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 on-line or off-line, 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

Working with your partners in the business: the Packaging Engineers/Technologists

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about the Packaging , or Packaging Engineers. I discuss what information they provide the team and what is key to get right in the relationship.

Read it online

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Featured Serialisation posts from Stephen McIndoe's blog

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If you have not started addressing the US DSCSA serialization legislation, Be4ward's accelerated serialization methodology and expertise might help you deliver what many believe is impossible in the time remaining.

Read it online

[Brazil, Russia and Taiwan serialisation update]

As ever, things are moving in the world of global serialisation legislation. Here are a few highlights from very recent activity. We are one step closer to the new PL4096 serialisation law being published as it has passed the constitutionality committee check. It will now progress through the normal process for signature by the President, which is now likely in November.

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[Brazil's ANVISA officially suspend 2016 deadlines]

I am pleased to let you know that ANVISA have now officially passed a resolution to suspend the deadlines for Brazilian pharmaceutical serialisation requirements in RDC54. There are, therefore, no residual Brazil serialisation deadlines pending. This means that the small residual risk that these requirements would be enforced has gone away and we can all look forward to the new law and its more realistic timelines being published in November.

Read it online

[EU FMD Serialisation and Vision Inspection Technology day, Ireland]

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.

Read it online

Emerging US DSCSA and wholesaler timelines and their implications

As I have discussed previously, the US DSCSA legislation has a number of key dates for manufacturers who must serialise products:

- November 2019 to serialise the smallest saleable units and homogeneous cases, but notably no aggregation
- November 2023 to communicate this information to customers.

Read it online

Serialisation posts

It may not be too late to start addressing US DSCSA serialization

If you have not started addressing the US DSCSA serialization legislation, Be4ward's accelerated serialization methodology and expertise might help you deliver what many believe is impossible in the time remaining.

The November 2017 deadline for the initial implementation of US serialization legislation is fast approaching, with a little more than a year to go. Furthermore, the capabilities required are increasing all the time, as US wholesalers realise that they need full track and trace from Manufacturers on day 1.

Any company that has started to address serialization, quickly realises that a complex interconnected web of business process, equipment, IT systems and organisation changes are required, often across several companies, in order to be able to continue to sell serialized product. Many would consider that those who are not already well on their serialization journey face an impossible task in the short time left.

The Be4ward team have helped many companies manage and deliver serialization solutions for over 10 years. We have put this extensive knowledge and experience into a new product that can help companies, who are late to the US serialization game, deliver serialized product by the deadline. If you are in this situation, contact us for more information about how we might be able to help you avoid losing valuable US sales come the DSCSA deadline next year.

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Brazil, Russia and Taiwan serialisation update

As ever, things are moving in the world of global serialisation legislation. Here are a few highlights from very recent activity.

Brazil

We are one step closer to the new PL4096 serialisation law being published as it has passed the constitutionality committee check. It will now progress through the normal process for signature by the President, which is now likely in November. Following this, ANVISA will then publish regulations explaining how the law needs to be implemented, although it is not yet clear when this will happen.

Russia

Those companies involved in Russia's serialisation pilot have been informed that the pilot will run throughout 2017 and that findings will be published in February 2018. Therefore, it is unlikely that implementation will be until later 2018 at the earliest.

Taiwan

The Taiwanese Food and Drug Administration, Ministry of Health and Welfare have apparently published requirements, although it is proving a challenge to get a copy of them. The implementation dates are being reported as:

- January 2019 for the application of GTIN, Lot and Expiry in a barcode
- January 2020 for the addition of serial numbers.

Draft regulations earlier in the year called for the supply chain to manage a traceability system and for APIs to have serialisation in 2021. I will update you when I see a copy of the final legislation.

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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

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As I have discussed previously, the US DSCSA legislation has a number of key dates for manufacturers who must serialise products:

- November 2019 to serialise the smallest saleable units and homogeneous cases, but notably no aggregation
- November 2023 to communicate this information to customers.

However, the wholesalers also have a key deadline of November 2019, at which point they need to authenticate returns, which in turn has an impact on manufacturers. In order to perform this authentication activity, the wholesalers will need serialisation information about the product from the manufacturers.

The HDA, the wholesale distributor industry organisation, are currently running pilots to determine workable options for them to meet these authentication requirements and we will need to wait until these have concluded before the details of how things will need to work are clear.

However, indications from wholesalers to our clients suggest that the wholesalers will be looking for communication of serialisation information from the beginning of 2019.

This has a number of implications that, for many Pharma companies, effectively bring the 2023 customer reporting deadline forward to the end of 2018, or

earlier, if you consider supply chain lead times and the risks of delayed go-live. Let me explain why

The logic goes like this:

Having said all of this, many companies recognise the additional cost and risk of a phased implementation, particularly as the EU goes live in this timeline and the market is already very capacity constrained. So many are aggregating from day one.

- Wholesalers need serialisation information on the products that have been sent to them,
- For commercial reasons, manufacturers will only want to send wholesalers data on product that has been sent to them,
- Manufacturers will need the capability to pick serialised deliveries to wholesalers, in order to segregate the information flow to them,
- Manufacturers' distribution locations, often 3PLs, will need to be serialisation-enabled,
- In order to make picking of serialised product practical, aggregation of at least saleable items to cases will be required,
- Packing lines will need to be enabled for full aggregation,
- A manufacturer will need an enterprise serialisation system to coordinate serialisation information between supply chain nodes.

Having said all of this, many companies recognise the additional cost and risk of a phased implementation, particularly as the EU goes live in this timeline and the market is already very capacity constrained. So many are aggregating from day one.

Read it online

Artwork posts

Working with your partners in the business: the Packaging Engineers/Technologists

The artwork service team works with many groups in the business, so my next series of blogs will look at the key ones. In this one I will talk about the Packaging Technologists, or Packaging Engineers. I discuss what information they provide the team and what is key to get right in the relationship.

The Packaging Technologists/Engineers provide the structure of the pack

It's the Packaging Technologist's/Engineer's job to work with the launch team to design a pack which protects the product, works for the patient and fits with the marketing image required. It also needs to be designed to run on packaging lines in a cost-effective way. The pack designed may be a similar format to existing products or be something quite new.

They will work very closely with the Equipment Engineering department, who will source and trial the equipment required. This might range from new change parts, to new equipment on lines, or to completely new packing lines. Emerging from this process will come a defined pack.

It is then their role to provide all the information required to the Artwork Coordinators so packs can be set up on the systems ready for launch, including of course having the artwork available for each market. Suitable drawings, in a clear unambiguous format, will be required. These drawings will be used for all subsequent pack changes.

It is important the artwork service team are clear what information is required

It is easy for some confusion to arise regarding the bill of materials or the artwork. I remember a launch being almost delayed due to the case reference

being incorrect and the cases arriving with no upper flaps. Another where the varnish free areas used for overprinting were missing.

So I always involve the Packaging Technologists/Engineers in the process redesign workshops. Any previous areas for confusion can be resolved. With drawings, it is worth taking the time to talk through each element of information required, bar codes, braille position, tamper-evident label positions, preprints that appear and what must be left text free. Making sure both sides are clear on the requirements and ensuring understanding is embedded in SOPs and training materials.

Early communication is required for projects which will involve changes to drawings

Large projects like the introduction of serialisation or major changes to lines will require impact assessments re the packs. The changes may be subtle but the change control process together with a good working relationships with the two groups should mean such changes are handled smoothly.

Equally the artwork team may have to highlight to the Packaging Technologists/Engineers a need for more space for text. A common problem on leaflets where the health authorities are demanding more content. It is vital these issues are raised early to enable new drawings to be generated and any trials and revalidation to be completed.

In my next article I will talk about the part played by another key group - Regulatory.

Read it online

Working with your partners in the business: Regulatory

I recently talked about the relationship with the Packaging Technologists/Engineers. In this blog I discuss working with the Regulatory

function. I talk through the regular interactions, the key information they provide the team and their responsibilities, and the role of senior sponsors.

The Regulatory organisation has many touch points with the Artwork service team

Whether it's a launch program, a large safety data change or a company-wide project, the group the Artwork Service team are probably speaking to most often, will be the Regulatory team. Each company varies, but its why, in many cases, the location of the Artwork Service team is close to the Regulatory group and why the reporting is sometimes also aligned.

In a launch program, the Regulatory group will be providing the content and timescales for each market. The Artwork team will be communicating with different parts of the Regulatory organisation, the central team as well as the regulatory contacts in the markets, and sometimes separate safety teams. Most packs are required to be changed on a frequent basis and the Regulatory group, as well as triggering the changes, provide the guidance on the phasing.

Regulatory are involved throughout the process, providing the core text and the review and approvals of the artwork brief and the final artwork.

Reducing the frequency of pack changes is only possible if good communication exists, so such changes can be 'bundled'together. Achieving very short lead-times for launches, post approval, are only enabled through close cooperation.

It is important the Regulatory team are clear on their roles and responsibilities

The Regulatory team advice on timings can vary in quality but the one area which they cannot get wrong is the core text content. The old adage 'garbage in, garbage out is applicable here and unfortunately I have worked with companies who have made great improvements with their artwork process but the step change we normally see has been hampered by poor quality of text input.

Responsibility for the content, translations, and the review and approval processes must be very clear if you are to achieve excellence in the labelling and artwork process. It's hard but the Regulatory contact in the affiliates can be easily forgotten in the process redesign so it important to involve them, understand their issues and then pick up their points, tailoring the SOPs and training material accordingly.

Good sponsorship will set up the project for success and enable further progress

I always ensure Regulatory have a strong presence on the project steering committee. It is vital changes required are owned by this group, as they 'touch' so much of the process. It is only through good senior sponsorship, with a reach to the whole regulatory organisation, globally, will you design a process with the potential to be world class. Post implementation, a senior Regulatory figure must be part of the Governance team to ensure the improvement in the process continues.

In my next article I will talk about the part played by another key group - Planning.

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I recently talked about the relationship with the Packaging Technologists/Engineers and with Regulatory. In this blog I discuss another key group - Planning. I talk through where the groups interact, what behaviours you see when the relationship is not so good and the impact on the customer and what you should see when teams are working well together.

Planning have touch points for both launch planning and pack changes

In a launch program the Artwork team will work with Planning, predicting dates for each market and feeding this information into the company planning process. This will provide vital data to decision makers coordinating the overall launch plans.

As markets get closer to launch and packs are being set up on the systems, Planning will often be involved, supplying codes and being part of the review and approval process for artwork briefs and the final artwork. They are also often the main link to procurement for sourcing of materials.

With pack changes the Artwork team will work with Planning to agree implementation dates and any constraints within those dates.

Planning controls the actual implementation dates

Although the artwork coordinators will plan the artwork activities associated with launches and pack changes, it is worth noting that Planning actually controls the implementation dates. Unless it is put into a schedule, no components will be bought and no orders will be produced.

With pack changes, the team will liaise with Planning on whether a pack change can be phased in, so stock can gradually be run down or whether there is a specific implementation date. Regulatory authorities may insist on a date where there is a safety change involved. This date may be when the stock must be ex-factory or available in the market warehouse.

It is important that the teams involved communicate clearly what the customer expectations are and the Planning and the Artwork teams work to meet these

expectations. An example of differing priorities is when running stock down is prioritised over the implementation date, resulting in the risk of a non-compliance situation with your customer.

Another challenging situation we sometimes see is when Planning feel they have been let down so many times that they say to the Artwork team, 'Once you have the artwork ready then come to talk to us! This might apply to both launches and pack changes and in either case it is the customer and potentially the company itself who loses if there are delays. Of course, the way to solve this issue is to improve schedule adherence, a subject I will come back to on a later blog.

Where you see good ways of working is when Planning and Artwork understand each other's requirements, where there is trust that the artwork team will deliver on time and where regular schedule review meetings are in place, potentially on a weekly basis, where projects are discussed and all plans are agreed and monitored.

In my next set of articles I will talk about the important subject of proof reading.

Read it online

Proof reading: a vital part of your process

In the next few articles I want to talk about the important process of proof reading. I will cover a number of different aspects, including the key steps involved, how these steps are controlled, selection and training of proof readers, what auditors like to see in your process, and the potential difference in proof reading centrally and in the affiliates. In first article, however, I would like to discuss what proof reading is and why you should include this as part of your process.

Proof reading - what it is and the key benefits

Proofreading is the process where text or artwork files are reviewed and checked, in a methodical manner, to detect errors so they can be corrected. Detection during the artwork and labelling process is essential to ensure no components with errors are produced, ensuring no product with artwork errors ever reaches the patient. In addition to avoiding the patient safety implications of an incorrect artwork, the detection of errors is essential to minimise the cost implications of artwork recalls, and also to maintain company reputation with patients, heath professionals and the Regulatory authorities.

A proof reading step will verify that required changes have been made accurately, confirm inadvertent changes have not been introduced and supporting data, specifications, drawings, etc. have all been utilised appropriately. It is one of the last defences before artwork is released to production.

Take care with your source information

Proof reading may not necessarily identify errors in the source information provided for the creation of the artwork, as the artwork is typically being compared to the source information. Therefore, if an incorrect code has been supplied or there is an error in the source text, this could go undetected. The adage of ‘garbage in = garbage out’ applies here. Hence it is critical that the accuracy of source information is verified before the artwork is prepared, and if necessary the proof reading step ensures comparison back to the master data where applicable.

The introduction of a proof reading process step will give you a step change in quality

Where proofreading is carried out by trained and competent staff, in key points in the process, it will greatly increase the assurance of your process. However, we still find artwork operations where the proof reading is limited or in some cases, not performed at all. The introduction of a set of fully comprehensive

and thorough proof reading steps can have a marked impact on right first time for relatively little effort.

When in the process should we proof read?

Proof reading should be undertaken after any artwork file is prepared or modified, including every revision loop. The whole artwork should be thoroughly checked each time to ensure that all required changes have been accurately incorporated and no inadvertent changes have been made by mistake.

Typically, there is a three-step process, a verification by the artwork operator that they have made the changes necessary, a full and comprehensive independent proof read and then a final verification of specific content by the Affiliate Regulatory personnel and other functional representatives required.

In my next article, I will explore this important subject in more depth.

Read it online

Proof reading: what is involved?

In my last article, I introduced the topic of proof reading and highlighted how including a comprehensive proof reading activity would significantly improve the quality of output from your business's labelling and artwork operation. In this article, I am going to talk about where you should consider performing these steps in your process, what is covered, how technology helps and finally the importance of creating the right environment for the proof reader.

Proof reading - the key steps

There are three main steps to proofreading. The first is undertaken by the artwork operator once they have created the artwork. The second step is what we describe as a full, comprehensive and independent proofread. This should be undertaken by a competent and skilled proof-reader. The third step is the functional and country reviews undertaken by the local regulatory personnel

and relevant functional representatives. A key issue here is making sure that all of these reviewers know what they should and shouldn't be checking, and how they should check it.

There are different types of checks - it is not all about the text

The temptation with proof reading is to focus on the text but, of course, there are the graphical and technical checks to consider. In the graphical check, the proof reader is looking at the logos, branding elements and the instruction/ warning symbols and ensuring they are correct and comply with regulatory and company requirements. The proof reader will confirm the correct version of the symbols are being used with the right colours, they are applied in the right locations, across all faces and they do not compromise any folds, cuts or creases.

In the technical check, the proof reader confirms the artwork has been produced to the correct size, matching it to the cutter guide. In addition, they confirm perforations, varnish-free areas, machine-readable codes and their positions are correct. Codes are checked with verifiers to ensure they meet the specification. Braille is checked to make sure the correct version has been used; it is in the correct position without obscuring any text.

Make sure the input text file is correct

It is obviously important to ensure that the text content is correct and this should really be undertaken when the text file is being prepared. If there are errors in this input text file, they will be incorporated into the artwork. To avoid this, the text file should be verified against source documents before the artwork is produced and the artwork then verified against the supplied and correct text file.

Electronic Comparison tools - reduce cycle time and are more accurate than humans

Checking artwork involves many detailed and repetitive tasks, which the human brain finds difficult even with the best-trained staff. Thankfully, the electronic

tools for text and pixel-to-pixel comparison now available, can perform these tasks accurately and in a shorter time period. However, these tools can't check everything, for example text embedded in images, so it is important that you understand what they can and can't check and supplement with manual verification.

It is important to get the environment right

A quiet place needs to be reserved for this task, ideally a separate office, equipped with the tools required and with excellent lighting. 'Do not disturb' signs should be used combined with the understanding by all staff that interruptions should be minimised.

In my next article, I will look at who is involved in the reviewing steps.

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reading, what proof reading technology actually does and what needs to be done when reviewers are having to do manual checks.

Reading - your brain fills in the gaps

Cna yuo raed tihs? 55 plepoe out of 100 can.

‘The phaonmneal pweor of the hmuan mnid, aoccdrnig to 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 rgh t pclae. Tihs is bcuseae the huamn mnid deos not raed ervey lteter by istlef, but the wrod as a wlohe.’

In the paragraph above you will see the middle letters of the main words have been scrambled with only the first and last letter being in the correct place. We effectively see what we want to see, so if I am looking for the word ‘dosage’from some source text and I see ‘doasge’in the artwork I am not likely to notice the error.

Proof reading technology is great but is not always available

The majority of these issues are overcome with proof reading technology but the tools must be used correctly. Text comparison tools work by comparing the font character codes of each letter in the two documents and will report any of the differences found, including differences in font, bold and italics. Graphical comparison tools work by doing a pixel-to-pixel difference test.

The proof-reader’s skill is making sure all text or graphics are compared exactly and correctly resolving all the false positives the tools highlight. It is also important the proof-reader understands any limitations in the technology, for example, most tools will not be able to read text embedded in a graphic image.

Key strategies to help with doing manual checks

Regardless of what electronic proof reading tools are used, there is always an element of manual checking. It is important you recruit the right people to do this function. Proof-readers have to be detail conscious, methodical and careful.

It sounds obvious but it is important to capture in your procedures a logical and systemic approach that assures that all elements are thoroughly checked. The people responsible must follow a procedure which identifies the area where the checks must be made (well lit, quiet, used for this purpose only), the source documents to be used, what tools and equipment are required and how to perform each check, as this will be different for text, graphics, braille etc.

There are many techniques to overcome the situation where your brain compensates and overlooks errors, for example reading text backwards. It is recommended you have a second check in your process.

In my next article, I will look at who is involved in the reviewing steps.

Read it online
