artwork processes and look in greater detail at the core and interfacing artwork processes. I highlight the 5 fundamental core process steps and examine some typical interfacing processes and their interaction with the artwork process.

As we have discussed in earlier articles, creating correct artwork is an activity that requires many groups to act together in an orchestrated way to deliver a successful result, on time. The way of ensuring that these people act together in a co-ordinated way is to define a set of processes that everyone adheres to.

Whilst there will always be many ways to reach the same result, and artwork creation is no exception, we will present a high-level process 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.

For the purpose of clarity, we will divide our discussions about artwork-related processes into three distinct areas:

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.

We will deal with each of the process areas in turn and will start here with the core process.

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, we have defined a high-level process consisting of five fundamental, or level 1 steps:

1 – Create Local Language Text

2 – Define Change

3 – Produce Artwork

4 – Produce Printer Proof

5 – Implement

We define each of these steps very briefly below. For a much more in-depth discussion on the Level 1 and 2 process in each of these steps please get a copy of our book Developing and Sustaining Excellent Packaging Labelling and Artwork Capabilities.

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.

2. Define Change

Define exactly what is required to be created or modified as part of this change.

3. Produce Artwork

Produce a new or revised artwork that complies with the requirements defined in the Define Change step.

4. Produce Printer Proof

Produce a modified artwork file that can be used directly 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.

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

5. Implement

Ensuring that, at minimum, the first time a new or modified artwork is used to create packaging components for use in the manufacture of real product, that they are correct.

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.

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 carried out 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.

In part four I will look in more detail at the third of our defined processes, Supporting Processes and influencing aspects of organisation design.

To help you with your artwork improvement programme, you can also find useful information in our book Developing and Sustaining Excellent Packaging Labelling and Artwork Capabilities

Should you have any questions about this or any other of my blogs, or would simply like to request a copy of any of our publications, please don't hesitate to contact me directly on my email: stephen.mcindoe@be4ward.com

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Ensuring Effective Translations – Initiate Your Project

Andrew R Love

As we continue this series of posts expanding the topic of *Ensuring Effective Translations* to help you establish your translation capability, we move to the next set of tips, based around step 2 – *Initiate your project.*

Define your project clearly and in detail
Before you start anything, you need to know what you want to do. You should think about what you want to be translated and why is it necessary to do it? What is the purpose of the document and how critical is the effectiveness of the translation? Who is the intended audience and what might you have to do to incorporate their needs?

Think about the final purpose(s) of the translation(s)
What are you planning to do with the translated document? Is it for publication, internal use, legal documents, product safety information? Each of these have different groups of readers and different requirements about the style of the translation and the accuracy of the content. Understanding the purpose of the translation should lead you to the best approach for undertaking the translation and the capabilities you may require from a translation provider. It will likely also impact the cost of the translation. Not all translation agencies are the same. They will have different language capabilities and technical expertise. Understanding the purpose of the translation will facilitate defining what type of translation provider you need. Understanding the purpose of the translation will also help you define what needs to be translated. There may only be specific parts of the source document that you require and therefore it would make more sense to only

have those sections translated into a new abridged version. This will reduce the translation cost and also speed up delivery.

Take the burden off the words
A picture tells a thousand words. Use of diagrams, pictures and illustrations can be more effective with international audiences than pages of highly technical text. Think carefully about the message you want to get across and how you can get the best mix of text and illustrations.

Set deadlines
In order to plan your project effectively, you need to be clear on the deadlines to be met. From your understanding of the project's purpose, it should be possible to determine what will need to happen to the translation once it has been approved and when approval is required. Is there a publishing deadline to be met, a date the translation must be submitted to print, or an event the translation will be used at? Any of these will dictate when the translation must be required by, forming the deadlines you need to meet.

Plan the project from start through to delivery
Planning your project is all about defining the what, when, who and how. For each step of your translation project be clear on what needs to be done, when that needs to happen, who needs to be involved and how it will be done. If you have a clear plan, you will know if you have been successful in delivering the project.

The key steps of what needs to be done should be set by your translation process, but for some projects there may be multiple documents to be translated or some additional steps that need to be undertaken.

The deadlines you have identified earlier are the starting point for defining the timelines for the plan. It is good practice to have standard lead-times for each step of your process that have been agreed upfront with all parties involved. Therefore, using the step lead times to back-schedule from the deadline to be met, will establish a plan. With careful planning, you should have sufficient time to deliver the translation to the deadline using the standard step lead times. However, reality says this is not always the case! Where the step lead times and deadlines don't match, it will be necessary to

adjust the step lead times to meet the delivery date. If this is the case, it is essential that these schedule changes are agreed with the impacted stakeholders, make them aware of the priority and assure their buy-in. A rushed translation will likely result in error, which will cause more delays.

Any translation project will require a number of people involved to prepare the information to be translated, create the translation, review it and finally approve it. It is important to define who this set of individuals are so they can be made aware of the project and how they need to be involved. When defining the translation, involving those approving it can ensure that they don't get surprises when seeing it and can therefore increase chances of quicker approval. Involving the translation provider early by sharing a draft of the proposed text can help them be familiar with the content.

How tasks are carried out refers to the methods used for each step. It is good practice to have methods captured in documented procedures. This ensures repeatability and builds in best practices. In many industries, it is a prerequisite to have such activities precisely captured in Standard Operating Procedures. As part of defining the methods, the quality criteria to be met should also be defined. What constitutes an appropriate translation? How will terminology be maintained? How will differences in opinion on wording and syntax be resolved? These could all be captured in a translation quality plan.

To achieve all of the above, you need project management that is likely part of your translation coordinator's role. There are two aspects to this role:

- Establishing the project as discussed above, ensuring all of the impacted stakeholders are effectively engaged and agree on the time, quality and financial expectations.
- Expediting the delivery of the project through monitoring that the steps are delivered on time, people are doing the required tasks appropriately, issues are addressed promptly, budgets are managed and the overall deadlines are met.

Effective planning of the project is a key step in ensuring a right-first-time and on time translation.

Manage risks and issues

Whilst effective planning is essential, things can go wrong and the project team need to address them as they happen. As a precursor to this, the project team should understand the risks and issues associated with the project.

A simple definition: A risk is something that could go wrong. An issue is a risk that has happened!

Having contingency plans in place for key risks and things that could go wrong will help ensure a successful project outcome.

In the next post we will look at the third step – *Prepare text for translation*; with tips on how to ensure that the text you are supplying for translation is prepared in way that allows for a high quality translation.

Should you have any questions about this or any of my other blogs, if you would like to discuss the artwork processes within your company or would simply like to request a copy of my booklets, please don't hesitate to contact me directly on my email Andrew.love@be4ward.com

Read it online

Ensuring Effective Translations – Preparing Text for Translation

Andrew R Love

As we continue this series of posts expanding the topic of *Ensuring Effective Translations* to help you establish your translation capability, we move to the next set of tips, based around step 3 to help you make sure that the text you are supplying for translation is prepared in way that allows for a high quality translation.

Prepare before you start

Prior to commencing, you need to prepare the text needing translation. The source document needs to be clear, concise and jargon free. The sections to

be translated need to be clearly highlighted (or better still, remove the sections that are not to be translated). Glossaries, style guides and technical terminology all need to be provided. In taking the time to prepare up front, you will ensure a successful execution of the rest of the project.

Finalise your text before starting the translation

It is often the mindset that doing translations takes a long time and therefore, it is essential to start as soon as possible. This can create pressure to commence translation before the source text is finalised.

This creates two issues:

– By starting translation before finalising the source text, you are guaranteeing that you will not be able to carry out a correct translation the first time around, and hence, will have to edit the translation a number of times as the remaining information is provided. This results in wasteful extra review cycles and subsequently extends the project timelines.

– Adding extra content requires careful version control of the documents to make sure that all additional comments are captured and added to the right previous versions. Missing such edits is a classic cause of error.

It is therefore always preferable to only begin translation once all information is available. In many cases this can actually be faster, but it requires a mindset change to wait until ready to execute.

In some cases, deadlines make this unfeasible and it is necessary to start the translation whilst finalising the source text. In such cases, version control and time and date stamping must be rigorously applied.

An often-overlooked part of creating the source text is the use of previously translated material. Firstly, in large organisations, is there the chance that someone else in the company could have created this translation? Secondly, are there parts of the source document that have been previously translated and could be incorporated into the document? Re-use of previous translations not only saves time and money, it can increase your brand consistency. To facilitate this, many companies use translation memory tools to store standard translation fragments. Translation memory (TM) is not to be confused with machine translation. A translation memory system stores the

source text and the corresponding translation in segments. This could be in either an electronic tool or paper format, depending upon the complexity of the organisation.

Pay special attention to your source documents

As with many other processes, the phrase ‘garbage in – garbage out’ is applicable to your translation process. There are a number of things you can do to the source text document to minimise this effect.

– The first is to think about the translation requirements during the writing process. This can provide opportunities to re-use sections of already translated content and to be concise to avoid unnecessary content requiring translation. Also, aim to avoid local colloquialisms that will be difficult to translate.

– Secondly, stick to standard technical terms from your company glossary. This allows translation providers to have pre-translated phrases in their library for these terms.

– Thirdly, thoroughly review the source document to make sure that any errors are eliminated in the source text before you translate.

– Finally, make sure that the format and layout of the source document makes it easy for the translation provider to produce the translation.

Follow technical writing best practices

There are some recognised best practices that should be followed to ensure effective translations:

– Write short, clear sentences.

– Limit dependent clauses. One thought per sentence helps translators and increases savings from translation memory matches.

– Avoid idiomatic expressions. These are easily misinterpreted.

– Avoid cultural references like sports metaphors or quotations from literary or pop icons, as these often do not work across cultures.

– Make sure symbols are internationally recognised. Don’t assume that a symbol (i.e. a stop sign) has the same meaning in other countries.

Be concise

Consider writing less, as fewer words will mean lighter translation costs. Also if the text is concise, it should be clear and easier for the translator to render for the intended language.

Think international from the start

When developing your source text, it is important to be thinking about the international impact of the text from the start.

The first thing to consider, is to make sure you are using plain English in your document. This means using simple and clear statements that minimise the risk of being misunderstood either by the translator or by the audience after translation. Avoid using jargon or culturally biased language – references to the human body and any anecdotes should also be avoided. Similarly, local sayings and colloquial terms can cause confusion and may be gibberish when translated. The objective should be to keep the text simple, concise and clear.

Secondly, consider what language your readers will be reading your document in. Languages are not consistent between countries, for example British English or American English, French from France or Canadian French. Many countries require multi-lingual documentation due to the variety of languages spoken by their citizens. Therefore, translation requirements between different countries can vary even if it appears to be the same language, and this should influence your choice of translation provider – translators who understand the local subtleties of language are key.

Thirdly, the type of audience you are aiming for will influence the writing style you may want. The style would be different if you are writing to consumers versus skilled technical people. Their requirements and expectations will differ. You therefore need to put yourself in their shoes and prepare your text from their perspective.

Finally, but importantly, you must take into account legal, regulatory and cultural requirements to avoid illegal or offensive text unwittingly. Translation providers who understand the local requirements and customs will guide you with such issues.

Use automation

Modern word-processing tools have many useful features that can help with the preparation of your source text. Use automation in your documents for table of contents, indices, cross-references, variables and internal/external links. Also, make sure to use style sheets so that any updates or resizing can be automatically applied.

Also, avoid using hard and soft returns in sentences as broken sentences cause problems for the translation teams and their tools.

Prepare for text expansion

If English is the language in your source document, remember that it is a relatively concise language and most languages are 20% longer. Therefore remember to account for text expansion when designing the layouts you propose to use. Also consider what size of document you want to use (A4, US letter etc.) to make sure that the translated text will fit as you would want.

Carefully prepare your graphics

Graphics are essential to enhance documents and make them easier to understand. There are a few things you should consider to improve how you work with graphics:

Whenever possible, try to link graphics in a document rather than embed them. This simplifies replacement in localised versions and future updates. Linking graphics also reduces file size, which is friendlier to use with translation tools.

Keep text out of graphic images, as the graphic will have to be recreated to incorporate translated text.

Use screenshots sparingly as they will be in a specific language and would need to be edited for your translated document.

Remember that, depending on language, text may expand when translated. Allow for expansion of the text associated with an image.

To ensure you are only translating what needs to be translated, store localisable images separately from non-localisable images.

Provide editable source files

Re-creating files takes time and adds to cost, so always try to provide editable source files to your translation provider. As discussed above, this should include editable images.

Also consider compressing files if they are extremely large to help protect corruption-prone fonts and speed transmission during very tight schedules.

In the next blog, we will look at the fourth step – choosing your translation provider; offering our tips to ensure that the translation provider you propose to use is fit for purpose.

Should you have any questions or feedback relating to this or any of my other blogs, if you would like to discuss the artwork processes within your company or would simply like to request a copy of my booklets, please don't hesitate to contact me directly on my email Andrew.love@be4ward.com

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