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

In this issue, we look at the topic on everyone's radar, Covid-19 and the impact the pandemic has had on one particular area of focus for us: *Product coding, Serialisation, Traceability and Anti-Counterfeiting capabilities.* We also share with you our latest webinar news, both upcoming and complete.

As always, we share our Consultant's thoughts and knowledge via a series of articles from the VP blogs, continuing our look at **Excellent Packaging Artwork Capabilities** and kicking off two new blog topics relating to **EU FMD alert codes** and from an artwork perspective we bring you parts 1 and 2 on **Ensuring Effective Translations.** You can find these in our Featured Blog Post section below, available for you to read on or off-line.

We're pleased to share with you our Executive Briefing for this issue: **10 Key Learnings From Artwork Improvement Projects** an online reference guide with ten important considerations for your artwork programme implementation.

One topic certainly dominates the headlines right now and its far-reaching effects have been felt throughout the industry. Counterfeit crisis aside, we have selected the best of the rest, a few Top News Picks from the industry that we think are worth a read.

We've received excellent feedback on the value of the content we share in this newsletter and appreciate you taking the time to enjoy sharing our news and updates. As always we welcome your thoughts and comment. If you and your business require advice or assistance in any of these areas, please do not hesitate to get in touch.

Kind regards,

The team at Be4ward

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Industry News

Covid-19 brings Serialisation into the spotlight

Much of the headlines around Covid-19 and the pharmaceutical industry has centred around the disruption to supply chains and the race for a vaccine, however many other stories have surfaced in the last month relating to the detection of falsified goods and medications. It's a sad fact that where disruption occurs the opportunists will swoop and in the case of the Covid-19 world crisis this has become apparent in the discovery of an abundance of counterfeit masks, medical devices, sanitisers, virus test kits and even Covid-19 anti-virals entering the market. This is alongside the escalation in the cases of counterfeit of the standard medications such as antibiotics, painkillers and inhalers where criminal organisations are taking advantage of a spike in demand due to panic buying, interrupted supply chains and a scarcity of supply.

The explosion in counterfeit goods in the healthcare industry has prompted the *Transnational Alliance to Combat Illicit Trade* (TRACIT) to issue a statement to consumers warning them of the surge in fake, falsified and substandard medical products and medicines. The statement, which can be read in full here, specifically reports the emergence of falsified versions of treatments such as

Hydroxychloroquine and Azithromycin and that joint operations by the World Customs Organization, Europol and Interpol to seize counterfeit and unauthorised goods have seen a significant increase in confiscated goods. In the statement TRACIT also calls for immediate action by governments, law enforcement, internet platforms and brand owners to protect consumers and secure the supply chain.

There is a clear message coming out of the industry, that now is not the time for authorities to relax regulations around serialisation or for manufacturers to delay the implementation of a serialisation strategy. It is of paramount importance that supply chains are fully protected against this increasing threat. Some relaxation of serialisation requirements has been proposed by various national authorities to ease the flow of supply at a time of crisis, this has already been seen in France and Luxembourg, yet there is widely held belief that this opens the door to counterfeit crime, creates confusion and ultimately compromises patient safety.

At Be4ward our international team of expert consultants remains in place, fully operational and available to offer your company the support and guidance you need to secure your products from the threat of counterfeits. We continue to deliver our clients uninterrupted service via virtual workshops, consultation sessions and remote support. We also have an extensive publication programme of materials relating to serialisation strategy and anti-counterfeit measures. If you'd like to receive further information or speak with one of our expert advisors, please get in touch at: enquires@be4ward.com

Further reading and our top picks on the topic of the Covid-19 counterfeit crisis can be found here:

- COVID-19 – Fighting the fakes
- OLAF launches enquiry into fake COVID-19 related products
- COVID-19: Beware of falsified medicines from unregistered websites
- Global operation sees a rise in fake medical products related to COVID-19
- Medical Product Alert N°3/2020
- How criminals profit from the COVID-19 pandemic

FMD recall hits the headlines

A significant event in the EU FMD timeline took place in February, the first recall of a product due to EU FMD. GlaxoSmithKline (GSK) initiated a recall of a batch of their *Beconase Aqueous Nasal Spray* after it was discovered that the physical product had been released onto the market with an incorrect status. When attempting to decommission at the pharmacy the status of the pack may report as “Destroyed”. This incident demonstrates the importance of having robust processes for the control of product status during manufacturing. It also sends out a clear message that the EU FMD must be taken seriously or you risk causing impacts on your commercial operations.

Now is an important time to ensure your company has a robust recall process in place which includes the specific EU FMD touch points. At Be4ward, we advise

conducting a mock recall to test this process and our expert consultants can assist with this process. If you require help or advice establishing your recall process please get in touch: enquiries@be4ward.com

This landmark FMD recall is reported here by *Chemist & Druggist*

- FMD recall issued for the first time in six months

GS1 Digital Link 1.1
Smart packaging standards for the 21st Century

In February GS1, the global supply chain standards organisation, released an update to the GS1 Digital Link standards [1]. This is a significant development in the ability for brand owners and manufacturers to enhance the user's product experience.

The GS1 Digital Link standards bring together the omnipresent consumer barcode, seen on almost every consumer and healthcare pack globally and used over 5 billion times every day, with the power of the internet, to web-enable physical products. This facilitates the digitisation of the product and enhances the ability to interact directly with the end consumer/ patient.

With the advent of smart devices and on-pack scanning features such as barcodes and NFC labels, the physical pack has become a very powerful channel to engage and interact with the consumer. 91% of consumers value in depth product information, beyond the label and 81% are willing to switch to a brand that offers more in depth information.[2]

"The release of these standards gives brand owners and healthcare manufacturers the ability to offer enhanced product experiences using open, interoperable and global standards," said **Grant Courtney, Principal Consultant at Be4ward and Co-chair of the GS1 Digital Link Standard Development Work Group**, "we are already seeing major brands adopting these standards to build exciting new offerings to their customers.

What's new in version 1.1 of the GS1 Digital Link Standards?

The updated standards now provide several new capabilities including 'link type' which allows a wide range of specific content to be provided such as electric leaflets, recall status, traceability information, ingredients, allergens and many more.

Another capability supported by the updated standard is compression of the data held in the barcode/ NFC label/ RFID Tag/ etc. Compression allows for more information to be held in a smaller barcode for example.

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[1] https://www.gs1.org/docs/Digital-Link/GS1_Digital_link_Standard_i1.1.pdf
[2] The Transparency Imperative, FMI with Label Insight, 2018

Be4ward Company News

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

An upcoming Be4ward | Optel | Jennason webinar

Wednesday, April 29, 2020 | 9am EDT (NA) / 2pm BST (UK) / 3pm CEST (EU-Central) | 60 min

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

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

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

The webinar will take place on April 29, 2020 at 2pm BST (GMT +1). Join us to learn about:

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

The webinar will include a question and answer period, during which participants will have an opportunity to interact with the three webinar speakers to question or clarify any of the issues surrounding the EU FMD.

Be4ward | Navitas | On demand webinar

Will you be ready to comply with DSCSA Verified Router Services?

Join serialisation experts including Be4ward VP Stephen McIndoe, as they explore the VRS requirement and discuss strategies and activities companies can

take to comply with the guideline as well as future-proof their supply chain for any future serialisation regulatory requirements.

This webinar examines:

- The DSCSA VRS Guidance and Serialization Data Requirements
- The overall purpose and need of a VRS System
- An up to date Industry benchmark
- Steps that you can take now to comply with the guidelines
- Onboarding options available for Manufacturers and Distributors
- Explore options for a VRS outside your Serialization Database Vendor
- Extending Edge solution to use VRS for Returns verification

Featured Blog Posts

By Stephen McIndoe

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

Associate blog from Grant Courtney -Principle Consultant Be4ward

It's been just over 12 months since EU FMD came into force and after initial problems bedding in the new systems, false alerts remain a problem preventing the realisation of the full benefits of the directive. With many grace periods now coming to an end, where are manufacturers on the EU FMD journey and what are the real consequences of unresolved alerts moving forward?

Principle Consultant Grant Courtney examines the reasons behind these alerts occurring and looks at the action stakeholders must take now to keep the supply chain flowing.

>> Read it offline

Read it online

EXCELLENT PACKAGING ARTWORK CAPABILITIES PART 2 – THE CAUSES OF ARTWORK ERROR AND THE IMPORTANCE OF A SERVICE CULTURE

VP Stephen McIndoe continues his blog series on the topic of Excellent Packaging Artwork Capabilities. Here in part 2 he looks at the causes of artwork error and the importance of a service culture as part of your artwork capability.

>> Read it offline

Read it online

Featured Blog Posts

by Andrew Love

ENSURING EFFECTIVE TRANSLATIONS – AN INTRODUCTION

In his new blog series our VP Andrew Love shares his expert knowledge on the topic of Ensuring Effective Translations. Here in part 1 he introduces the blog structure, based around a 10-step process to help you establish your translation capability.

>> Read it offline

Read it online

ENSURING EFFECTIVE TRANSLATIONS – DEFINE YOUR APPROACH TO TRANSLATION

In part two in the series of posts on Ensuring Effective Translations, VP Andrew Love takes a closer look at the activities you need to do in your organisation to set out how you will manage translations across the company.

>> Read it offline

Read it online

10 Key Learnings from Artwork Improvement Projects

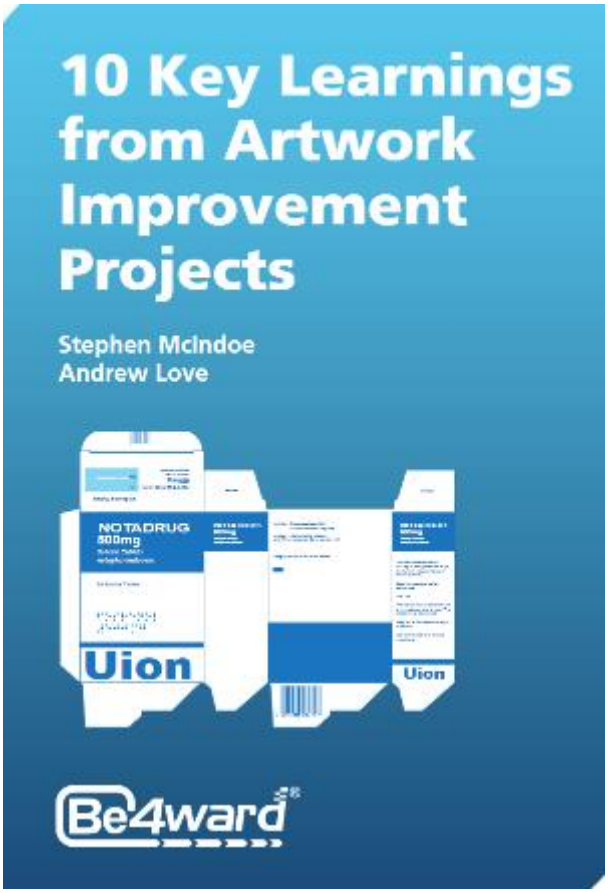
Executive Briefing

Stephen McIndoe
Andrew Love

Like all significant change activity, many artwork programmes commence, but not all are successful. Priorities change, resources are constrained, timelines can slip, funds can be withdrawn, and scope can be reduced: in other words, there are many different factors that can cause your artwork improvement project to fail. Over the years, we have learned many lessons from our involvement in numerous labelling and artwork improvement projects that we believe are key to ensuring success. In the largest organisations, artwork capabilities involve thousands of people, working across many internal functions, in more than one hundred countries, involving tens, if not hundreds of external organisations. The capabilities require the skilful design and management of integrated business processes, organisations and facilities, which are enabled by a suite of sophisticated information technology systems. In smaller companies, whilst the scale is reduced, the fundamental challenges remain unchanged. Establishing and delivering improvements in artwork capabilities is a significant, but achievable change management challenge. Delivering change in this area requires the management of a complex interaction of business processes: people in many different functions, organisations and countries using many, often validated information technology tools. This requires careful and skilled project and change management skills to do it effectively if significant compliance risks are to be avoided. We have captured these key learnings in this booklet as useful tips to carry your Artwork Program forward. We hope these are useful in shaping your projects and delivering success to your companies.

Read the Executive Briefing to learn more

>> Read it offline



Top 3 News Picks

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

Dispensing and pharma: Safety, security and sustainability

By Victoria Hattersley for *Packaging Europe*

The R&D efforts of Europe's pharma packaging companies when it comes to drug dispensing systems

Click here to read the article

How Covid-19 is affecting the pharma supply chain

By Reece Armstrong for *European Pharmaceutical Manufacturer*

EPM speaks to a range of pharma players to find out how Covid-19 is affecting the various aspects of the pharmaceutical supply chain.

Click here to read the article

The demand for sterile and antiviral packaging amid Covid-19 panic

By GlobalData Consumer **f**or *Packaging-gateway.com*

The coronavirus pandemic continues to rewrite the nature of global society in 2020, and with it the attitudes and behaviours of consumers now and for the foreseeable future.

Click here to read the article

Executive Briefing: read offline

10 Key Learnings from Artwork Improvement Projects

Introduction
10 Key Learnings you should consider for your Artwork Programme Implementation
Like all significant change activity, many artwork programmes commence, but not all are successful. Priorities change, resources are constrained, timelines can slip, funds can be withdrawn, and scope can be reduced: in other words, there are many different factors that can cause your artwork improvement project to fail.

Over the years, we have learned many lessons from our involvement in numerous labelling and artwork improvement projects that we believe are key to ensuring success. In the largest organisations, artwork capabilities involve thousands of people, working across many internal functions, in more than one hundred countries, involving tens, if not hundreds of external organisations. The capabilities require the skilful design and management of integrated business processes, organisations and facilities, which are enabled by a suite of sophisticated information technology systems. In smaller companies, whilst the scale is reduced, the fundamental challenges remain unchanged.

Establishing and delivering improvements in artwork capabilities is a significant, but achievable change management challenge. Delivering change in this area requires the management of a complex interaction of business processes: people in many different functions, organisations and countries using many, often validated information technology tools. This requires careful and skilled project and change management skills to do it effectively if significant compliance risks are to be avoided.

We have captured these key learnings in this booklet as useful tips to carry your Artwork Program forward. We hope these are useful in shaping your projects and delivering success to your companies.

Key Learnings

Key Learning 1
Compelling urgency — ensure business benefits are clear and a sense of urgency is built

Getting the necessary resources to implement any program is vital to its

success. In most organisations, competition is strong for those resources, so the need to act now needs to be compelling.

The majority of pharma and biotech artwork improvement programs are ultimately justified on the basis of reducing compliance risk. Therefore, for senior management to buy-in to the need to act, a compelling link between artwork issues and compliance failures and/or near misses needs to be established. Establishing this link will normally require a significant amount of effort to gather information related to issues and analyse their true root causes. You should be prepared for the fact that, in some cases, labelling and artwork do not turn out to be the root cause of the issue.

Furthermore, even if this cause and effect link is clear, it is also key to ensure the urgency of improvement is clearly established in the minds of the decision makers. For the purpose of justifying change, a currently unacceptable compliance performance is ideal, particularly one which trending in the wrong direction. Alternatively, a significant change in circumstance or environment which threatens imminent compliance issues can also be compelling. An example of the latter might be the merger of two companies.

Simply establishing the rational reasons for change and its urgency are not enough in many organisations. Considerable time and effort is then often required to “sell” this message to a broad group of decision makers and their influencers to ensure that, when prioritisation decisions are taken, enough of the right people back the artwork improvement over other programs.

Key Learning 2
Sponsorship — have you got the right Senior Management sponsorship for your project?

We talked about establishing a compelling reason for action in the last article in order to ensure your artwork change program is approved. However, once approved, the challenges to maintaining momentum and delivering success do not stop. Many significant change programs are subject to a continuous stream of organisational resistance that takes many forms. It is for this reason that identifying the right senior sponsorship is key.

Sponsors are senior individuals who are passionate and knowledgeable about the change, and have the seniority and influence to continuously champion the change across the organisation and help navigate through the inevitable storms of significant issues and resistance that are bound to occur. Typically, a sponsor will come from one of the functions most involved in the labeling and artwork process, the likes of supply chain, quality, regulatory or commercial.

Once a program has secured a sponsor, they need to find ways to keep the sponsor informed, engaged and interested in the program, so that they will continue to actively champion the change.

Key Learning 3
Vision — collaboratively develop your vision involving all relevant stakeholder groups

Good business change management practice tells us that, in order to maximise the chances of successful adoption of any change, we should involve those impacted by the change in designing the future state. Given that labeling and artwork processes are, by their nature, very cross functional, cross-organisational and global, in our experience developing a vision of the future in a collaborative way is critical to success. We have seen a number of change programs have significant difficulty or even fail outright because they did not perform this fundamental step in a collaborative way.

It is all too easy for the labeling and artwork subject matter experts to fall into the trap of believing they have all the answers and that it is just a matter of telling the rest of the organisation how they should do things. After all they would argue, it is only logical that they know how best to do things as they are the subject-matter experts. Unfortunately, this completely misses the key point that implementing any change is at least as much about changing the “hearts and minds” of those impacted, as it is about getting the technically ideal solution. In fact, we would go so far as to say it is much more effective to have a sub-optimal technical solution that everyone buys into, rather than to have a technically perfect solution that is never effectively implemented.

Other significant benefit of developing the future state design with representatives from across the impacted stakeholder groups are:

- Issues and resistance to the change are surfaced early and can more easily be dealt with at the design stage.
- A more robust solution is more likely to be developed that deals with all of the local realities effectively.

So we would recommend identifying a suitable cross-functions, cross-geographic and cross-organisation team to be involved in a well-managed and facilitated collaborative design development process. This team must be recognised by the organisation as representing them for this to be successful. This type of collaborative design process takes time and commitment from the organisation, so needs to be built in to plans and budgets accordingly.

Furthermore, the collaborative design process should include all elements of the potential change and would typically cover:

- Processes

- Organisation
- Information
- Tools and IT systems

Key Learning 4
Communication — communicate across the extended organisation. Help people understand what's in it for them

Labeling and artwork processes are typically highly labor intensive, involving many tens or hundreds of people from across an organisation and its partners. Furthermore, in many cases, the people carrying out the process are doing so for less than 10% of their time and do it in their own location. Therefore, the successful implementation of any change rests on a project's ability to effectively communicate with this very wide audience.

Don't forget that, in order to get any individual to fully accept a change, it is not only necessary for them to understand how the change impacts them, but also to understand what is in it for them.

One useful way to visualise the change management problem that communication plays a key role in helping, is to consider the child's game with different shaped pegs and holes, the objective being to match the right shaped peg with the right shaped hole. A typical change project will spend a lot of time creating the pegs. Communication, amongst other activities, helps create the corresponding holes, which in turn prevent the need for the project to use force to drive their pegs into non-matching holes, which in turn usually leads to failure of all or part of the program.

Also remember that people take time to understand and accept change. Therefore, successful communication is far from a onetime activity. One of the more well-known communication phrases is "7 times in 7 ways", which

not only captures the need for multiple communications, but also makes it clear that, to be effective, the communication needs to take different forms.

Communicating to such a large group of people, often spread across the world, requires a significant amount of planned effort on the part of a change program. It is not unusual for a large labeling and artwork change activity to have team members dedicated to the task of planning and executing communication throughout the life of the program.

Key Learning 5
Roadmap — ensure there is a path to deliver solutions. Involving the right groups in delivery

An Artwork Program usually is a compound of multiple projects that need to be orchestrated through a coordinated program. To keep each project going, you have to define all the members' roles, clearly stating who's doing what. It is critical to integrate all the relevant parts of the extended organisation and there should be no doubt that they will be held accountable for delivering their assigned components.
The artwork projects can be held over a very long period of time. With a number of people involved in so many projects, there is a great risk of losing track of the scope defined at the beginning, leading to not delivering the outcomes that were expected. Stating clear scope and boundaries for each project helps to remove any ambiguity that can rise over time on what has to be done by each team member.

Define your program like a journey, being clear on every step of the way. You have to know where you go right from the start to deliver the right solution at the right time. This trip has to focus on each step along the way putting the most important improvement first. To get going, the trip needs fuel. It is critical to provide the travelers with the right resources at the right

moment along the path to arrive on time and also at the right place as it was defined at the beginning of your Artwork programme journey.

Taking the trouble to shape all your projects with clear scopes and roles assigned for all participants in an Artwork Programme help them to understand the changes taking place and fulfill their active part in the realization of the project.

Key Learning 6
Keep momentum — how will you maintain interest to keep your program going?

We have already defined our Artwork Implementation Project as a long journey and demonstrated it was critical to provide the right resources at the right time. Such a long timeline can lead to Management losing their focus to get the programme to the finish line, leading to discouragement among the project teams. To avoid that, some tactics can help to keep your program going no matter the challenges met along the way.

As a living creature, an organisation is always in movement and modifies its priorities to adapt to its ever evolving environment. These external pressures can distract the leadership leading to pull on resources from your project to reassign to the new identified priorities. An Artwork project is always complex and represents difficulties to overcome and new technologies to implement. These issues usually create concern, sap the energy of the team and reduce the focus on what has to be achieved. It is critical to keep showing the leadership and the teams the improvements already delivered to maintain energy and optimism.

To maintain momentum during the implementation and avoid the risk of seeing your project stall, shape your project with short-term milestones.

These steps coupled with well-defined deliverables generate a sense of achievement during the project and look less daunting to the team members involved in the project.

These smaller steps enable such a big project to adapt to the new priorities set by the organisation, giving your Artwork Programme a better chance to be implemented with success.

Key Learning 7
The right leadership — ensure focussed and accountable leadership

We have already mentioned the importance of identifying the right sponsor to champion the change across the organisation for complex programs such as Artwork ones in the Key Learning 2 post (put a link to KL2). It is also important to have leaders capable to pilot this improvement project through all the challenges present in a cross-functional and cross-organisational change management project. Not only do leaders have to show technical knowledge, they have to be capable of dealing with people elements that are a huge part of a change management project.

Good leaders have to connect across the organisation to promote the Artwork Project to bring visibility and interest. They have to be capable of advocating their project outside of their close circle to engage and influence across the extended organisation to get a broad range of stakeholders on board. This require networking and communications skills to inspire and drive the project to the desired outcomes.
This cannot be achieved alone. In the same order, a leader will build up an effective network of change agents located at all the levels of the organisation that are just as enthusiastic about the project and ready to help deliver it.

The combination of all these qualities allows the leaders to overcome the difficulties and hence deliver superior results.

Key Learning 8
Governance — ensure there is effective cross-functional governance

We have now a pretty good idea of the main components of the structure and content of an artwork improvement programme. The cross-functional nature of it involves all kind of stakeholders located in different organisations and countries. This represent a big challenge to get a sound project correctly delivered.

Many parts of the organisation, very different from one another, such as Supply Chain, Marketing, Quality, IT, Regulatory and Third parties have their own needs and objectives in an Artwork project. Not only they have to own their specific part of the program, they have also to be held accountable for delivery. Decision making must ensure these disparate needs are considered in the management of the Artwork project.

Use of an appropriate Governance structure will help to gather these functions together and ensure their different needs are identified and represented appropriately. The Governance will have to integrate the functions in a cohesive way to maximise the outcome of the Artwork project and its adoption by the entire organization.

Key Learning 9
Partners — select your solution partners carefully

We are now pretty much near the end of our journey and we have to talk about the solution partners being established as part of an Artwork implementation program. They include translation firms, consulting firms, IT

solution providers and graphics houses. After spending a lot of time on designing the solution that fits your organization needs, the time has come to pick the right providers that will support your vision for a long time.

Choosing the right partners can be very daunting to serve the best interests of the organisation in the long run. Therefore, using appropriate criteria and evaluation processes are critical to make sure that you have qualified and agree decisions on the partners that will ensure the ongoing successful performance of your overall Artwork Service. Keep also in mind the level support needing to be provided during and after the implementation of the improvement program as per your contract with your solution providers, both from them to your company and from your company to them. The relationship with a solution provider needs to be a partnership to make it successful in the long run.

One of the most common errors is to have selected a solution provider and then try to force-fit it into the Artwork program with strategy and business cases that are extrapolated backwards to permit this. The vision must be initiated directly from the organization’s strategy for its future development and not the other way around and most of all be capable of standing the test of time. Keep this in mind, when the time comes to select the most appropriate solution partners for your Artwork service.

Key Learning 10
Sustainability — make sure your solutions stick

This is it. Everything is in place and you have passed all the hurdles along the way to implement your Artwork Program and you think your job is finished? Not so fast, now you have to see all the hard work put into implementing new solutions and new processes lasts and is adopted by all the stakeholders and ensure that the old ways of working are disabled.

They say ‘old habits die hard’. We have seen on pretty much all the Key Learnings such as the Key Learning 7 that the change management factor is really strong in all the aspects of implementing a new Artwork Programme. New ways of doing things is scary and unsettling for everybody. Therefore, the need to ensure that changes are sustainable is key to make the project a success. To do so, a list of key components must be addressed.

After implementing the changes, you have to ascertain people understand and agree to this changes, this new ways of working and behaviours are modelled and rewarded. The processes have to be built into technology solutions and measures must demonstrate successes of the changes introduced. Appropriate support capabilities need to be established – where do users go when they need help or discover things that don’t work as envisaged? Finally, the old ways of working must be completely disabled. All of these elements can be achieved by architecting the project from design, through implementation, to operation to consider your implementation a real success.

We hope these key learnings will help you and wish you the best for your Artwork programme implementation.

About Be4ward

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

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

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Featured Blog Posts : read offline

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

Associate blog post from Grant Courtney, Principle Consultant

It's been 14 months since EU FMD came into force and after initial problems bedding in the new systems, false alerts remain a problem preventing the realisation of the full benefits of the directive. With many grace periods now coming to an end, where are manufacturers on the EU FMD journey and what are the real consequences of unresolved alerts moving forward? Grant Courtney, Principle Consultant at Be4ward, examines the reasons behind these alerts occurring and looks at the action stakeholders must take now to keep the supply chain flowing.

On the 9th February 2019, new legislation was introduced within the EU with the aim of increasing patient safety by preventing falsified products from entering the pharmaceutical supply chain. The EU Falsified Medicines Directive (2011/62/EU) or EU FMD as it is known, called for a significant overhaul to the existing pharma supply chain system, requiring the establishment and implementation of new organisations and systems needed to authenticate every medicine distributed across the European market.

Initially most of the stakeholder effort was focused on meeting the compliance deadline. For manufacturers this included upgrading productions lines, putting in new IT systems, establishing new processes and running regulatory pack change programmes. Products were generally ready in time across the industry and from the 9th February 2019, as per the directive, all

packs which were released onto the market carried a 2D data matrix barcode with a unique identifier (serial number) encoded, along with a tamper evident feature to ensure the integrity of the pack. It would be wrong to believe that hitting the compliance deadline was the end of the journey. In many respects, February 2019 was just the starting point for the EU FMD.

Over 130 million prescribed packs are now scanned every single week. The scale of the systems is impressive, and the EU FMD has fundamentally changed the way in which prescription medicines are manufactured and how they are managed prior to dispensing. These changes present an even greater challenge than the technical ones already encountered, and the implications and impacts are only just starting to surface 12 months in.

For most of the millions of packs being dispensed each day, the pharmacists receive positive confirmation that the unique identifier is valid and, in a status, may allow the pack to be dispensed. When this occurs everything runs smoothly, however not all scans end with a positive confirmation.

The EU FMD systems are designed to identify any unique identifier on a pack which is not in the system or has a status which means it should not be dispensed. When a pack fails to authenticate, the system generates an alert which is distributed to several stakeholders including an alert to the Market Authorisation Holder (MAH).

Alerts generated by the system due to the unsuccessful authentication of a pack are vital as they flag a potential falsified product, allowing action to be taken to address the reason and any potential criminal activity. An alert raises concern over the quality and authenticity of the product, preventing it being dispensed to the patient.

Initially the level of alerts being generated were very high, running at about 6% of all scans. Many of these alerts were false due to two main causes. Firstly, some manufacturers had not managed to upload all the serial numbers into the European Medicines Verification System (EMVS) so missing data was triggering errors. Secondly, the pharmacy systems had not

been configured correctly and were introducing errors into the decoded barcode data. These errors included converting upper case characters into lower case and interpreting dates incorrectly.

During the past year, most authorities have taken a lenient view on the alerts, understanding that new software and processes have to stabilise and become embedded. In recognition of this many operated a period of stabilisation, whereby packs that triggered an alert could still be dispensed at the discretion of the pharmacist.

Many of these early problems have now been resolved, consequently the level of alerts has reduced to around the 1% mark as an average across EU countries. However, this level is still considered too high with many false alerts still taking place. It will be progressively more difficult to reduce this further and we can expect this to take many months more to resolve.

In part two of the blog, we examine in more detail the process that happens when an alert is triggered, what manufacturers should be doing and what's coming next in the EU FMD journey.

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

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

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Excellent Packaging Artwork Capabilities part 2 – The causes of artwork error and the importance of a service culture

By Stephen McIndoe - VP of Be4ward

In the opening part to my new blog series examining how to create and apply excellent artwork capabilities, I looked at why packaging artwork matters so much and what happens when you get it wrong. Here in part two I take a closer look at some of the main causes of artwork error, how to prevent them and how to create right-first-time packaging artwork. I also examine the importance of creating a service culture around the provision of labelling text and artwork and the benefits this can bring to the packaging artwork process.

Causes of artwork errors

I have divided the many causes of artwork errors into categories, discussing each of them in turn.

Process gaps and inconsistencies Alternatively termed as systematic errors, these occur when the design of the business processes is incomplete or are conflicting, leading to errors in the content of the artwork. A typical example of this would be a gap in the process definition for the provision of a particular piece of information.

Lack of competence Here, operators do not have the necessary skills, knowledge or instructions to carry out the tasks that are required of them in the business process. This may be due to issues such as an inadequate level of process definition or inadequate training and competence assessment. An issue of particular concern in artwork processes which I discuss later is that of ensuring the competence of people who perform tasks in the process only very infrequently.

Lack of quality time It does not matter how competent people are, if they do not have enough quality time to perform the tasks required of them then they are likely to make forced errors in one form or another. A lack of quality time to perform tasks is typically due to unrealistic process step times being expected, or an overall lack of adequate headcount resource. Clearly, this may also be a symptom of ineffective process and/or tool design.

Inappropriate decision-making In this type of situation, people will make inappropriate decisions during the execution of the business process which leads to errors in the resulting artwork. For example, management may set priorities which are interpreted by operations staff as needing to prioritise moving an artwork to the next stage of the process ahead of doing a task completely and correctly.

Ambiguity The artwork process involves many individuals providing detailed instructions to other individuals in the process, with the resulting opportunity for ambiguity in these instructions to lead to errors in the artwork. A lack of templates or instructions on how to pass on information and instructions in an unambiguous way can be examples of this type of issue. It must be remembered that many people working in the artwork process do so in their second language. This significantly increases the possibility of individuals misinterpreting instructions which are not entirely clear.

Errors in source information The age-old phrase “garbage in, garbage out” applies very well to the artwork process. If incorrect source information is used in the process then it is highly likely to cause errors in the resulting artwork.Typical examples of this type of issue include people using the wrong or incorrect versions of documents and the use of uncontrolled information sources such as ad hoc personal spreadsheets.

Human error A typical artwork process includes many steps where people are directly responsible for carrying out activities such as transcribing information from one source to another and performing multiple complex or repetitive tasks. It is natural for human beings to make mistakes; this can be for many reasons. Sometimes it will be due to limitations described elsewhere in this blog, sometimes it may just be because we are having a bad day. Whilst many steps can be taken to help reduce the possibility of human error, the fact remains that it can still happen and needs to be taken account of when designing artwork capabilities.

Technology errors Technology in the form of computer software and tools is often used to perform or aid the artwork process steps. However, without careful design and control, this technology can introduce errors into an artwork. Examples of the types of issues which may cause such errors include software operating incorrectly; systems not providing the user with a true image of a document and font transcription errors when moving information from one document to another.

Creating a service culture

The development of packaging labelling and artwork involves many different groups across the company and, more often than not, external service providers and supply-chain partners. As I have already discussed, the creation of artwork requires many elements of information to be drawn together in a way that ensures that every detail is correct in the end-result. Without careful orchestration, the separate groups involved in the artwork creation process, both from within and external to the company, will not deliver artwork of the required quality standard. Each person involved in the process must perform their task in the process in the correct sequence, using the right information and tools in order to achieve a quality result.

To facilitate this, it is beneficial to consider the provision of labelling text and artwork as a business service. In our experience, the best artwork capabilities are those that consider themselves to be providing a service to the key business stakeholders and strive to understand their service role and deliver it. Like any service offering, this will evolve over time as the customer’s needs change. The management of the artwork capability should recognise these changes and adapt the service accordingly in a managed and considered way.

The development of clear mission, vision and performance measures can go a long way to orchestrate the successful delivery of the service across the diverse groups that are involved.

Defining service requirements

When designing an artwork service, we have found it useful to take a systematic approach to the definition of the service requirement based on a number of key questions, which we discuss in more detail in our book *Developing and Sustaining Excellent Packaging Labelling and Artwork Capabilities.*

– What is the service producing?

– What is the scope of the service?

– Who are the customers?

– How do you measure success?

– What do you need the service to achieve?

– Who “owns” the service?

– Who is involved in the service?

Service statement

In order to answer the above it is good practice to capture the requirements of the service in a service statement of some kind. This may take the form of a service level agreement or any other similar document used in your company. It gives clarity to everyone within and outside the service on what the service is and is not there to do, how success is measured and how the service is expected to grow.

Guiding or underpinning principles

To support the service statement, it is also useful to define a set of guiding or underpinning principles on how the processes and capabilities will operate. These define the “rules of the game” and will help all parties involved in delivering the service when having to make decisions about how to move forward in a particular situation. We discuss typical principles further in our book.

Service culture

Developing a common service culture across the various teams involved in delivering the overall artwork capability is also a useful means to ensure successful delivery of the service. It must also be recognised that, in providing a service to a broad group of stakeholders, it is rarely, if ever, possible to please everyone all of the time. An element of good service management not only recognises this, but actively helps to ensure its key stakeholders also recognise this and are involved in collaborative decision-making for key aspects of the service delivery.

It is easy for an external supplier to develop a service culture; after all, it is inherent in the nature of the relationship between the two parties. Not pleasing your customer on an ongoing basis more often than not results in a clearly recognisable termination of the relationship.

When managing internal service functions, the service nature of the relationship between the artwork capability and the rest of the organisation is not as obvious to everyone involved unless it is carefully orchestrated. This requires activity not only on the part of the group providing the service, but also on the part of the customer groups. As with relationships with external providers, it is all too easy for a customer group to abuse the relationship and blame the service provider for all manner of issues. To be successful, the service group and the customer groups should strive to see the relationship as a meeting of equals for mutual benefit, not a master and servant relationship.

You will also recognise that the artwork service relationship, if it is to be successful, will last a considerable period of time. Indeed, if the service is provided by a largely internal team, there is little or no practical opportunity to stop the relationship. Everyone in a long-term relationship will recognise that, for the relationship to be successful, effort needs to be put into it from all parties. Managing an artwork service capability is no different and this effort needs to be budgeted for and the necessary work planned and executed.

In part three of my blog series on Excellent Packaging Artwork Capabilities I'll be looking at the core artwork process and interfacing processes.

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

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

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Ensuring Effective Translations – An Introduction

Andrew R Love

As globalisation increases and companies reach customers in many more markets around the world, the need for accurate and comprehensive translations increases. Translation activity is an often forgotten back-room process. It is rarely considered core to a company's operations, but failure in the process results in incorrect information being provided to customers, suppliers, regulators or shareholders. At minimum this is embarrassing and may not show the company in the best light. However, some errors can be significant, impacting the safety of the customer or agreements with regulators. These can seriously damage the company's reputation and lead to sanctions and fines.

It is therefore essential that a company has a fit for purpose translation capability. This should ensure that the processes, roles, suppliers and

systems necessary to deliver a quality output are available across the organisation for anyone involved in translation activity.

In this new blog series, I am going to look at a series of tips to help you establish your translation capability. It is based around a 10-step process as follows:

1. **Define your approach to translation**: the activities you need to do in your organisation to set out how you will manage translations across the company

2. **Initiate your project**: the steps you would take to start an individual translation project and set the project up for success

3. **Prepare text for translation**: tips for how to make sure that the text you are supplying for translation is prepared to allow a high-quality translation

4. **Choose a translation provider**: tips to ensure that the translation provider you propose to use is fit for purpose

5. **Translation specifications**: how to establish a set of standards for working with your translation provider

6. **Brief translation provider**: how you instruct the translation provider to undertake the project you want translated

7. **Prepare translation**: the preparation of the translation at the translation provider

8. **Review translation**: the quality assurance steps undertaken to make sure the translation is correct

9. **Approve translation**: the formal approval of the translation

10. **Securely store approved files and build translation memory**: how to ensure effective document management and how to start building a library of standard phrases

In my next post we will take a closer look at the first step: Defining your approach to translation.

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

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Ensuring Effective Translations – Define your approach to translation

Andrew R Love

As outlined in my previous post on this subject, in this blog series we are looking at a set of tips based around a ten step process to help you establish your translation capability.
In this post I look at the first set of tips, based around step 1 – *Defining your approach to translation:*

Take a strategic approach to translation
Translation is an important part of any business operation. The process provides information to customers, suppliers, shareholders and regulators. Errors can at minimum be embarrassing to the organisation and in the extreme can lead to sanctions and product recall. It is therefore essential that a strategic approach is taken to the provision of translation capabilities within your organisation. This needs to cover policies, processes and procedures, document creation and management, management of translation agencies and approval and use of texts. Policies need to be complied with and

management and in-country personnel need to buy into documentation processes.

Understand the ‘value-add’ from translation

Translation is a complex activity impacting many parts of the organisation and many different types of documents. It is often a ‘hidden’ activity in many companies, who don’t realise this complexity or the business impact when things go wrong. In light of this, it should be performed and managed by professionals of the domain to ensure a professional approach that assures and enhances corporate reputation.

The preparation, review and approval of a translation takes time – a translator usually translates around 2500 words per day. It is therefore important that individuals involved in the process are given appropriate time to perform the quality critical steps they undertake. Moreover, much of this activity may be performed outside your organisation by translation service providers. These suppliers need to be appropriately selected, engaged and managed to ensure performance meets business requirements. A partnership approach is recommended, involving the translation providers in the translation projects and process improvements you are undertaking.

Manage terminology and style through glossaries and style guides

The use of glossaries and style guides can provide a level of standard for translations undertaken. A company-wide glossary of English terms, that is vetted by management and reviewers, will help ensure that all teams agree on the core terminology that is unique to your organisation. The glossary could include the following conventions that are used in your company: corporate/product nomenclature, abbreviations and acronyms, terms that remain in English (i.e. product names, copyright items, etc.), and “lingo” that should stay consistent across languages.

A style guide explains the “voice” and tone that each language should have. This assists in ensuring consistency of the style if translations in the same language are being undertaken by different teams across the organisation.

Resist the temptation to do it yourself

Being able to speak a language does not guarantee being able to write effectively in that language. In most cases your written command of a foreign language will be immediately recognisable as “foreign”. Being bilingual is not a guarantee of being able to translate a document. It is a misconception that anyone who is bilingual will have fluency in writing or skill in translation. If you want your organisation to appear professional, you need to be served by a professional approach. Moreover, in many cultures, awkward or sloppy language is not considered amusing and can be considered insulting.

Most lead translators have a minimum of 5 years of experience in translation. They either have a university degree, relevant experience in a specialised field of work, or equivalent professional qualifications. All reputable translation companies would go through a strict vetting process before enlisting any translators and their work will be regularly monitored. Translators will only translate into their native language and will have experience in the industry they are translating for.

Centralise your translation projects and energy

Translation requirements can arise in many different parts of an organisation, but typically these are not coordinated centrally, but instead local teams undertake the activity in isolation, to local standards and processes and often creating a plethora of translations service providers.

It is far more effective from a quality and consistency point of view to centralise language projects into a centralised coordinator role and outsourcing translation to rigorously selected and preferred suppliers.

It would therefore be recommended to assign a translation coordinator who selects, assesses, communicates with and manages your translation providers and coordinates all translation projects for your company. If you have a large spread of required languages, it is unlikely that one translation service provider would be able to meet all needs – they may rely on local subcontractors to support them, and you would need to ensure that these local subcontractors are appropriate for the task and effectively managed by

the lead service provider. This may drive you to a shortlist of preferred suppliers, in which case it will be necessary to ensure when people select a provider, they select on the right basis of competency, specialisations, languages, prices etc.

Use a Document Management System

A Document Management System will help with version control, effective QA and reviews and promote re-use and consistency. It should be available for everyone involved with the process, whether inside or external to your company.

In the next post we will look at the second step – *Initiate your project*.

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

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