Trusted Experts in Serialisation Labeling and Artwork

Interesting serialisation, labelling and artwork articles from the Be4ward team

We have had a number of requests from people asking to be sent the articles we publish in email form so that they are more readily accessible to them. Therefore, we have created this email newsletter that allows you to read our most recent articles online or offline, whichever is more convenient for you.

We hope you will find these interesting and we would welcome any feedback.

Kind regards,

The team at Be4ward

Featured Artwork Posts from Andrew Love's Blog

Proof reading: Who is involved?

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Read it online

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Read it online

Measuring your artwork service

You have reviewed your artwork service, perhaps in response to a recall incident, made some improvements to the process and tightened up your training but have the changes given you the outcome you desired? The danger is, unless you have some metrics in place, you do not know for sure. In this article, I introduce the need for measuring your artwork service, what measures are key and the part played by the Governance team.

Read it online

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I always consider that ‘Right-First-Time’ is the fundamental metric for an artwork service. This is a simple pass or fail metric - did the artwork pass through the process once or was any change required? This is difficult to achieve on a consistent basis and requires focus and persistence. Therefore, in the next series of articles, I am going to explore this subject further.

>>Read it offline

Read it online

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Read it online

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I believe right-first-time is a key metric and mind set for your artwork process and, in this article, I continue my series on top tips to improve it, raising the need for a detailed understanding of why the errors are happening.

Read it online

Right-first-time tip 3: Make sure all the information is correct before starting, using an artwork brief

Right-first-time, I believe, is a key metric and goal for your artwork process and this week I talk through my third tip, ‘Make sure you have all the information before starting’. Unfortunately many companies start with incomplete information and so here I talk through why this happens, why having the information upfront is so important and how to manage the process.

Read it online

Featured Serialisation posts from Stephen McIndoe's blog

FDA Public Meeting key messages: Progress Toward Implementing the Product Identification Requirements of the DSCSA, 14th October 2016

I was fortunate enough to have attended the latest in the FDA's public meetings discussing the Drug Supply Chain Security Act (DSCSA).

The focus of this specific event was to allow those impacted by the law to make representations on progress and share learning to date. Therefore, the event consisted of a number of presentations, some with slides and some deliberately without.

Read it online

EU FMD serialisation event, Ireland

Don't forget that we are holding another in the series of serialisation technology days with PCE Mettler Toledo, this time with IPT Ltd, Mettler Tolledo's representatives in Cork, Ireland. The events we have done in the UK recently have been a resounding success and I am sure this one will be no exception.

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I will be at the US Healthcare Distribution Alliance (formerly the HDMA), Traceability Event on 9th - 11th November, so hope to meet some of you there.

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The legislation is for pharmaceutical product sold into Oman under tender.

Read it online

Join Be4ward and rfXcel for an informative webinar that will address the DSCSA compliance deadline

We will address the November 2017 DSCSA serialization requirements for Contract Manufacturers (CMO's). This session will help clarify some of the confusion Contract Manufactures are facing when it comes to meeting the DSCSA requirements by November 17, 2017. The webinar will address the key areas of the law that must be met, challenges that will arise, what trading partners are looking for, and how you can accelerate compliance while creating value for your company.

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Serialisation posts

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The focus of this specific event was to allow those impacted by the law to make representations on progress and share learning to date. Therefore, the event consisted of a number of presentations, some with slides and some deliberately without.

In terms of speakers, there was a good cross section of the impacted supply chain, including:

- The FDA themselves
- Rx Manufacturer - J&J
- Generic manufacturer's association - GPhA
- 3rd party logistics: UPS
- The wholesalers: HDA, AmerisourceBergen & McKesson
- Pharmacies: PDSA
- Suppliers: Optel Vision.

There was a lot discussed, some of which I will go into in more detail in separate blogs in the next few weeks. In the meantime, here are the messages that stood out for me.
I would characterise the overall message from the speakers as follows: It's very difficult; We are trying hard; We need some FDA guidance in specific areas; We will probably need more time to implement.
As yet, the FDA has not published any guidance to State licensors. It was

reported that some proactive States are changing their licencing rules in line with what they believe is required by the DSCSA. However, in the absence of FDA guidance on this topic, there are inconsistent requirements being implemented. There was a plea from several speakers for the FDA to issue guidance as soon as possible.

There were lots of calls from the presenters for the clarification guidance from the FDA on grandfathering. The FDA simply stated that guidance was being developed and would be published sometime.

There was a lot of confusion reported on how to encode product NDCs into GTINs. It seemed that this issue was mainly originating from product produced in India and destined for the US market. Initial GS1 India guidelines appear to have been open to interpretation and have caused incorrect coding. There were several requests for clarification on this from the FDA. For those in confusion, I suggest reading the GS1 US guidance on the subject.

Wholesalers are clearly concerned about the use of the term ‘transact’ in the DSCSA regarding the 2019 deadline. Does it mean buy and/or sell/re-sell and/or return?

Several presenters spoke of the need for the FDA to provide additional guidance on topics in the form of ‘guide rails’, i.e. don’t tell us ‘how’, but do put guidance in place that sets the boundaries of ‘what’. However, nobody gave the FDA much in the way of hints as to what guide rails they wanted.

Astellas and J&J informed the FDA that they are investing in aggregating everything from day 1. A number of our clients are doing the same thing, in which case they are not exposed to any risk associated with not aggregating.

All the wholesaler presents talked about their learnings from piloting: However, the HDA was basically keeping their powder dry, as they intend to release their results at their November annual HDA conference. McKesson and AmerisourceBergenn (AB) were both more forthcoming, presenting findings from their individual pilots. The messages that stood out to me were:

- They have been focusing on the transaction from Manufacturer to Wholesaler so far in pilots.

- They were all emphasising that they will need aggregation and inference, so need guidelines on it fast.
- With 60 million returns per year, there was a clear emphasis on data being needed to support returns verification activity in 2019.
- It's a lot more complex than they thought to manage both exceptions and the complex variations in which products move.
- AB are going to be doing more piloting (with 12 manufacturers, 50-100 skus & 4 DCs) in Q1 2017, focusing on:
    - Wholesaler to Pharmacy transactions.
    - Exceptions, e.g. Data, no product; Product, no data; Packaging/labelling issues.
- McKesson will publish another letter early in Q1 2017, clarifying some things from the previous letter and issuing guidance on implementation.
- GS1 US announced their upcoming DSCSA implementation guidelines

More to follow in the next couple of weeks.

Read it online

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With Pfizer, Tracelink, CI Vision and, of course, Be4ward and PCE Mettller Tolledo presenting at the event, together with hands-on software and equipment demonstrations, I am sure it will very educational.

It would be great to see you at the event if you can make it. To register for the event please follow this link: http://www.ipt.ie/content/register-here-our-track-and-trace-event-dublin-november

Read it online

HDA Traceability Event, 9th - 11th November, Washington

I will be at the US Healthcare Distribution Alliance (formerly the HDMA), Traceability Event on 9th - 11th November, so hope to meet some of you there.

As I discussed in my article about the recent FDA event the event is going to headline the results of the HDA DSCSA Pilot that has been going on this year. This should give a clear signal from the US wholesalers about what they will require and when, in order for them to meet their obligation to authenticate returned product in 2019.

I will report back on what I learn shortly after the event. In the meantime, if you have any specific questions you would like me to try to get answered at the meeting, please just ask.

Read it online

Oman publish serialisation requirements

Oman has now published it's 'Barcoding System' requirements in Senate of Oman Ministry of Health requirement MH/DGMS/DSS/M/7043 dated 26/10/2016.
The legislation is for pharmaceutical product sold into Oman under tender.
The implementation timing is as follows:

- 31 December 2017: GS1 Data Matrix containing GTIN, Lot and Expiry
- 31 December 2018: Addition of a serial number

The requirements appear to be in line with GS1 standards as GS1 have been working closely with the Oman authorities. However, there are not many details in the short requirement statement.

Read it online

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Don't be left behind, register today for this informative webinar.

We will be running the same webinar twice, so pick a time that suits you best. After registering, you will receive a confirmation email containing information about joining the webinar

Click here to Register Today!

To find out more about the webinar click here.

Read it online

Is aggregation required for US DSCSA serialization?

Some companies seem to be understandably confused as to whether aggregation is required to meet the US DSCSA requirement. Indeed, the question came up again on a recent GS1 call this week. So let me try to help clarify the situation.

Before I go any further, let me clarify what I mean by aggregation for the purposes of this discussion. Aggregation information is the information that describes the physical relationship between 'parent' shippers, e.g. homogeneous cases, and the 'children' contained inside them, e.g. secondary packages. Hence people will often talk about the 'parent child relationships' when discussing aggregation. This information is typically constructed in

electronic system databases during product packaging and distribution activities.

First of all, the US DSCSA legislation does not directly mandate aggregation. It only mandates the application of unique identifiers, often referred to for simplicity as serial numbers, to secondary packaging and homogeneous shipper cases by November 2017, and the reporting of this information to supply chain partners by the latest in November 2023. When asked recently at the FDA Public Meeting on Progress Toward Implementing the Product Identification Requirements of the DSCSA, they reiterated that aggregation was not mandated by the law and that this was a supply chain issue.

However, the reality of moving product in the supply chain, coupled with the need to understand where each unique identifier is, does require aggregation. The easiest way to think about this is to consider the situation where a company is selling a full case of product to a customer and the seller needs to communicate the serialization information about this product to the customer. If aggregation information is available to the seller, then the seller simply needs to scan the single case unique identifier when picking the sales order. They can then infer what is in the case from the aggregation information and transmit this information accordingly. However, if aggregation is not present, then the seller would have to break open the case and scan every single secondary pack in the case. This would clearly take much more time and create increased risk of error.

The wholesalers understand this practical necessity for aggregation and have therefore issued instructions to their suppliers that they will require serialization and aggregation from secondary package to pallet level. Therefore, whilst not mandated in the DSCSA Law, aggregation to the pallet level effectively becomes a requirement of the supply chain for many manufacturers.

Clearly, there are certain situations where aggregation would not be required. For example, where product is sold in less than full case quantities and shipped

directly from manufacturer to patients or dispensers. Unfortunately, for many manufacturers, this is not the situation.

Therefore, for a significant number of manufacturers, aggregation becomes a requirement to be able to sell product into the US supply chain, and many are putting in capabilities accordingly.

Read it online

Artwork posts

Proof reading: Who is involved?

My recent set of articles has been looking at proofreading. I have talked about the step change it can make in the quality of your process and what is involved. In this article, I am talking about the difference between what each group reviews and how to control that and what happens at centre versus the affiliates.

Proof reading - it is important to be clear what needs to checked and by whom

The first check is completed by the artwork operator with the second step being the full, comprehensive and independent proof read completed by a proof reader. Normally after that there would follow reviews by the functional and country representatives. It is important to distinguish for each group the checks required. Procedures must explain in detail the elements to be checked and who must perform the review. Checklists are a common way to differentiate the different tasks required for each group.

It is probably useful to look at an artwork element to illustrate this point. So let’s look at storage conditions. After creating the artwork for a launch, the artwork

operator does a simple check - have the storage conditions been added in accordance with the brief? The proof reader, however, will go further and as well as checking against the artwork brief will check against the source text document and separately with what is registered.

Procedures - it is important to mention the 'how'

It is important; procedures detail not only what people are reviewing, but also how they are going to perform the task. So when checking the EAN bar code, the SOP needs to describe what needs to be checked and how to use a bar code verifier to make sure the code reads correctly and is displaying the right information.

There is a significant difference between the checks performed by the central and local affiliate regulatory groups

In most companies and for some markets, it is the central regulatory group who will produce the core text in English for use in all the products' artwork components. It is often the affiliate's role to translate the core text for use in the artwork brief, although often translation houses are used. Sometimes there is a mismatch regarding the information held centrally versus what is registered locally. Therefore, the checks performed by the local affiliate can pick up issues in this area.

The local regulatory team has a key role when checking the artwork from a native speaker's point of view. It is important that they check there has been no change or loss of meaning, due to the way the artwork has been laid on the component. The classic example being when artwork is laid onto a leaflet, in columns as is normal, and it states 'Take three times a day' and then on the other column it states 'with food'. The meaning is potentially lost and only a native speaker can confirm if there is a problem or not.

In my next article, I will look at the importance of training for all those involved in the reviewing steps.

Read it online

Proof reading is a GMP activity: this is why training is essential

In my recent set of blogs, I have been talking about the need for and benefits of proof reading in the review and approval of artwork. In this article, I will highlight the need to train the staff involved, talk about the difficulties of covering all reviewers in the company network and what training opportunities are available.

Reviewing artwork - a GMP activity

The regulatory authorities in the US and EU and other authorities require management to have systems to ensure patient safety on labelling. The FDA CFR 211.125 insists strict control shall be exercised over labelling issued in drug product labelling operations. In CFR 820.30 for medical devices, the FDA says any changes to labelling must be formally reviewed and authorised before implementation. The MHRA have issued guidelines on best practice for the design of labelling and in EC GMP guide part 1 they talk about QA principles regarding labelling. These are only principles but they look for responsibility and active management by senior management, all quality-related activities are defined and documented, responsibilities are defined (in writing) and release of material only occurs after controls are completed.

Review and approval of artwork is a GMP activity so it is important that procedures are in place, staff are trained, assessed and the results documented in their training records. If you are audited tomorrow, are you confident your company would be in compliance for all staff involved in your labelling and artwork process?

The difficulty of training all the reviewers in your company network

I generally find the central regulatory and artwork groups have very detailed procedures. It can be a very different story with the affiliates. Even where procedures exist, and often they don't, it is usually a very 'thin' procedure which doesn't detail the specific responsibilities of the affiliate reviewer. 'Training' often is just a request to read the SOP and there is no assessment prior to

permission to undertake these GMP tasks. In addition, affiliate reviewers are often changing making it difficult to remain in compliance.

It is key, however, that a native speaker who knows what is registered locally reviews the artwork correctly, and management must consider this group, as well as the central group, when looking at training and compliance. All reviewer groups must be trained, assessed, and details documented in training records.

Training opportunities for proof readers and reviewers

In most cases, I would recommend the reviewers have role-specific checklists within SOPs and are trained to understand what documentation they need before they begin a review, what specifically they are checking and, importantly, how to check that particular element. As proof readers undertake a broader range of checks, their training must encompass all of these activities, hence is even more comprehensive.

Unfortunately we find sourcing suitable training is a challenge and often limited to Company SOP training or guidance from other reviewers or proof readers. At Be4ward we have looked to help fill this training gap. Please refer to the attached link for more information on proof reading training, applicable to anyone involved in the review and approval of artwork in your company.

http://www.be4ward.com/proofreading-training-signup2/

In my next article, I will look at the importance of measuring your artwork service.

Read it online

Measuring your artwork service

You have reviewed your artwork service, perhaps in response to a recall incident, made some improvements to the process and tightened up your training but have the changes given you the outcome you desired? The danger is, unless you have some metrics in place, you do not know for sure. In this

article, I introduce the need for measuring your artwork service, what measures are key and the part played by the Governance team.

You have made changes to your process but has anything improved?

The company artwork service is not usually a focus for senior management until there has been some sort of crisis. Examples are when artwork is going to be a bottleneck in the launch plans, or there has been a recall caused by artwork errors. Then management swings into action, investigation and improvement teams are established, changes are made but have these made a difference?

It is important that leaders establish what improvements are required, and ensure they are aligned with customers' needs. We often find that no measures have been established for the artwork service, or if they do exist, they are not robustly reported. So, it's key to decide what metrics are important, and get a baseline measurement before changes are made. If you don't know your baseline performance, how do you know the change has been successful?

Choosing the right metrics for your service: 'Right-first-time' is always relevant

We always consider that 'right-first-time' is the fundamental metric for an artwork service. This is a simple pass or fail metric - did the artwork pass through the process once or was any change required? Focussing on getting artwork right-first-time means things that are not correct are eliminated early in the process and potential sources of errors are designed out. The later errors are caught in the process, the greater the risk of an error not being detected and resulting in product recall. This is equally relevant in product launches and routine changes.

Getting artwork through right-first-time will also improve capacity, reduce lead-times, and improve schedule adherence, as it will not be cycling through each team 2, 3 or maybe 4 times. Stable and predictable lead-times enables more robust launch plans. Therefore, measurement of lead times, schedule

adherence and numbers of artwork cycles are important to demonstrate your service performance is in control.

Measuring how many artworks are raised and closed is necessary to ensure you are managing your capacity. This will give you the volumes of work and the resources required, but also indicate if the service is providing the necessary throughput or becoming a bottleneck. Obviously, if more are being raised than are being closed, you are heading for an issue. Improving capacity by investing in extra resources will certainly help, but you need to know where to target this resource - it may not be in your company!

Ownership of the measures by the team and the Governance group is key

In previous blogs I have talked about the importance of having a cross-functional governance group, as improving quality is only achievable if all the various groups work together. The saying goes ‘you only manage what you measure’ and it certainly sharpens everyone’s minds if the metrics are reported at weekly team meetings and a monthly governance meeting.

In my next series of articles, I will look at various tips to improve your right-first-time measure.

Read it online

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I always consider that ‘Right-First-Time’ is the fundamental metric for an artwork service. This is a simple pass or fail metric - did the artwork pass through the process once or was any change required? This is difficult to achieve on a consistent basis and requires focus and persistence. Therefore, in the next series of articles, I am going to explore this subject further.

The Importance of accurate artwork for your company

Is the importance of having accurate artwork stressed in your company? Do people assume that artwork needs several versions before it is approved?

What happens when your affiliates spot errors that, thankfully, have not reached the customer and what is the reaction when unfortunately there is a recall, when one gets through?

It is essential to remember, a company can only sell its product when they are correctly packaged, can only ship its product when the text on the packaging is correct and at the end of the day, patient lives rely on the text being absolutely correct. If this is forgotten and management live with a lacklustre right-first-time record then the company's reputation and profits will be directly impacted when errors do occur.

So why is getting artwork right-first-time so important?

Accepting that the first version is unlikely to be correct is a risky business. The closer you get to the launch or the implementation deadline you see what I refer to as the concertina effect - less and less time to deliver. In this environment when chasing for the final version through multiple iterations, the stress increases, confidence drops and the potential for mistakes increases.

Alternatively, when you focus on getting artwork right-first-time, things that are not correct are eliminated early in the process and potential sources of errors are designed out. When lead times are squeezed, as they often are in these types of situations, your risk of an error has hopefully passed and the likelihood of a recall reduced. Focusing in this area will have the additional outcome of more consistent lead-times, capacity will increase and everyone will have more confidence in schedule adherence.

Achieving a high standard in right-first-time requires focus and attention to detail

Best in class organisations achieve a right-first-time figure in excess of 95%. However, to achieve this requires continual focus and likely enhancement or redesign of your artwork process, combined with a degree of focus on what is required at each stage. It will also require regular support from a senior management team, made up from the groups involved. Technology will have a

part to play to enable a high quality process, both for the production and checking of the artwork itself but also in the tracking and approval process. Finally, the right culture will be required, displayed across all the teams, to ensure success.

In the next series of articles, I will explore this topic further and outline a series of tips, based on the experience I have gained working with many companies, to help deliver an excellent right-first time measure.

Read it online

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Do not underestimate the amount of resources required for serialisation

To read it, please click here.

Read it online

Right-First-Time tip 1: Measure it

Right-first-time, I believe, is a key metric and goal for your artwork process and in these next set of articles, I will discuss my suggested top tips for improving this measure. In this first article, I will talk through the need for measuring, who looks at the figures, where in the process to measure and what types of changes to include.

How to measure right-first-time and where are the figures reported

There are many ways you could measure right-first-time, but in our view it is a simple pass or fail metric - did the artwork pass through the process once or was any change required? The calculation should be straightforward - the number of artworks completed right-first-time divided by the total number of

new artworks created (note: we would not include non-right-first-time revisions in this total). This gives a percentage right-first-time. This can be used to give a baseline performance and set targets for the process. As you remove sources of error this will enable the team to track the improvements.

You manage what you measure

It is important the team own this measure and use it to drive improvement and there are a few points to consider here. Trending the measure will show all if performance is improving or declining. Setting clear targets to be achieved shows the performance gap to be closed. A process for the team to analyse the reasons why the artwork requires reworking will help understand what is going wrong (and I will talk about this later in a further tip).

In addition, the figures need to be reviewed regularly by the cross-functional governance group. Errors can arise from many sources and the support of the governance team will be required to help resolve these across the many impacted departments.

So where in the process do you measure and what do you include?

Many companies already measure right-first-time, but there are many differences in the scope of what is measured.

There are numerous points through the end-to-end process where right-first-time should be checked: at the approval of the artwork brief, after creation of the artwork, after proof reading, after artwork approval, after receipt of packaging materials, to name a few. You need to consider the milestone and rework points in your process and measure right-first-time at those points. To avoid the risk of an error being released to the public, you need to drive your right-first-time performance as early in the process as possible.

There are numerous types of artwork change - new products, safety updates, technical changes, line trial components. Some are easier than others, but even though it may be difficult to achieve right-first-time for some, it doesn’t

mean you shouldn't manage. However, you may wish to report different types of change separately with different initial targets for each.

Artwork quality standards should be as high as expected for a production document

GMP drives your manufacturing and packaging operation to produce a high quality process so the products produced are safe for the patient. Producing artwork should be considered in the same way. Errors need to be driven out so you end up with a safe, repeatable right-first-time process.

In the next article, I will explore this topic further and discuss my second tip, which looks at categorising the types of errors found so you can eliminate them one by one.

Read it online

Right-First-Time tip 2: Categorise and root cause the errors

I believe right-first-time is a key metric and mind set for your artwork process and, in this article, I continue my series on top tips to improve it, raising the need for a detailed understanding of why the errors are happening.

Categorise the types of errors

Measuring your right-first-time will tell you what your performance is but not why. You will need to delve deeper into the data. I suggest you set up a system for collecting and categorising the errors found, reporting them monthly. You need to determine the broad categories, and recognise this list may change, as you understand the issues more clearly. A typical set of error categories may include errors attributable to file identification/properties, text content, graphical content, supplied data, process failures and the technical aspects of the artwork. You may even need to break these broad categories into more specific error types.

Recording the reasons for a non-right-first-time artwork will then let you track the frequency and volume of different types of error, to identify the ones that are most significant. This is where you then need to target your energy for improvement.

A clear differentiator of companies that have excellent right-first-time performance is that they are obsessive about eliminating sources of errors by designing them out of the process. They have managed to minimise the effort they expend on cleaning up after an incident and instead channel that resource and energy into eliminating the potential for errors to occur.

Develop a good root cause process - consider the five why's approach

Once you have decided which category you need to focus on, you need to make sure you root cause the sources of the failures. This will ensure you are applying the right corrective actions.

Every company has their preferred method to root cause but I will suggest you consider the 5 why's method as it is easy to train and very effective. Simply, you ask 'why' for as many times as you need to, until you get to the ultimate root cause.

Looking at an example: an error has been discovered where the braille on a launch pack is obscuring some key information and there have been complaints.

Why has this happened?
Answer: The job was rushed and the team say they were not clear braille was needed until the last minute.
Why did they not know it was needed and where it was to be positioned?
Answer: This information was not clear at the point prior to when the artwork was being generated and had to be added later.
Why was this information not available at this point in the process?
Answer: There is no discipline for providing all the information prior to starting the artwork and people put the braille where it normally fits.

Why is there not the discipline at this point for both of these points?
Answer: There is no process for gathering all the information and signing it off prior to starting. People don't know where to put the braille in general.
Why don't people know where to put the braille?
Answer: The line drawing doesn't show where braille should be.
The actions from this process would be to update the drawings to show the braille location and put into your process the discipline of having all the information available, using an artwork brief, prior to the artwork generation process starting.

Having implemented solutions continue to measure to ensure sustainability

Once improvements have been made you should continue to measure the error categories to ensure the frequency of occurrence for the ones you have targeted for improvement have reduced. This will tell you if your improvements have been effective and also sustainable. The last thing you want is the same errors occurring again, especially if you think they have been addressed.

In the next article, I will explore the topic of right-first-time further and discuss my third tip, which looks at the artwork brief.

Read it online

Right-first-time tip 3: Make sure all the information is correct before starting, using an artwork brief

Right-first-time, I believe, is a key metric and goal for your artwork process and this week I talk through my third tip, 'Make sure you have all the information before starting'. Unfortunately many companies start with incomplete information and so here I talk through why this happens, why having the information upfront is so important and how to manage the process.

People mistakenly think starting early will make it faster

Why is it that there are so many issues with pharmaceutical artwork? Well getting artwork right is tricky. It requires gathering all the correct different elements, from different departments in the company, often from different countries, and making sure they are placed onto a piece of artwork in exactly the right position, accurately.

Companies often jump straight into designing the artwork, thinking that getting ahead of the game will speed up the overall process but they are mistaken. Consistently, I have seen that proceeding this way not only makes it more likely for mistakes to happen but often the overall timescales are longer.

One analogy is to think of the situation where you are arranging for your house to be painted. You test to get the colours you want and then agree that up front with your painters. You don't get them to try different colours until you see one you like and you don't want to have to pay them again if they use a colour you don't like!

A good artwork brief defines 'the change' completely, with no ambiguity

Events either inside or outside a company will result in the need to introduce new artwork or change existing artwork. So a 'change' is required. I always recommend to clients, to have all the information before starting and make sure it is correct. The 'change' is captured in an artwork brief, signed off as approved by key parties before starting. A perennial source of artwork not being right-first-time is incorrect input information or a key stakeholder not agreeing the change during artwork approval.

A good brief is a clear and concise record of the change required with no room for any misinterpretation and contains the following information:

- The standard cover page with all the relevant information on the change and the data required
- A standard implementation workflow with the people who will be involved in the change and their agreed dates

- A draft bill of materials with the component numbers required, both new and existing
- The electronically marked up artwork amended and presented with suitable software
- The source documents selected from a recognised repository.

All this information is collated and presented as one brief.

It is important the same groups who approve the artwork, sign off the brief

A powerful use of the brief comes from the key stakeholders agreeing this is the change required. The signatories will need to be defined for each part of your company and their approval forms a critical control point in your process.

The final artwork review and approval would be made against the artwork brief, by the same signatory departments and ideally the same people who approved the brief, making sure all the changes required have been implemented and that no other changes have been made inadvertently.

In my next article I will talk through my fourth tip - making sure you have a clear process.

Read it online

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