Trusted Experts in Serialisation Labeling and Artwork

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

Our VP Andrew Love had the pleasure of presenting at this year's *HCPC European General Assembly* in Freiburg earlier this month, he also shared his knowledge on the subject of *Successfully co-managing your Clinical and Commercial artwork in a Complementary Process* with the BSMA community via an excellent informative webinar.

We've continued to share our Consultant's thoughts and knowledge via a series of articles on the VP blogs, on the topics of The impact of Serialisation on Product Packaging and Portfolio Strategy Development and the opening part to a new blog series Managing Clinical Trials Artwork: Key Considerations to Support Effective Clinical Trials . You can find these in our Featured Blog Post section below, available for you to read on or off-line.

Our focus for this newsletter is Proofreading and we're pleased to share the details of our popular online Proofreading Course along a wealth of information in our Be4ward Executive Briefing: *The top 15 Causes of Proofreading Errors* which draws on our expert, award-winning experience to identify a number of errors which are typically seen in the design and execution of proofreading capabilities.

We have also selected some Top News Picks from the industry that we think are worth a read.

We hope you will find this newsletter of interest and 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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BSMA

BIO SUPPLY MANAGEMENT ALLIANCE

Building Supply Chain Excellence End to End

SEPTEMBER WEBINAR NEWS

Successfully Co-managing your Clinical and Commercial Artwork in a Complementary Process

Andrew Love

"I sincerely enjoyed Andrew's assessment of history, present and future challenges associated with Clinical and Commercial Packaging and Artwork. I especially enjoyed learning the distinct issues found with each type, as well as the potential synergies associated with a future blending of both toward a project-based approach for optimized operations and drug delivery to patients. I look forward to reading more in your book" - Attendee feedback

Thank you to all those who joined us for this webinar presented by VP Andrew Love and hosted by BSMA, the feedback from our attendees was excellent. If you were unable to join us for the live event and would like further details of the content, please get in touch.

Web-based Training Course

Packaging Artwork

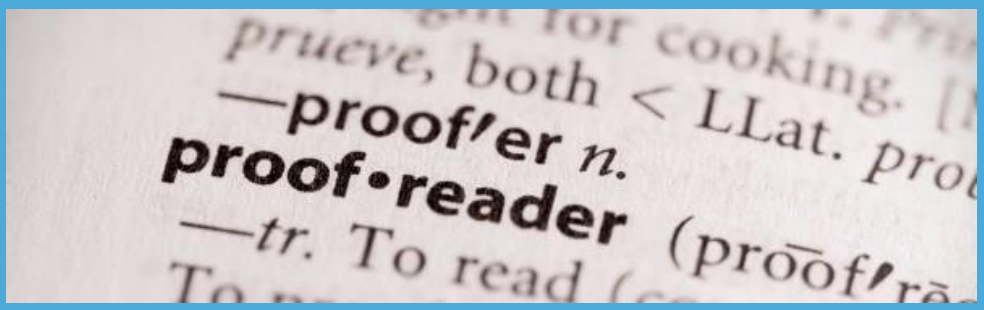
Document Verification and Proofreading

Artwork recall remains one of the highest causes of recall in the healthcare industry and carries the risk of serious consequences for patients.

Getting artwork right is a critical requirement for companies providing products to healthcare providers and patients, whether they be pharmaceuticals, biologicals or medical devices manufacturers. This relies on having the right capabilities in place - processes, tools and skills. Proofreading is a key part of these capabilities.

Pharmaceutical Artwork Proofreading can be seen as one of the last defences before the drug product is released to production. Yet, few people involved in proofreading have had formal training in the different aspects of manual and electronic proofreading. Where else would you encounter a critical quality control task that was not supported by formal, recorded training?

This is the reason why Be4ward artwork experts have put together this one-of-a-kind web-based training course, created to help artwork professionals to be fully capable and competent in this topic, whether they are in artwork, central and local country regulatory, packaging engineering or any other team providing critical data.



If you are a professional involved in the checking, proofreading or approval of packaging, labelling and artwork documents, this course will help you ensure that you do your job efficiently and effectively and help eliminate patient safety related errors.

The course has been developed by professional proofreaders and experts in the artwork field. The web-based training allows you to learn where and when you want and at the pace that suits you. At the end of the course you will receive a certificate for your training records.

Further course information and sign up here

Featured Blog Post

by Stephen McIndoe

The impact of Serialisation on Product Packaging and Portfolio Strategy Development

Stephen McIndoe -VP of Be4ward
Grant Courtney - Principle Consultant at Be4ward

How does serialisation impact your packaging and portfolio strategy?
What extra considerations need to be taken into account?
What are the challenges and risks and are there benefits?

These issues are addressed by VP Stephen McIndoe and Principle Consultant Grant Courtney in their blog post: *The Impact of Serialisation on Product Packaging and Portfolio Strategy Development*

>> Read it offline

Read it online

Featured Blog Post
by Andrew Love

Managing Clinical Trials Artwork: Key Considerations to Support Effective Clinical Trials

Clinical trials are a vital endeavour for a pharmaceutical company, the success of which is dependent on the effective design of the trials and their

underpinning artwork process. In his new blog series, VP Andrew Love will be examining four vital considerations in the clinical trials artwork process, starting here in part one with the importance of effective artwork management and the criteria the artwork process must deliver to support a successful clinical trial.

Read Andrew's first blog in the series: ***Managing Clinical Trials Artwork***.

>> Read it offline

Read it online

Top 15 Causes of Proofreading Errors

The Top 15 reasons why pharmaceutical labelling and artwork proofreading fails to identify packaging labelling and artwork errors.

Stephen McIndoe
Andrew Love

Be4ward

Executive Briefing

Andrew Love
Stephen McIndoe

Proofreading is a critical quality control step in the process of ensuring that the packaging labelling and artwork of finished pharmaceutical product is correct. Mistakes in this artwork can put patient safety at risk. Therefore, ensuring that there are adequate processes, people, facilities and tools in place to perform high quality proofreading activities is essential to patient safety. This Executive Briefing identifies a number of errors which are typically seen in the design and execution of proofreading capabilities which should be avoided to ensure a quality proofreading result.

Read the Executive Briefing to learn more

>> Read it offline

Top 3 News Picks

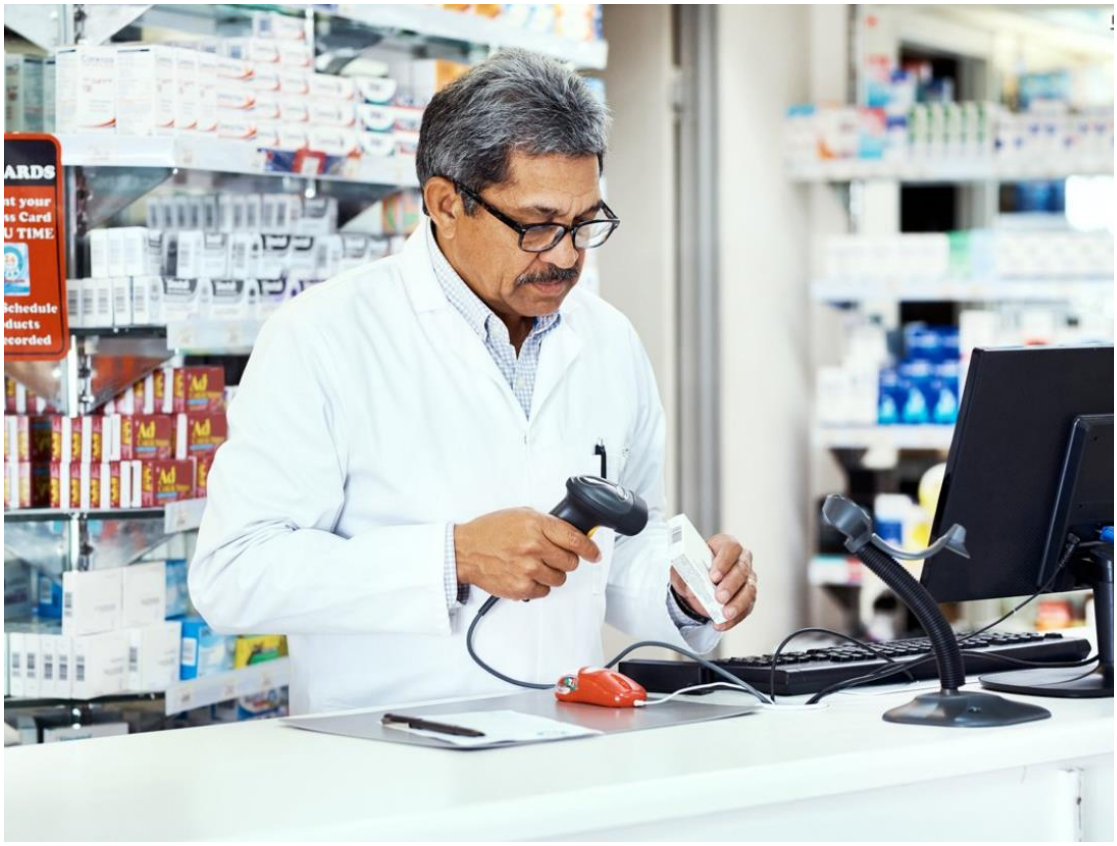
We share some of the latest worldwide news picks, on topics related to Serialisation, Artwork, Proofreading, Packaging and Supply Chain Optimisation. Here are three links from the many recently shared articles in the industry that we think are worth your time.

DSCSA: Where Are We, and Where Are We Going?

By Dirk Rodgers for *Logistics for the Life Sciences.com*
17 September 2019

Recapping current progress, the Nov. 2019 saleable returns deadline and the supply chain transformation expected in 2023.

Click here to read the article



FMD deadline – has it been met?

By Victoria Hattersley for *Packaging Europe.com*

30 September 2019

The Delegated Regulation EU2016/161 to the Falsified Medicines Directive came into force in February this year, creating a huge task for pharma companies and CMOs to update their systems to meet the deadline. As the dust settles, Victoria Hattersley looks at the wider impact of the Directive, and how companies have been working to achieve compliance and improve their approaches to security and traceability.

Click here to read the article

European medicine supply: Access in the spotlight

By Ben Hargreaves for *Pharmatechnologist.com*
25 September 2019

Drug shortages, created by consolidation of manufacturing and pricing policy, a ‘growing concern’, the EFPIA suggests.

Click here to read the article

Executive Briefing: read offline

Top 15 Causes of Proofreading Errors

The Top 15 reasons why pharmaceutical labelling and artwork proofreading fails to identify packaging labelling and artwork errors.

Stephen McIndoe
Andrew Love

Introduction

Proofreading is a critical quality control step in the process of ensuring that the packaging labelling and artwork of finished pharmaceutical product is correct. Mistakes in this artwork can put patient safety at risk. Therefore, ensuring that there are adequate processes, people, facilities and tools in place to perform high quality proofreading activities is essential to patient safety. This booklet identifies a number of errors which are typically seen in the design and execution of proofreading capabilities which should be avoided to ensure a quality proofreading result. Whilst this document is written specifically with packaging labelling and artwork proofreading in mind, many if not all the points hold true for proofreading activity of any documentation or design. We hope you find this information useful. For a comprehensive suite of self study and face-to-face proofreading training, contact us at enquiries@be4ward.com.

Definition of Proofreading

For the purposes of this document, proofreading is taken to mean any activity which seeks to verify that the content of a finished document, artwork

etc, meets the appropriate requirements and it's content is correct. We will consider proofreading to include the following elements:

• Text content.
• Graphical content.
• Technical aspects.

Text content review

The text verification ensures three aspects of the text in any given artwork. Firstly, it is important to verify that text has been correctly transcribed from source documents. It must be verified that all text has been transcribed on to all relevant faces of the artwork and that none of it has been inadvertently hidden. Secondly, checks should be made to ensure that critical information such as product name, strength, dosage etc is correct. Finally it is important to check that the layout of the text has not altered its meaning.

Graphical content review

The graphical checks verify that all the graphical elements of the artwork are as required. Graphical elements may include logos, branding images, colours etc.

Technical review

The technical review ensures that all other aspects of the artwork are correct. This will include checks to ensure that items such as dimensions, barcodes, varnish layers etc are correct.

Cause 1 – Not having a comprehensive set of work instructions, training and competency assessment

Just like any other task, anyone responsible for performing proofreading activities needs to understand exactly how they are supposed to perform each task in an optimal way. Work instructions and procedures should be designed to explain exactly what needs to be done and the best methods for

carrying out individual tasks. As we discuss later, the specific methods used in proofreading are particularly important given the human mind's ability to subconsciously correct mistakes without an individual being aware of it. Education and training needs to ensure that these work methods are explained, demonstrated and practiced sufficiently in order to ensure that people can reliably repeat the tasks required of them each time they are required to perform them. Particular attention should be paid to people who will not perform their proofreading tasks on a regular basis, or who perform the tasks in isolation, to ensure that methods are consistently and completely adhered too. Given the critical role of proofreading in the artwork context in ensuring that artwork mistakes do not find their way into finished products, the competence of individuals should also be verified before they are allowed to proofread production artwork. Answering a small number of questions to demonstrate a procedure has been read is very unlikely to be adequate to ensure proofreading competency.

Cause 2 – Not being clear who should be checking what

As we discussed in the introduction, proofreading in the context of this discussion consists of a number of distinctly different types of checks. Furthermore, artwork typically contains information from many different sources. We have observed many instances where individuals are asked to check a document, but when asked, they have little or no idea exactly what they are being asked to check. At best this results in several checks on the same information being performed. At worst, it results in elements of the artwork not being checked at all, with the inherent risk that errors will then make their way through to the finished product. Another symptom of a lack of clarity in this area is that comments and requests for change come from people who have no accountability or responsibility for the element of the document being commented upon. This tends to lead to inefficient operations and extended lead times. Therefore, it is essential that any individual asked to perform a proofreading activity is clear exactly what they

are being asked to check. Furthermore, it should be recognised that it is highly likely that different people will be required to check different things during the overall proofreading and approval process.

Cause 3 – Not proofreading the complete document

Packaging artwork contains information and elements such as barcodes and Braille from many different sources. In many cases, this information becomes available, or final, at different stages in the process of preparing and approving the artwork. We have encountered situations where artwork has been proofread and approved at a stage in the process where all the information was not yet included in the document. Subsequently, this information was added to the document without further adequate proofreading activity being performed. Clearly this situation introduces the risk that the new information added to the artwork is incorrect and finds its way onto finished product unchecked. Furthermore, as we will discuss in greater detail later, there is also the opportunity for inadvertent changes to be made to the artwork during this information addition which again could find their way onto finished product. Therefore, the artwork process should ensure that all elements of the artwork are present and appropriately proofread.

Cause 4 – Not checking for inadvertent changes

The nature of the artwork process means that there are many occasions where only a small part of the artwork needs to be updated to affect the desired change. This may be because the overall change in question is only minor, or it may be because a small change needs to be made during a correction cycle within a more significant overall change. It is very tempting in these situations for proofreading activity to only check that the elements which were intended to have been changed/added are correct. However, this approach can lead to a significant number of errors going undetected that were caused by artwork operators or tools inadvertently changing another

part of the artwork by mistake. Therefore, we would recommend that, whenever a change is made to an artwork, no matter how small it is intended to be, that the complete artwork is then proofread. In this way, any unintentional changes to the artwork will be picked up.

Cause 5 – Not checking multiple instances of the same information

Packaging artwork often contains multiple instances of the same information. For example, the product name and strength will often appear on multiple faces of a carton, or will be stated many times within a leaflet. Many recalls have occurred because one or more instances of this information were correct, but others were not. For example, it is easy to imagine how this sort of mistake can be made by an individual who verifies one instance of the information is correct and then assumes the other instances are the same. Therefore, we would recommend that proofreading methods explicitly require all instances of the same information to verified as correct whilst proofreading activity is being performed. Furthermore, we would also recommend that critical information such as product name and strength are checked across all artworks of the same finished product to ensure that these are also the same.

Cause 6 – Not using techniques that "disable" the human mind's ability to auto-correct

The human brain is excellent at filling in gaps in information and correcting mistakes in information so that it can see meaning very quickly. As an example, try to read the following: Cna yuo raed tihs? 55 plepoe out of 100 can. i cdnuolt blveiee taht I cluod uesdnatnrd waht I was rdanieg. The phaonmneal pweor of the hmuan mnid, aoccdrnig to a rscheearch at Cmabrigde Uinervtisy, it dseno't mtaetr in waht oerdr the ltteres in a wrod are, the olny iproamtnt tihng is taht the frsit and lsat ltteer be in the rghi t pclae. The rset can be a taotl mses and you can sitll raed it whotuit a pboerlm. Tihs is bcuseae the huamn mnid deos not raed ervey lteter by

istlef, but the wrod as a wlohe. Many people have little difficulty reading this example; however it does have to be said that some people will find the text unintelligible. Indeed, on first reading, some readers will not notice any issues at all with many of the words. If you look closely at the text, you will see that the middle letters in all the words are actually scrambled, with only the first and the last letters of each word being in the correct place. This has profound implications on proofreading, particularly when comparing text. We effectively see what we want to see. For these reasons, people doing manual proofreading activity need to be taught to compare information in a way that attempts to stop the human mind making these subconscious corrections. Furthermore, it may be beneficial to select proofreaders who are less susceptible to the sub-conscious correcting process.

Cause 7 – Not ensuring source data and documents are correct

The act of proofreading inevitably means verifying information from source documents or systems with the information contained in the finished document. Many artwork errors have occurred because individuals have used the wrong source data or documents. The first example of this would be the use of personal stores of information or documents. This circumstance frequently occurs when corporate information sources are difficult to access or use and individuals resort to holding their own store of information to make their jobs more efficient. The obvious risk here for proof reading is that the source information that is referenced from the local store is, in itself, incorrect. This may be because it has been incorrectly transposed by the individual collecting it, a situation often occurring when individuals collate their own spreadsheets of information useful to them in their day to day work. Alternatively, the information may be drawn from a document which has subsequently changed in a later revision. Because the source document was held in a local uncontrolled store, the individual is not aware of the change to the information being checked. Therefore, we would recommend that work instructions state clearly where source information is

to be taken from in order to perform the proofreading activity effectively. It is important that anyone providing source information to the artwork process is responsible for ensuring the accuracy and currency of that information.

Cause 8 – Not proofreading all instances of an artwork

Artworks often exist in a number of different forms, each one having subtle differences. Take for example the situation where a single artwork is used to create one or more print ready files for one or more printing machines. In this case the artwork, although ostensibly the same is actually two or more different artworks. For reasons we discussed in (4), it is easy to assume that these different instances of the artwork are the same for all material purposes. After all, the printer's artwork file only has some specific printer codes and markings added to it. Nothing in the artwork that will appear to the patient is changed. By now you will have realised that, even if the intent is not to change the artwork when creating these instances, it can happen by mistake. Unless there is a validated method that prevents material changes to the artwork occurring, we would recommend that each time any iteration of the artwork is created that it is proofread appropriately.

Cause 9 – Not using checklists to ensure everything is being done

Proofreading requires a great deal of concentration and can often take a considerable period of time. For example, it is not uncommon for a manual proofread of a long multi-language leaflet to take a day to complete. Furthermore, because of the nature of the task, proofreaders need to take frequent breaks to maintain adequate levels of concentration whilst proofreading. Given that proofreading requires people to repeat many detailed tasks over a long period of time, it is not surprising that it is easy to forget to do certain tasks unless there is some aid memoir built into the process. Checklists provide an excellent way to remind people of the detailed tasks they need to perform during each and every proofread and give them a convenient way to record their progress. Completed checklists

can also form a useful part of the audit trail for a change at critical verification and approval points.

Cause 10 – Not ensuring that people have the right skills and temperament

If we were to list some of the attributes of someone ideally suited to the proofreading task it might look something like this: • High process compliance focus.

• Strong attention to detail.

• High self discipline.

• A completer finisher.

• Ability to concentrate on a task for long periods.

• Happy working alone for long periods.

• Low natural tendency to subconsciously correct errors in text.

• Ability to resist management pressure to rush work.

Without these attributes, it is highly unlikely that an individual is going to be able to do a good job of proofreading if they are called upon to do so for a significant proportion of their time. Some would argue that, even if they only perform proofreading for small periods of their time, unless they have most of these attributes, they will still do a poor proofreading job. Firstly, we would recommend selecting individuals who meet a profile suitable for proofreading if they are to be asked to perform proofreading duties for a significant part of their jobs. Secondly, we would recommend that organisations look closely at the roles which are required to perform proofreading in the artwork process and consider if the typical skill set of individuals in these roles lends itself to effective proofreading. If not, then consideration should be given to changing the process to put critical proofreading activity in the hands of those with the appropriate skills.

Cause 11 – Not ensuring people have the right environment to work in

Proofreading requires concentration on often large documents for extended

periods of time. A small desk and laptop in a busy, noisy open plan office is hardly conducive to performing this task well. In all cases we would recommend that the office environment in which proofreading is performed has the following features:

• Ergonomic desk and seating design to ensure comfort for long periods of sitting still.
• Comfortable temperature for sitting still for long periods.
• Lighting suitable for long periods of concentration on documents containing small text.
• Quiet area, free from audio and visual distractions.
• Adequate clear desk space to lay out large documents and checklists.

If proofreading is to be done on-screen, then we would also recommend:

• Large high quality screens.
• Multiple screens to allow easy comparison of multiple documents.

Cause 12 – Not ensuring that people have quality time to do their work

As anyone involved in Quality will tell you that not providing adequate quality time to perform tasks is a sure way to introduce errors and non-compliance. Proofreading is no exception to this rule and seems to suffer particularly badly due to the nature of artwork changes and the position of proofreading in the artwork process. Firstly, for many organisations, the artwork process is often poorly understood or appreciated. This often leads an organisation to systematically expect the tasks involved in the process to be performed in less time than can be reasonably expected. Secondly, the nature of artwork changes means that they are often on the critical path of getting product out of the factory. This further increases the time pressures. Thirdly, proofreading occurs towards the end of the process, at which point, any time pressures are magnified as things are often already running late. It is easy for management to forget that, even if only small changes are being made, there is no essential difference to the time it takes to perform proofreading

tasks. Therefore, we would recommend that effort is put in to a number of things to help this situation:

• Explaining to the organisation the requirements of proofreading.
• Setting standard times for proofreading activity.
• Monitoring performance and taking corrective action where issues occur.
• Monitoring workload on proofreaders to ensure they have adequate capacity on an ongoing basis.

Cause 13 – Not proofreading all elements because of a lack of tools

One very simple reason for inadequate proofreading being performed is that the appropriate tools are not available. At it's simplest level, we have come across situations where there was no way for the proof reader to print out documents at full size and perform the required technical dimensional checks. More often, this situation arises when features like barcode and Braille are present in the artwork. In these cases it is necessary to provide validated tools to inspect these features and report to the proof-reader what is found. Furthermore, when considering features such as barcodes, the process must ensure that both the information contained in the feature is correct (e.g. the product code) and the specification of the feature is correct, e.g. barcode type, cell size, modulation, quiet zones etc.

Cause 14 – Relying on electronic proofreading tools to do everything

Modern electronic proofreading tools provide an excellent way of minimising the risk of artwork errors going undetected. Table 14.1 lists the typical types of tools used during proofreading activity.

Table 14.1 Typical Proofreading Tools

Table 14.1 Typical Proofreading Tools

Tool Type	Typical Uses in Proofreading
Text Comparison	Comparing source documents, such as regulatory source text documents, with finished artwork.
Graphical Comparison	Comparing revisions of artworks to each other to verify what has and has not changed.
Technical Verification	Verifying that technical elements such as barcodes are correct.

Firstly, before any such tools are used, they need to be validated, managed under an appropriate quality system and users need to be adequately trained to use them. Like all sophisticated tools, it is easy for operators to adjust settings and misuse them in such a way that the results will be misleading and errors will not be detected. Secondly, all these tools have their limitations which must be understood and then the process designed to mitigate these short comings. As an example, many text comparison tools have limitations when it comes to comparing text in tables due to the differing ways that source document software and artwork graphical software manages the text in tables. This often leads to the need for manual proofreading of all tables in documents, which sometimes represent the majority of the artwork. Furthermore, the residual risk of errors going undetected when relatively comprehensive electronic proofreading tools are employed can be significantly increased if the remaining manual activities are undervalued. The residual manual activity still needs to consider all of the causes of error we discuss in this document.

Cause 15 – Electronic tools not identifying errors due to a lack of validation

Proofreading is a critical quality control step in the process of ensuring that the artwork that appears on finished product is correct. Mistakes in this artwork can, and have, put patient safety at risk. Therefore, we would

recommend that any tools that are relied upon to carry out part of the proofreading verification activity need to be validated and managed under an appropriate quality system. The process of validation and subsequent management will ensure that the tools perform as they are intended to do so initially and on an ongoing basis. We would caution against arguing that these tools are “just back-ups to the manual process” and therefore do not need to be validated. In our experience, once tools like this are in place, people rarely continue to perform a rigorous manual process, believing that the electronic tools will find any errors they miss. Clearly this is an unacceptable risk situation where non-validated tools are being used.

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Featured Blog Posts : read offline

The impact of Serialisation on Product Packaging and Portfolio Strategy Development

By Stephen McIndoe - VP of Be4ward and Grant Courtney – Principle Consultant at Be4ward

When launching a new brand or product range the development of a Product Packaging and Portfolio Strategy has always been important, however serialisation presents further considerations, which must be taken into account when defining a robust strategy.

One such example where portfolio design is impacted by serialisation, relates to the EU FMD. We know that currently under Article 22 of the Delegated Regulation, products which are intended to be distributed outside of the European Union (EU) need to be verified and decommissioned,

therefore the sharing of product between EU and non-EU countries introduces additional processes into the supply chain.

The need to understand the relative value of reduced SKU complexity verses the need to operate additional decommissioning steps within your supply chain is just one of the factors which must be considered in this context. A leaner portfolio with less SKUs will improve production line OEE (Overall Equipment Effectiveness), however in this example it will decrease the efficiencies in the supply chain processes further downstream. Without operating aggregation of unit packs to logistic items, decommissioning relies on the unpacking, scanning, decommissioning and repacking of each individual pack. This is a labour-intensive process and can also be error-prone depending on the volumes and decommissioning solutions in place. It calls into question whether the OEE gains are outweighed by the additional cost and lead-times added into the supply chain.

In addition to this issue of supply chain complexity, many companies are now seriously considering reducing the amount of product which is shared between the EU and international markets due to the potential risks posed by this sharing. Illegal parallel trade and falsification of products can be made easier where the pack is already common across regions. Currently, ever-increasing numbers of countries are introducing serialisation requirements, therefore moving product which is serialised for one country or region into another, presents further challenges and risks.

However, whilst serialisation can present these issues which need to be factored into portfolio design, it can also offer benefits which have the potential to reduce complexity. Where regulators and legislation have allowed the use of Global Standards, some of the labelling and product coding requirements have been harmonised, removing the barriers to sharing packs and therefore reducing portfolio complexity. Countries which previously needed country-specific barcodes are now allowing the use of product codes and barcode formats which comply with global interoperable

standards. This opens the opportunity to share packs between countries which could not previously do so. This is good news for manufacturers, especially where product volumes are low and consolidation of demand into fewer SKUs will increase flexibility of supply and ultimately make products available to more patients, thereby increasing sales.

The rules around Global Standards can be complex and the transition from legacy coding is not without its challenges, consideration must always be given to the users of the pack and the barcodes contained on them. It may be necessary to maintain existing coding on the packaging whilst stakeholders transition their systems and processes.

The principles which have traditionally been used to develop a Product Packaging and Portfolio Strategy clearly need to change to factor in the benefits and risks associated with the disruption serialisation brings.

If you require help, advice or assistance with developing a Product Packaging and Portfolio Strategy, understanding the impacts serialisation has on these processes, or any other aspect of your company's serialisation, packaging or labelling strategy, please don't hesitate to contact us at Stephen.McIndoe@be4ward.com or Grant.Courtney@be4ward.com

If you would simply like to request a copy of any of our booklets, please get in touch.

Be4ward provides specialist consulting services to the pharmaceutical and other highly regulated industries. We deliver value to our clients through a combination of deep subject matter expertise and excellent consulting skills. Whilst we have a thorough understanding of the supply base in our areas of focus, we pride ourselves on providing entirely independent advice to our clients.

Read it online

Managing Clinical Trials Artwork: Key Considerations to Support Effective Clinical Trials

Andrew R Love

As pressure to deliver new products intensifies in an increasingly complex regulatory environment, clinical trials are a vital endeavour for the pharmaceutical company. If things go well, it will mean approval of the drug and potential revenue for the company. However even slight errors have the potential to cause delays in the trial, wasting time and resources. Significant errors could lead to more scrutiny of the drug, with the potential for stopping the trial and preventing the drug from reaching the market. Therefore the design of effective clinical trials and their underpinning processes, is essential to ensuring the satisfactory execution of those trials.

In this blog series I will examine four important considerations in the clinical trials artwork process, starting with the importance of artwork management as one of the required underpinning processes for a clinical trial.

There are a number of criteria that this process must deliver to support a successful trial:

•In the clinical trial, information will be constantly changing as the trial evolves. This will be driven by numerous internal and external factors, for example feedback from the trial, the company's target labelling outcomes and opinion from external regulators. Therefore the artwork process needs to be sufficiently flexible to cater for this volume of change.

•The timescales involved in clinical trials are typically compressed and thus the expected lead-times for process steps are constrained.

•The working environment for clinical trials is typically a project type environment with a dynamic feel and high dependency on other activities.

•Volumes for clinical trials can be small and often supplied using local or online printing capabilities. The artwork process can therefore require the supply of artwork files in formats other than traditional PDF, requiring specific additional features to support the local printing technology.

•As well as using the active product and placebo for trials, comparative studies against other marketed products from other companies can be undertaken. This requires repackaging or over-labelling and can drive a significant range of required artwork profiles.

•The range of suppliers involved in the trial such as contract clinical trials providers, internal or contract packaging facilities and packaging component suppliers, creates a complex network of internal and external stakeholders who all need to be integrated into the artwork change process.

•Through execution of the trial, the product safety profile and instructions for use are being detailed and defined. This has significant impact on the final commercial product, so the artwork process needs to support effective decision making from relevant impacted stakeholders.

•Finally, the process must ensure accurate and repeatable artwork is provided to support a successful trial.

The artwork process is just one of the underpinning processes for clinical trials. The criteria above define some of the important considerations to be incorporated in the design of an effective clinical trials artwork process and meeting these will help facilitate successful trials.

In my next post, I will discuss what opportunities exist to leverage the commercial artwork process to support artwork for clinical trials.

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

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Trusted Experts in Serialisation Labeling and Artwork

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