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

Putting together the Labelling and Artwork organisation

In this article I will talk about putting the team together, the benefits of having a specific team and what I would suggest are the typical roles.

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The Anti-Counterfeit Drug Issue: It's Real

The issue of counterfeit drugs continues to increase, with regulators and the pharmaceutical industry taking multiple courses of action to address it. In this article, I discuss the problems presented by counterfeit medications and what is being done to address them in terms of regulations, investigations and product protection.

Read it online

IQPC Pharmaceutical Packaging and Labelling Summit, 22 and 23 June, Geneva

I had the opportunity to attend, chair and present at the IQPC Pharmaceutical Packaging and Labelling Summit in Geneva on 22 and 23 June. Many thanks to Katherine Gordon, Daniella Ndeh and the team at IQPC for organising the event.

Read it online

Governance key with your new Labelling and Artwork organisation

About supporting processes I stressed the importance of establishing a Governance group. So here I will explain a bit more about why such a group is required, what its purpose is, the roles of the team members and how its focus changes as you move from project implementation to post-project operational support.

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Outsourcing - a useful strategy but needs to be carefully considered

In this blog I look at a popular topic often raised by our clients, the question of whether or not to outsource activities involved in their labelling and artwork process. This can indeed be a useful strategy but, as you will see, there are some important areas to look into before making that decision.

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Technology- range of tools available

In this week's blog I am going to look at the use of technology in the artwork process, why it can be particularly helpful, the range of tools available and a short discussion on some of the potential downsides.

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The importance of the artwork brief

In our book 'Developing and Sustaining Excellent Packaging, Labelling and Artwork Capabilities' we say it is a key part a world-class process. So here I talk through why I see it as being so important, why some companies believe they don't need one, and for those who embrace the change, the continued discipline in its use, post implementation.

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Featured Serialisation posts from Stephen McIndoes's blog

Should you aggregate or not?

I have had a lot of questions recently that boil down to the question of whether or not to aggregate product. So here are some thoughts about the things you need to consider

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Algeria Update

Algeria have now formally announced their new serialisation regulation, the details of which are emerging and should be published shortly.

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Brazil - Are we on the starting blocks again and is the end of 2016 risk over?

Not only have Brazil decided what to do about their President this week, but they have also made another significant step towards passing new serialisation legislation.

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Serialisation posts

Should you aggregate or not?

What do I mean by aggregation?

First of all, let's just clarify what I mean by aggregation in this context. For the purposes of this discussion (and for the purists amongst you, forgive me as I know this is not the classical definition of the term), I take aggregation to mean several things all packaged together:

- Putting Unique Identifiers (UIDs) on the smallest saleable product packages, typically cartons.
- Putting UIDs on one or more levels of shippers, e.g. cases and pallets.
- Building the relationship between the UIDs on the various levels of packaging in a database as the serialised cartons are packed into the serialised cases and then the cases put onto serialised pallets.

In what I will term Track & Trace (T&T) legislation, aggregation is required for very practical reasons. In this type of legislation, the sale of products from one commercial owner to another is tracked in some way at the individual UID level. As product passes down the supply chain it would often be impractical to scan each smallest saleable unit UID as it was sold. Therefore, the likes of wholesalers and hospital chains, who often handle the product in shippers, simply scan the shipper UIDs and infer the serialised contents using the database information discussed earlier.

In what I will term an End to End (E2E) model, UIDs are applied to the smallest saleable units and serialisation information is compiled in a database. Shippers are not strictly required to be serialised in the purest form of this model, as the only time the UIDs are needed is at the end of the supply chain, when the product is (mostly) being handled at the smallest saleable item level. This is a much simpler and cheaper model than T&T as packing lines are less complex and distribution supply chain nodes do not need to be serialisation enabled.

So you can see immediately that, if you are only dealing with product that is destined for a pure E2E legislative model, then there is no legislative reason to aggregate and this could be much cheaper to implement.

A few factors to consider

However, there are a few factors you should consider before deciding how to move forward:

- Are the legislations you are considering pure E2E or, like the EU FMD, are they potentially T&T, at least for some products?
- A number of legislators are starting with E2E models, but are intending to move to T&T in the near future.
- Are the assets (packaging lines, warehouses, etc.) handling only pure E2E products?
- Will the evolution of your business mean that your assets are likely to need to handle T&T models in future, particularly with short lead times?
- Are there other benefits that you might derive from aggregating?

In our experience, the net result of these and other considerations often leads companies to implement aggregation capabilities on many, if not all of their serialised packaging assets, even if they do not necessarily aggregate all serialised product on these lines.

Read it online

Algeria Update

Algeria have now formally announced their new serialisation regulation, the details of which are emerging and should be published shortly. The good news is that discussions with the authorities at local and international events have shown that the Algerian authorities are very open to improvement suggestions, so long as they can achieve their primary objectives, which have been stated as:

- Anti counterfeiting
- Traceability
- Reimbursement management.

As you would expect, to meet the first two requirements, the intention seems to be that **product cartons will need to be serialised with GTIN, Lot, Expiry and a Serial Number in a GS1 compliant 2d data matrix. The timing for this requirement is currently being stated as 2019**.

Unfortunately, the reimbursement requirement seems to be driving an additional requirement to add a **sticker on the product carton** including all of the carton information and the addition of the **product price**. The timing for this requirement is currently being stated as **the end of 2018**.

Clearly, this sticker requirement does not conform to any other legislative requirements and creates a number of real and significant issues for manufacturers, including:

- Timing and location of application of the sticker to ensure the price is correct.
- Technical ability to create a serialised label with the same critical information on it as is on the carton, namely product code, lot and expiry date.
- The significant risk that the wrong stickers will get applied to the wrong product.

The Algerian Social Security agency have stated that they do not have a database to help them manage reimbursement at present. Therefore, it is somewhat understandable why they are requesting these stickers in the short term. In discussions, they have been adamant that the sticker requirement needs to stay. This is clearly not good news for manufacturers.

However, in the medium to long term, it seems clear that database solutions will be implemented to support efficient and effective operations in local reimbursement management. This would almost certainly render the stickers redundant. It therefore seems very wasteful to enforce their implementation as a temporary measure, knowing the issues and risks they will create. There are surely simpler, lower risk solutions that could be considered.

To help influence the Algerian authorities, please contact your local Algerian representatives, or alternatively, contact GS1 who are also working hard with their members to influence the eventual detailed requirements to help meet all stakeholders' requirements.

Read it online

Brazil - Are we on the starting blocks again and is the end of 2016 risk over?

Not only have Brazil decided what to do about their President this week, but they have also made another significant step towards passing new serialisation legislation. This is good news because it means we are a relatively small step away from the current law, with it’s end-2016 deadline for full serialisation, being superseded.

On Tuesday this week, the Brazilian Commission for Social Security and Family passed the latest version of the new serialisation law PL4069/2015 (PLS 276/2015 in the Senate). It will now go for constitutional verification and then be sent to the President for signature. Assuming all goes well, this new law may be approved in October, starting the clock on the implementation timeline.

Great news for the many companies who had either completely stopped work on Brazil serialisation late last year, when the 2015 Pilots requirement was suspended, or had only proceeded with pilot work. There was always a risk that the current legislation would not be superseded.

See a previous blog for an outline of what is in the new legislation. I will have more on the details in an upcoming blog.

Read it online

Artwork posts

Putting together the Labelling and Artwork organisation

In a previous blog I have talked about the design of the core artwork process and emphasised the importance of having the design in place before looking at the team structure. So here I will talk about putting the team together, the benefits of having a specific team and what I would suggest are the typical roles.

Ideally the new Artwork Team leader should be involved in the design process

There needs to be a clear methodology for the design of the new process involving all impacted functions. Credible representatives from each function, who can both provide detailed knowledge of the requirements of their function and have the respect of other members of their function should be selected. These individuals will be key potential players of the new artwork service, facilitating and leading changes in the functions they represent. Moreover, the proposed leader of the artwork team should be involved (whether that be an existing incumbent or new appointment) to ensure they have the knowledge and network to facilitate the changes required.

One of the questions you might ask would be ‘Why have a specific artwork team?’ Well one clear reason is that it gives the customers a single point of contact for all their changes with specific responsibilities for the pack change planning and coordination process. Some organisations use external artwork service providers, instead of producing artwork ‘in house’, and again the Artwork team can manage them. Also this team can coordinate the approval of printer proofs and packaging samples.

Each team member requires a different skill set

Typical roles in any artwork team are the Artwork Team manager, the artwork coordinator, the artwork operators and the proof reader. Depending on the scale of the operation these roles may not be discrete jobs but may be combined.

The manager is responsible for the quality and delivery of the service to its customers, staff management and ensuring there is enough capacity with the team to deliver the expected demand. Ideally the manager needs to have artwork, regulatory and supply chain planning appreciation and the artwork team may sit as part of a Technical, Regulatory or Supply Chain Planning function.

The artwork coordinator is a key role within the team and is responsible for planning the changes, executing the changes and resolving any issues that arise.

The artwork operators are responsible for production of mock up artwork and illustrations, production artwork and the creation of brand guidelines.

Finally the proof reader is the member of the team responsible for checking the content of text, graphical elements and performing technical checks.

Each team member will require a different skill set, the Manager requiring leadership, people management and operational planning skills plus the ability to network for the benefit of the whole team. The Coordinators will require communication, organisational and coordination skills as well as an ability to

manage issues as they arise. Artwork Operators, are not really graphic designers but should have some design knowledge and understanding of the print process and be highly competent with the relevant design software packages required. The Proof Reader must demonstrate a high attention to detail, be able to concentrate for long periods of time, working alone and use the relevant electronic proof reading tools.

Read it online

The Anti-Counterfeit Drug Issue: It's Real

Legislation is being put into place, but it is still essential that we all play a participative role in the continued fight to protect the patients that rely on our product.

Introduction

The issue of counterfeit pharmaceutical product is growing on a world-wide basis, with increasing instances of identification and seizures being reported each year.

In this article we will discuss the underlying causes of this growing threat and the actions authorities and pharmaceutical companies are taking to combat it.

Before we go any further, we need to define what counterfeit product is. The World Health Organisation’s taskforce on counterfeit product (the International Medical Products Anti-Counterfeiting Taskforce (IMPACT)) defines such product as substandard, spurious, falsely labelled, falsified, counterfeit (SSFFC) medicinal products. This shows that there are a number of different types of product that could be considered counterfeit.

What is the problem?

The global Pharmaceutical market-place continues to grow with forecast sales potentially set to top $1.1tr in 2015 and with a 40% growth rate in China.

Unfortunately, this makes pharmaceuticals a target for criminal gangs through the supply of counterfeit drugs.

Counterfeit drugs are now estimated to be the largest black market in the world at $200bn . It is a global issue with counterfeiters looking for opportunities around the world, employing complex global supply chains. Counterfeit product has been detected in all regions of the world and whilst India and China are responsible for most of the manufactured volume of legitimate product, these countries are unfortunately also the prime source for counterfeit product.

Counterfeit medicines seized at the outer border of the EU tripled between 2006 and 2009 reaching approximately 7.5 million items and over 30 million counterfeit medicines have been seized at internal and external EU borders over the same period.

In Africa, most pharmaceutical products like anti-malarial drugs are sold over the counter and, due to the informal sales models in typical African marketplaces, control is challenging to achieve. Since borders are very porous, there is very little control on most imported drugs. There are attempts to regionalise approaches to control, but this has proved difficult to do.

In one 10 day operation across Africa supported by the World Customs Organisation, 460 containers were inspected and 1 billion fake products were intercepted, half of which were pharmaceuticals . However, major operations like this cannot practically be orchestrated frequently, and due to the vast volume of goods flowing through customs operations, it is impossible for customs officials to inspect more than a tiny fraction of the shipments.

The other significant source of counterfeit products are on-line pharmacies. The European Alliance for Access to Safe Medicines (EAASM) estimates that 97% of online pharmacies are illicit and there are over 50,000 fake pharmacy web-sites live at any time . Particularly common are fake on-line pharmacies claiming to originate in Canada offering cut-price mail order product to US consumers where drug prices are traditionally higher. These online pharmacies are rarely based in Canada. The Counterfeiting Superhighway research

undertaken by EAASM revealed that 62% of medicines purchased online are fake, counterfeit or sub-standard.

EAASM undertook a trial in Germany in collaboration with some of the PharmaCos where they established a fake online pharmacy. In 9 weeks they had 365,000 hits making them the third highest ranked online pharmacy in Germany.

The latest activity to legitimise real online pharmacies is DOTpharmacy. The domain .pharmacy is going to be available to online pharmacies that have been formally approved and registered.

Why does this problem need to be addressed?

It could be considered that counterfeit product is just a response to high drug prices and, like counterfeit luxury goods, are essentially harmless, however, not in this case. Counterfeiters are purely profit motivated and counterfeit drugs are intrinsically dangerous. The types of issues found with counterfeit drugs include; no active ingredients present, mostly adulterated product, the manipulation or refilling, poor storage, expired product and cold chain interruption. All these result in putting the patients' safety at risk from products which are unsafe and/or not effective.

The most popular types of drugs to be counterfeited are pain killers, anti-inflammatory, anti-tuberculosis and anti-malarias. It is estimated that a third of malaria drugs around the world are fake and 30% of emerging market product is counterfeit.

The World Health Organisation estimated in 2013 that there were 100,000 deaths/year due to fake pharmaceutical product. Due to the healthcare models in Africa, this is probably underestimated and the International Policy Network estimates that 700,000 malaria and tuberculosis deaths each year are attributable to counterfeit medicines.

Finally, we need to consider the facilities being used to manufacture counterfeit product. Legitimate pharmaceutical manufacturing facilities are constructed and

controlled to exceptionally high standards and subject to rigorous regulatory standards, licensing and inspections. This provides a safeguard and assurance to the patient that the product they are taking is safe and effective for the intended use. This safeguard and assurance cannot be provided for products manufactured in fake pharmaceutical manufacturing facilities. Thus, patient safety is significantly compromised due to supply of adulterated products from these facilities.

What is being done at a legislative level to combat this?

Based on this growing threat, governments across the world have been developing legislation targeted at securing pharmaceutical supply chains. The 2011 EU Falsified Medicines Directive and the 2013 US Drug Quality and Security act have defined strong legal frameworks for the manufacture and distribution of medicines. Compliance with these rules are obligatory for pharmaceutical manufacturers and other supply chain partners in order to keep counterfeit medicine out of the legitimate supply chain.Further legislation is being developed, approved and implemented in many other countries (for example Serialisation legislation in Turkey, Argentina, Brazil and South Korea) targeted at prescription pharmaceuticals and products that are reimbursed by governments and other healthcare providers. These legislative requirements will control the passage of pharmaceutical product around the world and failure to comply will stop the flow of product. This will aid the control of counterfeit product but will also mean that pharmaceutical companies who cannot comply with relevant legislation will not be able to sell products in affected markets.

However, across the world and as is the case with the development of much legislation, there is no one solution being developed by governments. Individual countries or regions, for example the EU, are defining requirements to address the issues they are witnessing with the solutions they consider appropriate. Therefore, the requirements and product scope can vary, and as the legislation evolves through consultation processes, will change with time. Consequently, the requirements for prescription pharmaceutical products and the application

of legislation to vaccine products, other cold chain products and over the counter or consumer health products, can vary by country or region.

In addition to these legislative activities, organisations such as the World Health Organisation (through their IMPACT taskforce) and the World Customs Organisation (WCO) are helping to define and shape solutions. As well as enforcement actions, the WCO have developed a secure on-line tool (IPM) to improve communication between the private sector and customs officers. The information shared will help customs officers know the risks and how to communicate suspicious product. Launched in 2011, it is expected to be rolled out to 120 countries by 2017. It is a web based tool where companies can provide information on their products including the presentations available, comparisons with counterfeit product, expected trade routes and who to talk to. It also provides opportunity to recognise customs officers for work they have done.

Finally, there are multiple influencing bodies championing specific causes, (for example EAASM and on-line pharmacies) or developing specific solutions.

The European Stakeholder Model is a coalition of European bodies:

- European Association of Euro-Pharmaceutical Companies (EAEPC)
- European Federation of Pharmaceutical Industries and Associations (EFPIA)
- European Generic medicines Association (EGA)
- European Association of Pharmaceutical Full-line Wholesalers (GIRP)
- Pharmaceutical Group of European Union (PGEU)

These organisations re jointly developing the European system for pharmaceutical product serialisation and authentication that will be operated by the European Medicines Verification Organisation (EMVO). This will be deployed through the delegated acts of the FMD legislation to provide a pan-EU serialisation solution.

How are companies addressing this?

Many pharmaceutical companies have strategies in place to combat counterfeit products. These strategies are typically comprised of five key activities:

1. **Collaborating with local authorities and professional organisations**- This would include involvement in Industry groups e.g. EFPIA and policy/legislative bodies to help define and shape relevant legislation and practices to help secure supply chains.
2. **Cooperation with official bodies** - Examples of this would include participating with WCO on seizure operations and the collaboration some PharmaCos undertook on the EAASM fake pharmacy exercise.
3. **Dedicated permanent cross-functional structure to coordinate and implement strategies** - The impact and prevention of counterfeit product impacts many parts of a Pharma Co and extends outside the company to other supply chain partners. The establishment of appropriate governance bodies involving relevant functions and parties permits effective coordination of strategies.
4. **Proactive securing of drugs**- The use of technologies to protect product and help identify counterfeits. We will discuss this further in the next section.
5. **A dedicated product security and investigation Team and laboratory**- To support the comparison of real and suspected product to determine if the product is counterfeit.

To provide an effective brand protection capability to a company, it is important that each of these elements be present and sustained. There is no quick fix - these capabilities need to be invested in for the long term to ensure the security of the product supplied.

However, due to the complex nature of pharmaceutical supply chains and the multiple partnerships that exist, coupled with the world-wide nature of both the pharmaceutical industry and the counterfeit problem, a pharmaceutical

company cannot tackle the problems on their own. It requires a joined up effort from the many impacted participants to enable secure pharmaceutical supply chains.

What are the technological solutions that are being applied?

A number of different measures can be employed to combat counterfeiting of products:

- Verification features can be included on the product packaging to help determine if the product is genuine. These verification features can be overt or covert.
- Tamper evident packaging, usually through gluing or labelling the opening of the pack identified if the pack has been tampered with.
- Serialisation and traceability provides a unique serial number for a specific pack that can then be used to authenticate the pack through the supply chain and ensure that the chain of custody is intact.

Implementation of Serialisation legislation

The gestation period for serialisation legislation has been long, however with the publication of the 2011 EU Falsified Medicines Directive and the 2013 US Drug Quality and Security Act, along with the subsequent firming up of expected timetables and the implementation of legislation in other countries like Turkey and China, this situation has changed and most companies are now establishing programmes to meet the issue. Companies need to have a clear strategy for tackling serialisation legislation that will ensure risks to product supply are adequately mitigated.

Strategies need to be sufficiently flexible to deal with the nuances and differences in legislation and potential future requirements that may emerge as the environment evolves.

Moreover, whilst the primary objective of many organisations will be to meet the requirements of the new legislation, there are also opportunities which result from this and these need to be considered in a strategic response.

From a commercial perspective, for example, serialisation and product coding can be used to provide additional services to patients by linking information and services to the coding on the pack through such things as cell phones. This provides opportunities to further improve patient safety, through the likes of improving adherence, increasing knowledge about the patient and product use and improving relationships directly with patients.

From a supply chain perspective, particularly in track and trace models, serialisation capabilities can be harnessed to provide improved supply chain visibility, leading to improved customer service and efficiencies.

In Summary

The threat to patients from fake medicines is real and growing. However, the healthcare community is taking action on a global basis to tackle the issue. Legislation is being implemented to provide a framework for action and many groups and coalitions are tackling different aspects of the problem. Many new capabilities and technologies are being introduced to provide solutions and it is considered that the market size of countermeasures is set to double in the next five years.

However, there is no magic bullet and success lies in the considered application of multiple solutions to provide layers of protection. For example, there is little value in serialising the carton if you cannot control access to the contents.

Moreover, as each new solution is introduced, counterfeiters will try to determine methods to overcome them, so combating counterfeit product will be a continual battle where the counterfeiters seek new areas of opportunity and the industry develops further solutions to maintain secure supply chains.

It is essential that your company is playing a full and participative role in this continued threat to protect the patients that rely on your product and has a comprehensive strategy to deal with it.

Read it online

IQPC Pharmaceutical Packaging and Labelling Summit, 22 and 23 June, Geneva

I had the opportunity to attend, chair and present at the IQPC Pharmaceutical Packaging and Labelling Summit in Geneva on 22 and 23 June. Many thanks to Katherine Gordon, Daniella Ndeh and the team at IQPC for organising the event. I presented on the importance of achieving artwork right-first-time and the impact that has on lead times and workload. I discussed a number of tips with practical examples on how companies can improve their artwork right-first-time and define a roadmap for their improvements. The presentation can be accessed via the following link in the online version.

Other presentations from the Artwork stream of the event included:

The Brazilian Heath Surveillance Agency (ANVISA) present an overview of their serialisation Requirements - *Lisana Reginini Sirtori, Health Regulation Expert, Office of Packaging and Labelling of Drugs and Biological Products, Brazilian Health and Surveillance Agency (ANVISA)*

Lisana presented on the challenges facing the labelling office in ANVISA. The regulatory framework in Brazil is evolving with new regulations awaiting approval by the ANVISA Directorate. These are expected to provide greater clarity on many aspects of labelling including Braille, age marking of products, presentation of Expiration Dates and Serialisation. There are likely to be impacts on both Rx and OTC products, but from Lisana's perspective it was too early to say what these would be.

Lisana also highlighted a local issue regarding differentiation of products in Brazil. Many products are supplied by the Health Ministry and in the late 1990s, as a response to counterfeit medicines, the use of heavily standardised trade dress was introduced. This has resulted in little differentiation between many products in Brazil, a situation that the labelling team is hoping to resolve.

Artwork Asset Management and Workflow Technologies - *Nadine Zimmermann, Artworks Specialist, Medinova*

Nadine presented on the artwork management activities within Medinova. They supply 40 markets and have about 220 artwork projects per year. As is often the case, timelines are compressed and errors are costly so good coordination is required. This is achieved through use of ESKO's WebCentre tool that allows all of the parties (including the CMOs) to be involved. All of the packaging information is held on the system and available to all.

WebCentre is used for collecting requirements and managing approvals. All of the projects can be managed by 1FTE. The next stage is introduction of the Artwork Editing capability.

Packaging and Labelling Management: How to avoid errors, recalls and minimise risk - *Simon Cavanagh, Executive Account Brand Owner, ESKO*

Simon presented on how to provide a seamless flow of information to the patient and how to align physical and digital assets to move to a single version of the truth. Product information is now available online as well as the traditional paper copy leaflets, etc. and to date most companies have built independent siloed operations to manage different parts of this information. This needs to be joined up. A single repository giving a single source of truth supported with the correct processes ensures that assets can be properly tracked from the beginning. Simon then presented on the ESKO organisation and the artwork software suite of tools they have developed.

Child Safety with Openability for Elderly People - An Impossible dream? Not when you get it right! - *Stephen Wilkins, Chairman, Child-Safe Packaging Group*

Children are intrinsically attracted to harmful products - this was confirmed in a study in the Netherlands last year. Stephen presented on two themes:

- How pharmaceutical packaging can be made safe for children and how child resistance testing is undertaken.
- The impact of child resistant packaging on the elderly and how the aging process affects us all in using our pharmaceutical products.

Stephen also gave an overview to current pertinent legislation and the development of new standards for openability and product testing.

The Need for Quality Management and Process Control in a Pharma Artwork Studio- *Suzanne Ivory, Global Head of Quality, Perigord Premedia*

Suzanne presented on the need for quality control in Artwork studios. Drawing on the experiences from Perigord, she discussed the need for a QMS covering the entire end-to-end artwork process and ensuring close relationships between the artwork studio and their customers, regardless of whether these are in-house or external. She highlighted that there are no GMP rules for artwork within the industry so many different approaches have been adopted. Also that the industry is not an early adopter of technology but needs to be careful it doesn't miss out on the benefits technology can bring.

Suzanne emphasised the need for clear processes and unambiguous instructions, appraisal of service level agreements and metrics.

Life on the Sharp Edge of Anti-Counterfeiting Operations- *Bawan Ahmed, Senior Pharmaceutical Assessor, Kurdistan Medical Control Agency*

Bawan presented on the counterfeit market in Iraq in comparison to the rest of Middle East, Europe and the US. The Kurdistan region is an autonomous part of Iraq and has its own Medical Control Agency. There are 500 registered

pharmacies and 6000 unregistered pharmacies which is an outcome of the many years of sanctions against Iraq. This informal supply base is uncontrolled, with pharmaceutical product being sold in market stalls, shops and even butchers! Product may be manufactured locally or imported and is shipped around the region in taxis. Bawan and his team are seeing around 1000 cases of counterfeit medicines a year but with only 5 staff in a dangerous and fluid environment, it difficult to police. The situation is improving through greater collaboration between enforcement parties and the pharmaceutical companies and improved training of staff.

Artwork Compliance- *Rajesh Lakshmanamoorthy, Manager, Operational Graphic Design, Novo Nordisk*

Rajesh presented on artwork compliance within Novo Nordisk. 27 people are employed in the Novo Nordisk artwork centre in India which is part of the regulatory organisation. They have a standard global artwork process and Rajesh discussed how they control a number of topics to ensure the artwork supplied is accurate, for example barcodes, the quality of images and control of fonts. They have also developed comprehensive design manuals and shared repositories containing details of country specific requirements.

Implementing EU Variations on Time- *Chika Jasmin Umenyiora, Global Quality Manager, Roche and Vasiliki Ntafi, Quality Manager for Artworks, Roche*

Chika presented on the work that Roche have been doing to enhance their processes and systems to ensure safety updates are implemented on time. They have defined four scenarios for the phase-in and phase-out of components to cater for different market rules and different requirements for change. They have then established a number of checkpoints through the process to ensure that the artwork and production plans remain aligned.

Roche manage artwork execution in SAP so this allows them to monitor the execution of the end-to-end process across the supply chain.

Impact of the Implementation of the FMD for Packaging and Labelling- *Maarten Van Baelen, Market Access Director, European Generic Medicines Association*

The EGMA has been rebranded as Medicines for Europe - generics manufacturers are moving into other areas of the market so the branding of the organisation was becoming too restrictive.

Maarten presented on the latest status with the EMVO as part of the establishment of European-wide serialisation solution. Countries will need to establish national systems and the EMVO can provide support to this through the blueprint approach they have developed.

The payment model is being defined. MA holders will receive invoices from each relevant national system and the national systems will be billed from the central hub for use by the central hub. There will be a flat fee per MAH, so companies with many licenses will pay more.

A Patient-Centric Approach to Packaging: Involving Patients in a Longer Dialogue- *Karel van der Waarde, Pharmaceuticals Consultant and Graphic Design Researcher*

Karel's presentation looked at medical packaging from the perspective of the patient. He looked at the design of packaging and the provision of information. Finding the right information is challenging due to the graphic design and layout of the text. He also showed how information provided can be misleading and in many cases doesn't help the patient use the product properly or effectively.

Legislation exists and is supported by readability guidelines, but many products on the marketplace fall short of these. He proposed some simple improvements to the design of packaging, layouts and the provision of information that could have significant patient safety benefits.

A case study: using Wolke M600 OEM Thermal Ink Jet to offer a powerful track and trace solution- *Heidi Vanheerswynghels, Global Strategic Account Manager, Videojet*

Heidi presented a case study using a Wolke M600 OEM Thermal Ink Jet to offer a powerful track and trace solution. She gave a short overview of the FMD requirements and, in particular, the quality requirements for printing. These were used to develop the requirements for a printing solution that considered reliable performance, seamless integration, necessary data handling and appropriate productivity.

She explained why thermal ink jet has become the preferred coding method for track and trace, and emphasised the need to use equipment that is very flexible to provide opportunities to work with the space available on packing lines.

Ensuring Compliance - Top Regulatory Highlights to Focus on Right Now. European Standards for Pharmaceutical Packaging Tamper Verification Features- *Dieter MÃ¶ÃŸner, Chairman of the, Packaging Standards Committee NAVp at the German Standards Institute DIN*

Dieter presented on the work that is underway to define standards for tamper evidence as required by FMD. He explained that there is no mandate for the EU Commission to regulate the ant-tampering device in detail and that it is a decision of the manufacturer on which approach to use. The manufacturer must assure that the anti-tampering device is working at the point of dispense.

To support the application of anti-tampering devices a standard for tamper evidence (EN16679:2014) has been developed. Dieter walked through the standard and how it applies to various types of packaging and various tamper evidence solutions. He then discussed how you would go about implementation.

GS1 Discuss the FMD- *Christian Hay, Senior Healthcare Expert, GS1*

Christian discussed the GS1 standards and how they can help combat counterfeiting. GS1 standards underpin most serialisation and authentication solutions. He explained the requirements of authentication and traceability, and GS1's involvement in the Joint Initiatives Council which is shaping solutions to the counterfeit drug challenge. He then discussed how medication

management in the healthcare sector can operate using serialisation capabilities developed to GS1 standards. Christian discussed the development and content of the standard CEN ISO TS 16791 ‘Health informatics - Requirements for international machine-readable coding of medicinal product package identifiers’.

Read it online

Governance key with your new Labelling and Artwork organisation

In my blog about supporting processes I stressed the importance of establishing a Governance group. So here I will explain a bit more about why such a group is required, what its purpose is, the roles of the team members and how its focus changes as you move from project implementation to post-project operational support.

To deliver an excellent artwork service you need excellent cross functional support

When we work with a new customer a requirement that appears to be missed in many cases, in my experience, is the need to have ongoing cross functional leadership. It is often recognised as being necessary during the implementation phase of a project but not thought of as necessary when you move to day-to-day operations. So why do I feel so passionately about its importance?

When you ‘walk’ the complete artwork process from end to end you realise it touches many departments and external groups. In most cases, not only is it cross functional and cross organisational, it is international as well, with several functions being located in different countries. So yes, you need ‘buy in’ from those groups during the design phase but if your ambition is to have an excellent artwork service, that is sustainable, you will need a senior governance group.

In most cases this is a new group, as existing groups do not have appropriate cross functional or geographical representation, or do not have the bandwidth to do the job effectively. The members need to be selected with enough authority to carry out their responsibilities and represent their functions/geography effectively. As a result the members need to be much more senior than the implementation team.

The Governance group provides leadership

During the design phase the Governance group which is, at this stage, a Steering committee needs to provide a clear vision of what they want to see as the capability of the new artwork service and how they want to see it develop for the future. Good sponsorship should then follow, ensuring this vision is communicated out to the organisation, resources provided and any stakeholder conflicts resolved. The team should set out the standard required of the service and agree how its performance will be measured.

The transition to supporting ongoing operations

Post implementation, the Steering committee will transition to the Governance group. It is likely that some of the members of the team will change but it would be my recommendation that this should still be seen as a senior team to provide the sponsorship and leadership required. The purpose of this group is to oversee the ongoing performance of the service, monitor and set ongoing targets, agree priorities for future improvements and sponsor the resolution of issues arising in ongoing business.

The frequency of meetings will depend on the organisation but I would recommend setting them up on at least a quarterly basis.

In my next blog I will consider the opportunities of outsourcing, what to consider and what are the pros and cons.

Read it online

Outsourcing - a useful strategy but needs to be carefully considered

In this blog I look at a popular topic often raised by our clients, the question of whether or not to outsource activities involved in their labelling and artwork process. This can indeed be a useful strategy but, as you will see, there are some important areas to look into before making that decision.

Considerations for outsourcing

When considering this question it is useful to understand the drivers on your business:

- What is the product mix and scale of your business and what will give your business a competitive advantage?
- What internal capabilities are available?
- What are the external opportunities?

These drivers can have an impact on the strategy you choose. Is your company rapidly expanding into new markets with multiple launches for a key product or perhaps launching a pipeline of products? Having a capability to launch as soon as approvals are received, with high quality artwork, will offer you a competitive advantage. Do you have tenders where you need a short timescale capability? You may need to be highly responsive.

What you may keep in house and what to outsource

In these circumstances artwork is likely to be on the critical path so you may wish to maintain control of key activities in house. Potentially a mixed model may also apply, using external partners to give you additional capacity.

Looking at your current internal capability and reviewing the gaps should be the next area to consider. Do you have the capability to develop artwork in house and do you see it as a core organisational capability? I always recommend proof reading to be part of your process and you may decide to recruit for this function or use external providers. If you are launching across multiple markets,

will you be able to cover the range of languages required internally or will it be useful to use external partners for translation, artwork or proofreading?

Looking externally you may find there are some excellent potential providers who could offer a high quality of service at competitive prices. As ever, how much leverage you have with them will often determine both the price and the service they can provide. When selecting suppliers think long term.

Assessing and selecting external providers

Assessing and selecting your suppliers involves being very clear on your requirements, evaluating their technical and quality set up and ensuring you look for suppliers which will fit with your company's ambitions for the longer term.

It is important to recognise you are managing a long-term professional relationship here and the accountability for the process still lies with your company so to make it work you will need mutual respect and a commitment to put in the effort to make it work for both parties. Outsourcing doesn't come for free.

Also don't outsource a process that doesn't work, it will not solve the problem and will likely make things worse.

So hopefully you will see that outsourcing is not an easy option but can definitely be a useful approach as long as you go into it with your eyes open.

Read it online

Technology- range of tools available

In this week's blog I am going to look at the use of technology in the artwork process, why it can be particularly helpful, the range of tools available and a short discussion on some of the potential downsides.

Technology can be particularly helpful where the potential for failure is high

I have explained in previous articles about how humans are pretty poor at checking detail. In a typical artwork process you have people responsible for carrying out activities such as: transcribing information from one source to another; performing multiple or repetitive tasks. So technology can be particularly helpful when used in the areas where the potential for failure is high.

In addition technology can reduce lead times and cost by ensuring everyone has the right, up to date information available to them when they need it, aiding coordination of the different groups and finally ensure process adherence.

There are technology solutions for different parts of the process

Artwork creation is the obvious place to start and for which there are a number of options available. These tools create documents, artwork, drawings, 3D visualisations and also deal with barcodes and braille. These are proprietary, off the shelf packages generally used within the studio and the main issue here is ensuring you are working with industry standard software versions.

Document management tools securely store documents, ensuring versions are managed effectively and that audit trails are maintained. An important consideration is to decide the scope of documents that will be held within the document management functionality of your artwork management system versus other document management systems that may exist in you company. Where will you keep core text documents, local translations, native and master artworks, drawings, packaging specifications and proofreading history reports?

The next key IT functionality is workflow - tools that let you map your process and execute your artwork projects. These route documents through the process to relevant users and are typically part of your artwork management system. They ensure the change is executed correctly, permitting a piece of artwork to be requested, produced then issued to the multiple parties for review, comment

and ultimately approval. Compliant electronic signatures can eliminate the need for paper approval, speeding up your process.

Further IT functionality includes planning tools, forecasting and budgeting and performance reporting and analysis.

It is important to understand the strengths and limitations of the tools you have introduced

One aspect of the artwork process which I am passionate about is proof reading. The introduction of electronic tools for text and graphic proofreading have been a great benefit and there are a number of excellent tools available. These greatly reduce the risk of human error in proof reading but each tool will have some limitations where manual checking is still required. For example, if text is embedded within a pixelated image it may not be detected and checked by text proof reading tools. Therefore understand the limits of the tools you are using and make sure there are appropriate manual checks to augment.

So the use of technology can indeed be really useful enabler, making up for people's common mistakes, ensuring process compliance and enabling a quicker response. There are multiple packages available with different strengths and opportunities. Making the selection is an important decision that should involve representation from all of the functions that will be involved in the implementation, use and maintenance of the chosen solution.

Read it online

The importance of the artwork brief

This week I want to talk about the importance of the artwork brief. In our book 'Developing and Sustaining Excellent Packaging, Labelling and Artwork Capabilities' we say it is a key part a world-class process. So here I talk through why I see it as being so important, why some companies believe they don't

need one, and for those who embrace the change, the continued discipline in its use, post implementation.

‘Introduce an extra step, an artwork brief, but won’t that extend our lead-times?’

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 recommend to clients, as part of their move to excellence, that the ‘change’ is defined in an artwork brief and signed off as approved by key parties before starting.

A common reaction by companies is to think it unnecessary and I often get push back on the idea. They would much prefer to jump straight into designing the artwork using existing artwork as a vehicle to gather all the necessary information. They believe adding an extra step will slow the process.

However by analysing their existing processes I am able to show their current way of working results in artwork going round the development cycle several times, resulting in very long lead-times, frequent omissions or errors and some very stressed staff!

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

In reality the brief is a collection of the information required and the source documents. A good brief is a clear and concise record of the change required with no room for any misinterpretation. The marked up artwork should be amended and presented with suitable software and not done by hand, for example.

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

Once a piece of artwork is produced its review and approval would be made against the artwork brief, by the same signatories, making sure all the changes

required have been implemented and that no other changes have been made inadvertently.

It is important to maintain discipline in the process

If an error is discovered with the artwork, caused by an incorrect brief, it is an important all parties realise a new artwork brief is required, with the correct information and there should be no temptation to ‘fudge’ the process.

It is hard discipline to start with and it needs to be continually reinforced by the process owners, but only by forcing people to stick to the correct process will you find that your ‘right first time’ metrics improve. Reducing the number of times artwork has to go through the process will then reduce lead-times overall, as well as making them more consistent.

In my next set of articles I will talk about the part played by various groups, starting with the packaging technologists/engineers.

Read it online

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