Be4ward® Trusted Experts in Serialisation Labeling and Artwork

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

In the past couple of months we've shared our thoughts and knowledge via a series of blog posts on the subjects of *Optimising Your Packaging Facilities* and the important artwork metric of getting it *Right-First-Time*. You can find these in our Featured Blog Post section below, available for you to read on or off-line.

Serialisation remains a hot topic since EU FMD regulations came into effect almost two months ago. We share with you our recent Be4ward Executive Briefing EU FMD compliance tool developed in response to pressing regulatory deadline with an introduction to our popular compliance tool which has helped many businesses achieve compliance in a quick and cost-effective fashion.

We have also selected some Top News Picks from the industry that we think are worth a read. Click the links to go to the articles, or scroll down to find them below, handy for reading off-line.

We hope you will find this newsletter of interest and as always we welcome your thoughts and comment. If you and your business require advice or assistance in any of these areas, please do not hesitate to get in touch.

Kind regards,
The team at Be4ward

Go to Featured Blog Posts

Go to Executive Briefing

Go to Top News Picks

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Be4ward Company News

Be4ward is proud to have been awarded:
BEST PHARMACEUTICAL LABELLING MANAGEMENT ADVISORY 2018
by GHP in the Pharmaceutical Manufacturing & Packaging Awards

We are delighted to be supporting Making Pharmaceuticals Exhibition and Conference again this year, sharing our expert knowledge via four speaker slots.

Packaging Complexity : How to Cope With Increasing Numbers of Small Volumes
Andrew Love

Serialisation: The Deadline for FMD Was February 2019 – Where Are We Now?
Andy Cummings

Packaging Artwork : How To Improve Your Right-First-Time
Andrew Love

Making Pharmaceutical Packaging That is Easy for Elderly People to Open
Stephen Wilkins

Find us in Room C, on Tuesday 30th April, from 11:30am

Featured Blog Posts
by Andrew Love

Optimising Your Packaging Facilities: Part 2

How does your product packaging design impact the complexity of your packaging facility?
How can you best manage your packaging complexities?
What are the consequences to your company of mismanaged complexity?
These are some of the issues I address in part two of my blog series: *Optimising Your Packaging Facilities.*

>> Read it offline

Read it online

Optimising Your Packaging Facilities: Part 3

How can you drive maximum value out of your product portfolio?
This is the question I address in part three of my blog series: *Optimising Your Packaging Facilities,* via 5 tops tips looking at:

- Understanding the product / therapy strategy and the value of complexity
- Understanding portfolios, volumes and the life-cycles of SKUs
- Processes for portfolio changes
- The benefits of regular portfolio reviews
- Maximising opportunities via shared components and packs

>> Read it offline

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Featured Blog Posts
by Stephen McIndoe

Right-First-Time : Part 2

Are you getting your artwork process right first time?

Why does it matter?
How can you measure it and manage it?
If errors are being made, where are they happening and why?

In the second part of the Right-First-Time blog series I look at the crucial first steps in the artwork process including how to create a strong artwork brief and the importance of stakeholder roles and responsibilities.

>> Read it offline

Read it online

Right-First-Time : Part 3

Are you getting your artwork process right first time?
Why does it matter?
How can you measure it and manage it?
If errors are being made, where are they happening and why?

In part three of the Right-First-Time blog series I examine effective staff training and suitability, cross functional governance groups and some of the key tools available for IT support in the artwork process.

>> Read it offline

Read it online

Executive Briefing

Stephen McIndoe

EU FMD Compliance Tool developed in response to pressing regulatory deadline

As 2018 drew to a close, I looked at the situation for businesses facing the threat of interruption to supply chain come the EU FMD compliance deadline in February this year. Is your business serialisation ready? Do you face an interruption to supply chain due to non-compliance? Read my article below to see how we can help deliver you to compliance in a quick, safe and cost-effective manner.

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.

Industry Regulation

Medium read from Pharmaphorum

The great regulatory catch-up

Medical device manufacturers have a lot to learn from the pharmaceutical sector which, for well over a decade, has been subject to the sorts of rigorous electronic reporting standards soon to be faced by device producers. To ignore the parallels and start from scratch with MDR and other standards now being imposed by international authorities, could double the work companies face. Drawing on pharma's experiences, AMPLEXOR's David Gwyn distils some best practices for medical device companies

Click here to read the article

Brexit

Short read from PharmaTimes

ABPI warns of greater exposure to fake meds under no-deal Brexit

The Association of the British Pharmaceutical Industry (ABPI) has expressed fears that the UK will drop out of the “safest medicines system in the world” in the event of no-deal Brexit.

Click here to read the article

FDA DSCSA

Short read from CNBC

FDA issues warning letter to drug distributor McKesson for allegedly shipping 'illegitimate' opioid products

- The Food and Drug Administration has sent a warning letter to major drug distributor McKesson.
- The FDA accuses McKesson of failing to identify, investigate and stop people from tampering with its opioid shipments.

Click here to read the article

Executive Briefing: read offline

EU FMD COMPLIANCE TOOL DEVELOPED IN RESPONSE TO PRESSING REGULATORY DEADLINE

With the US DQSA compliance deadline now upon us and the EU FMD February 2019 deadline hot on its heels, now is the time for businesses to examine the current landscape of pharmaceutical serialisation, looking at the lessons learned from US businesses and how they can be applied to EU businesses ahead of deadline. It's imperative that any business affected by the EU FMD regulations assesses their current position and their capability of delivering the data requirements in line with the directive. For any business facing potential non-compliance come 9th February 2019, I would like to take this opportunity to introduce a pioneering tool we've developed, which has the capability of delivering your data in the format required, in the event of any inter-system communication issues. This translation tool can assist those businesses who are already on the road to complete serialisation yet have found that, for a number of possible reasons, their planned solutions will not be ready in time. If your business is currently facing a potential interruption to the supply chain as a result of non-compliance, we have a short-term solution to deliver you to compliance in a quick, safe and cost-effective manner.

The problem

As specialist consultants in this field, at Be4ward we've seen a huge rise in the number of clients looking to us for serialisation solutions, more recently due to the failing of their 'plan A', clients who have found that their level 4 solution simply can't support all the communication protocols that their CMOs are able to provide. Their planned serialisation system is not going to be ready by deadline and they're facing either the resource drain of a manual transfer of the data files or a complete failure to deliver the data and the potentially catastrophic repercussions of non-compliance.

There are many possible reasons for these system failures. Miscommunication between immature and evolving systems can leave gaps in the data processing, or the enterprise systems adopted by some businesses may have been created as a 'big picture' solution but failed when faced with the uniqueness of a real business. In some cases, specialist serialisation solution vendors have oversubscribed and found themselves unable to service their fast-expanding client base. Some businesses may have faced a lack of available resource as the demand for troubleshooting solutions has risen to unprecedented levels, leading to a squeeze on the limited resource available in this very niche area. This has come about as a result of the US and EU deadlines hitting within less than 3 months of each other and we're currently seeing this effect at play in the US and increasingly across Europe as the demand for the services of experienced consultants, IT and system providers soars, the limited pool of resource is drained.

What is clear from the situations facing many of these businesses is that a one-size-fits-all approach does not work as a solution to serialisation, the variables are too numerous. The needs and requirements of each individual business must be examined and a bespoke solution applied. This was the case with one such Be4ward client who, after the breakdown of their plan A, could see non-compliance looming. Frustrated that their process was incomplete and finding themselves unable to comply within an ever-decreasing timeframe, they called upon our troubleshooting services as serialisation consultancy specialists. We examined their systems, identified the problem and created a solution.

The solution

In partnership with Jennason, a leading provider of product serialisation solutions, we have created a tailormade, bespoke solution to our client's problem. We've developed a software capable of capturing, gathering and communicating the essential supply chain data required to ensure EU FMD compliance, specific to our client's needs. This translation tool is capable of taking inputs from across the supply chain, reformatting and then delivering the data to any other system. Acting as a short-term, bridging device between miscommunicating systems, this tool takes existing output files from for example a CMO line, translates them as required and delivers the unique identifiers to their required destination system, for example EMVS.

We assessed the suitability of the tool to meet our existing client's needs and devised a quality and validation approach which maximised the leverage of the tool in addressing our client's unique situation.

As a short-term serialisation solution, this tool comes with a host of benefits:

Bespoke: adaptable, custom-made software designed by industry experts to address your specific business needs.

Accessible: simple and easy to install, the software can sit on a standalone laptop to troubleshoot individual areas of the supply chain or be rolled out across a chain-wide system.

Cost effective: a low-cost solution to fixing a high-cost issue.

Rapid: with deadline looming your business can be compliant inside of 8 weeks.

Flexible: an ideal interim solution to ensure short-term compliance whilst the long-term serialisation landscape unfolds.

Universal: the software can be adapted to report data from any stage of the supply chain, in both Europe and US.

Tested: having passed its initial test phase the software is already in use.
Supported: the software comes with a dedicated client-support package from installation to aftercare. We offer a short-term solution, so you become compliant, coupled with long-term support, so you stay compliant.

This tool can be deployed to any business facing an interruption to the supply chain via non-compliance. It serves as a temporary, interim solution to ensure large scale businesses are still able to distribute product globally and for the smaller SMEs the software may prove sufficient to ensure long-term compliance. Contact us now so that we can assess the suitability of this software for addressing your immediate serialisation needs.

Regardless of what stage your business is at in its serialisation journey, should you have any questions about the EU FMD legislation or would simply like to request a copy of any of our serialisation booklets, please don't hesitate to contact me at

Stephen.McIndoe@be4ward.com

Read it online

Featured Blog Posts : read offline

Optimising Your Packaging Facilities - Part 2

In this blog series I'm looking at the, often very necessary, issues of product packaging complexity and how these can be addressed via appropriate product portfolio, optimising the packaging facility design and examining key attributes of product packaging. In part one I looked at portfolio complexity and the impact of portfolio on packaging operations. In this my latest post, I address optimisation of the packaging facility, the impact of packaging design and the consequences of mismanaged complexity.

Optimising the Packaging Facility

Often the first issue within the packaging facility can be the packaging equipment itself. Old, unreliable equipment that is slow to change over might just need to be upgraded.

However, it may not be the whole line that is the issue. Packing lines consist of numerous components, each doing part of the packaging process. The overall reliability and speed of the line is a function of the reliability and speed of each component. Replacing one part may beneficially impact the overall line performance.

It is also worth considering the line specification versus the product requirements to be packed. We often see complex, high speed, automated and highly integrated packaging machinery being used for low volume short run packaging batches and can also see manual lines being used to pack larger volume SKUs. A more flexible line may be more appropriate.

Facility layout can also impact productivity. Many packaging facilities evolve over time. How is the flow of materials in your facility? Is there unnecessary handling or waiting? Where are there bottlenecks? Where are you wasting time and effort?

Finally, consider the effectiveness of business processes supporting packaging operations. Are processes optimised and efficient? Moreover, are the collective cross-functional processes tuned to work in unison or do dependencies between processes promote delays wasting time and effort?

Is the product packaging designed to meet the meet the needs of the optimised product portfolio and packaging facility?

There are many competing requirements to be considered when designing the product packaging. It must be easy to use, meet regulatory requirements, protect the product and be robust for shipping operations. It also must play its part in ensuring the most appropriate packaging solutions can be used.

Packaging techniques such as late stage customisation and postponement may have specific requirements for structural and artwork design, and these might require different solutions to those typically applied. Packaging engineers and artwork designers need to consider the overall packaging supply system when developing their designs to ensure they are fit for different solutions that may be applicable for different volume profiles.

There are consequences to a company when complexity is not managed appropriately

Packaging complexity creates some consequences for companies and their customers, including:

1) **Compliance issues:** Correct products and components must be supplied to the correct markets with the latest approved product information. With ever-increasing

portfolio complexity, exercising appropriate jurisdiction control over what is supplied and to where, gets more difficult. Many companies have tried to overcome this complexity by supplying smaller markets with standard ‘general export’ type packs, only to find unexpected and uncontrolled local repacking. This practice obviously presents an unacceptable compliance risk if not managed effectively.

2) **Lost commercial opportunities and product unavailability:** Sometimes the financial trade-off between suppling a unique pack variant to a market versus the cost of supply doesn’t merit selling that product in that location. That may be considered a victory in minimising complexity, but it is a lost commercial opportunity leaving patients in that market unable to benefit from that product being made available to them. It is therefore a hollow victory that could be avoided if the company had more cost-effective capabilities to supply such variants.

3) **Packaging inefficiencies:** Small volumes mean small pack runs and lots of changeovers. We have seen examples where the packaging line spends more time being changed over than packing product. Complexity can also create needs for specific additional tooling, equipment and hand finishing.

4) **Support function inefficiencies:** There is a whole ‘hidden factory’ in the support functions supporting the product and component range e.g. additional regulatory staff maintaining licenses and product information or more purchasing activity. This is often invisible and not considered in the cost of supply.

5) **Obsolescence:** There are two relevant types of obsolescence; packaging components and finished product. Economic order quantities result in purchased volumes of packaging components that have a disproportionate amount of forward cover, causing high amounts of write-off when components change. Similarly, high inventories of low volume finished pack stock, caused by minimum packaging order quantities, risks either product write-off or repacking due to shelf life expiry.

In my next post in this series, we will look at some of my top tips for ensuring your product portfolio is appropriate for your packaging facility.

Should you have any questions about this or any of my other blogs, if you would like to discuss the packaging complexities 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

Read it online

Optimising Your Packaging Facilities - Part 3

In this blog series I'm looking at the, often very necessary, issues of product packaging complexity and how these can be addressed via appropriate product portfolio, optimising the packaging facility design and examining key attributes of product packaging. In part two, I looked at optimisation of the packaging facility, the impact of packaging design and the consequences of mismanaged complexity. Here in part three, I will be offering some top tips on what to consider to drive maximum value out of your packaging portfolio:

Tip 1: Understand the product/therapy strategy and value of complexity

Is the commercialisation strategy for the product and therapy and the subsequent value of complexity understood?

Different products will have different requirements for the complexity of the packaging componentry and SKU portfolio. This can be driven from many factors, including but not limited to:

• Therapeutic, titration and dosing requirements
• Unmet medical needs
• Legislative requirements of the countries into which the product will be marketed
• Competitor activity and the competitive environment
• Commercialisation strategies for the product
• Market positioning and product cost profile
• Product life-cycle, line extension and patent expiry strategies
• Combination products, starter packs, special usage requirements and other opportunities to drive adherence and assist patients and healthcare providers
• Product protection, temperature and security requirements
• Local dispensing requirements

Prior to undertaking any complexity optimisation activities, it is important to understand and document these requirements to:

a) Ensure they are clearly defined and met
b) Ensure they are maintained as needed

c) Ensure appropriate control can be provided to prevent further non-essential requirements emerging

Tip 2: Understand the portfolio, volumes and life-cycle of SKUs

Is the portfolio, volumes and life-cycles of your SKUs understood?

The next step in a complexity reduction activity is a detailed understanding of the target SKU portfolio. The scope of this may be certain brands, geographic areas, supply chains or perhaps your entire company portfolio. For the chosen portfolio, you will need to understand:

- The description of each SKU – product, dose form, strength, volume.
- Where are they supplied from? Which market(s) are they supplied to? Which distribution lanes are used?
- What is the subsequent component range?
- What are the SKU volumes?
- What is the financial contribution of each SKU?

In addition, it is important to understand where each SKU is on its product life-cycle; are volumes increasing or decreasing? Typically, products go through a standard life-cycle: launch, growth, maturity, and tail off. The value of portfolio complexity often varies through this life-cycle. Therefore, it is important to understand where a product is on its life-cycle as products where the volumes are likely to increase need to be considered differently from tail products where the volumes are declining.

Tip 3: Have clear approval and control processes for portfolio changes

Do you have clear approval and control procedures for adding and removing SKUs from your portfolio?

Firstly, do you have the appropriate cross-functional governance to ensure that all relevant impacted parties are engaged in the decision making and represented appropriately at a senior level? Failure to have a balanced governance will likely result in sub-optimal decisions and low levels of buy-in. Secondly, do you have a clear set of principles endorsed by the senior governance team to manage the portfolio? These define the ‘rules of the game’ and set the criteria that decisions should be made against. Thirdly, do you have rules and processes in place for adding or deleting SKUs and components? These processes need to ensure that the decision-making hierarchy aligns with the complexity of change occurring. Processes should also include routine reviews of the portfolio (see Tip 4). Finally, do your processes ensure that the costs for change are considered in decision making and preferably charged to the groups in the

organisation driving those changes? For example, charging the cost of artwork change to the originator.

Tip 4: Prune the portfolio regularly

Is there a regular process to review the portfolio and prune unnecessary or non-performing SKUs?

The performance of the portfolio is dynamic, changing due to many environmental and life-cycle factors. Therefore, a review process should ideally be performed on a routine and repeating basis to maximise the effectiveness of the portfolio. The review should be designed to categorise the portfolio. One way we would suggest is these three groupings:

Capitalise: the best performing SKUs, those contributing most of the revenue, where sales efforts should be focused to maximise return.
Control: SKUs that should be maintained in the portfolio, either because volumes are growing, but not yet providing revenue to get to the next category; volumes are in decline, but not yet critical; or they provide portfolio support to other Capitalise SKUs. These SKUs should be monitored to ensure on-going viability.
Challenge: SKUs with low volumes and/or low revenue. These SKUs should be subject to challenge to remain on the portfolio, either being discontinued, substituted or shared with other markets.

Two things to consider carefully:
• When substituting SKUs, ensure the financial benefit exceeds any potential lost sales.
• Small incremental reductions in the portfolio can have little effect on complexity at supplying sites. Savings are often only generated when lines or facilities are rationalised or eliminated.

Tip 5: Share components or packs

Are you maximising the opportunities to share components or finished packs?

Shared components and packs can provide a great opportunity to increase component and pack volumes. However, to make this happen it is necessary to identify markets and products that can successfully share components or packs. There are a number of criteria that you should consider when looking to group markets for sharing. These include geography, languages, regulatory rules, regulatory approval timelines and sale price. Choosing markets to share products needs to be considered carefully as it requires close collaboration between those markets when changes are being implemented. Therefore, it is better to have consistent groupings of markets rather than

vary the sharing groups by different product. Standard market groupings also simplify the ‘where used’ assessment during the change impact assessment. A significant challenge with shared packs comes when there are different approval timelines or locally driven changes. This can result in more than one version of the shared pack being required; effectively driving you back to market specific packs.

In my next post in this series, we will look at some of my top tips for optimising the packaging facility design to deliver optimal service levels at minimum cost.

Should you have any questions about this or any of my other blogs, if you would like to discuss the packaging complexities 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

Read it online

Right-First-Time: Part 2

I always consider that ‘Right-First-Time’ is the fundamental metric for an artwork service. This is a simple pass or fail metric – did the artwork pass through the process once or was any change required? This is difficult to achieve on a consistent basis and requires focus and persistence. This is the subject I am going to explore further in this series of Right-First-Time blogs, along with 10 essential tips to help you get it Right-First-Time.

Right-first-time tip 3: Make sure all the information is correct before starting, using an artwork brief
People mistakenly think starting early will make it faster

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

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

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

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

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

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

- The standard cover page with all the relevant information on the change and the data required
- A standard implementation workflow with the people who will be involved in the change and their agreed dates
- A draft bill of materials with the component numbers required, both new and existing
- The electronically marked up artwork amended and presented with suitable software
- The source documents selected from a recognised repository.

All this information is collated and presented as one brief.

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

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

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

Right-first-time tip 4: Ensuring you have an effective end-to-end process
Map the end-to-end process

When you start to measure the right-first-time figures, your approach to improve it may be to root cause each incident as it arises. This is a good idea. However, there is a risk, even when you have thoroughly investigated incidents, that you only fix parts of the problem. Issues continue to arise because fundamentally the current process is not ideal.

To really improve your right-first-time metric it is best to review the process as a whole and where possible get external independent expertise. This will enable you to design a process which uses best in class principles and is more likely to include elements which 'future proof' the process.

Map the end-to-end process considering the various different scenarios that arise in your company. The steps for external artwork approval in the EU will differ to that of the US.

Mapping the 'as-is' process and redesigning it will require a number of workshops and support from the senior management team. However the effort will be worth it as you will end up with a process that works, is understood by all and has received full team commitment.

Define the outcome for each step

When mapping each step be clear what should be done, by whom and ensure the performance expectations for each step are defined and agreed. Look at it with fresh eyes where possible. Take the opportunity to achieve your ideal process.

Map the roles and responsibilities for each step

It is useful when mapping the process not to be too bound by the current staffing structures as this can constrain the thinking and prevent a more streamlined process from emerging. This process will almost certainly result in changes in certain roles and you can expect some friction but if this mapping process is done as a group and agreed

with the senior team, then it is more likely people will be engaged and go along with the changes.

Make sure there is a clear information flow

Once you have designed the new process, you should ‘trial’ it prior to implementation or configuring any software. Choose a number of scenarios and trial it with the people from each department involved on a day-to-day basis. Then walk through each scenario testing each step and checking they work as expected. Doing this properly will ensure that all the steps are there and in every case, someone is accountable. Only then should you have the confidence to update procedures and configure any systems.

Right-first-time tip 5: make sure the right quality checks are in place
The importance of the review and approval steps in the process

There is typically a four-step process to assure the quality of the master artwork file.
– The initial check carried out by the artwork operator who has created the file, following the brief.
– The second check is a full and independent proof read, carried out by the proof reader, reviewing all text and graphics against the brief and including a detailed technical check.
– The third check is done by the regulatory group reviewing the text and content, ensuring any local requirements are met.
– The final check is done by QA or their representative, checking only that the correct process has been followed and documented.
All these people in the chain must be aware of the responsibilities they are undertaking when reviewing and approving at each stage.

The danger of being vague

There is a danger that we are not prescriptive enough when saying what needs to happen when performing a check. If procedures are too vague there is the potential for elements of the artwork to not be correctly reviewed. In particular we often see ‘thick’ SOPs in the central artwork team versus very ‘thin’ SOPs for the regulatory checks done by the affiliates.

Be clear who checks which elements

So it’s important to spell out in SOPs the responsibilities for each stage and back this up with detailed checklists showing which elements must be checked and by whom. Don’t fall into the trap that everyone checks every element, because actually not everyone is

qualified to perform some checks. Only the local language expert can check the context of the language on a leaflet, for example, to confirm how the text will be understood by the local patient or medical professional.

Define the 'what' and the 'how'

It is important to define not only what needs to be checked but how it will be done and with what equipment, if required. State exactly what is involved in each check and what to check against. Regulatory checks will need to be referenced to listed key documents, for example, as well as the brief. Proof readers will need to be clear what equipment they need, for example, to check bar codes and braille.

In the next article, I will explore the topic of right-first-time further and present tips six, seven and eight, which look at the importance of effective staff training and suitability, cross functional governance groups and some of the key tools available for IT support in the artwork process.

To help you in your Artwork Improvement Programme, you can also find useful information in my 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 my booklets, please don't hesitate to contact me directly on my email: stephen.mcindoe@be4ward.com

For more information on artwork, go to our free download section.

Read it online

Right-First-Time: Part 3

I always consider that 'Right-First-Time' is the fundamental metric for an artwork service. This is a simple pass or fail metric – did the artwork pass through the process once or was any change required? This is difficult to achieve on a consistent basis and requires focus and persistence. This is the subject I am exploring further in this series of Right-First-Time blog posts, along with 10 essential tips to help you get it Right-First-Time.

In parts one and two of this blog series, we've looked at why right-first-time matters, how to measure it and manage it and the importance of a strong artwork brief and clear

process mapping. Here in part three we examine effective staff training and suitability, cross functional governance groups and some of the key tools available for IT support in the artwork process.

Right-first-time tip 6: Ensuring effective training
Each role has a different set of requirements, you need the right 'fit' for each role

You need a range of skills throughout the end-to-end process. Each step requires a different set of abilities, from creation of the artwork through to the several review and approval stages. People need to show they have the right skills to perform the role but also demonstrate they can use their skills to perform the job successfully. Having the right mind set gives the complete capability for the role.

The artwork coordinator who orchestrates the whole process will require a different skill set to the proof-reader who does the most detailed check of the artwork. The proof-reader needs to be highly detail conscious and be comfortable working alone for most of their working day. The coordinator must be much more people-oriented to ensure the artwork is progressed through the business. So, it's important to define what you are looking for in each role, value the differences and select people accordingly.

Recognise some staff are performing tasks daily, some more infrequently

It's important to recognise that, although there are many people involved in this process, many do it only as a small part of their role. In addition, regulatory people in the affiliates who perform the local language review and approval checks, will be doing these tasks quite infrequently. Also, these people tend to change more frequently than those in the central artwork and regulatory teams.

This situation means it is likely there are less experienced people performing tasks in some roles, so it is important to plug this gap with good standard operating procedures (SOPs) and training. Procedures in these areas must give the correct level of detail to enable people to do the job effectively and controls need to be in place so access to systems only happens when the staff have completed the required training modules. Unfortunately, often when we review the SOPs, held centrally and at the affiliates, we discover that the comprehensive SOPs cover the tasks done centrally but SOPs for work done in the affiliates are very high level, lacking essential detail. It should be almost the other way around.

Education and training are key – monitor the effectiveness of the different approaches

SOPs are important but to ensure people have the correct skills and are competent to do the role means effective education and training needs to be provided. Initial training when a process is revised, new starter training, specialist training for certain roles like proof-reading and special focus for those involved in the review and approval steps needs to be considered.

The range of people to reach means a variety of approaches need to be taken. Staff in more remote areas may have web-based training, on and offline training and even recorded videos. There should be a requirement to pass an assessment, following the SOP training.

The effectiveness of the different approaches needs to be monitored, so when issues arise it is useful to identify if inadequate training has been the root cause.

Right-first-time tip 7: Ensuring effective training and cross-functional governance
Governance group – required as the process works across many departments

When you 'walk' the complete artwork process from end-to-end you realise it touches many departments and external groups. If the ambition is to achieve an excellent artwork service, then each part has a contribution to make in achieving right-first-time.

I always recommend putting in place a governance group with representatives of the key functions. 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. If a steering committee was in place for a process redesign the governance group may grow out of this but potentially with more senior members. The members need to be selected with enough authority to carry out their responsibilities and represent their functions/geography effectively.

Leadership needs to take accountability for the performance of their function

Reviewing the right-first-time figures at the governance meeting, with sufficient root-causing activity, should highlight areas where the process just seems to 'get stuck'. Each representative then needs to work to resolve issues that have arisen in their areas of responsibility, in the interests of the whole artwork supply chain.

The leadership team needs to agree to a common vision and sponsor improvements

Good sponsorship means ensuring they agree to a common vision and 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, of which right-first-time will be one of the main measures. The group will also agree priorities for improvement projects identified.

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

Right-first-time tip 8: Ensuring appropriate IT support, quality time
There are a range of tools available to support artwork operations

I am not going to go through every tool in this blog but instead highlight some of the key types.

Document management and workflow tools allow you to manage your documents in a controlled electronic environment and route them to key users to perform the process tasks necessary. These tools sometimes also permit planning of artwork projects. Document review and approval tools allow users to view, comment and approve documents electronically (usually with an electronic signature). These above tools are the typical functionality of Artwork Management Systems.

Electronic proof reading tools allow you to electronically check text, graphics, barcodes, Braille and, depending on the package, other artwork elements. Artwork and drawing tools are typically used by artwork operators to generate artwork and engineers to create the profiles and templates for components.

Technology helps right-first-time

Two of the ways technology can assist with right-first-time is to automate activities and reduce opportunity for human error. A frequent source of error in a manual process is mistakes with document versions. An electronic document management system can avoid this as they typically provide closed loop version management, automatically version-numbering iterations of a document and ensuring it is obvious which is the most recent version.

Human error is always a challenge when proof reading large documents which require long periods of focused attention. Electronic proof-reading tools can assist here by providing an electronic means of proofing that is consistent and accurate.

Technology presents some downsides that need to be considered

We often hear the same thing when we engage with a client that has undertaken a major technology project – ‘We have implemented a new system but our right-first-time

performance has not improved – why?'. The answer to this is pretty simple – application of technology is part of the solution, not the whole solution. If you look back through this set of blogs, there are many things that need to be done to raise performance beyond technology: addressing process, people and organisational issues. Missing these means that you are unlikely to achieve an holistic outcome.

Another downside is that technology costs money, both in the initial cost of the tool and in implementation, maintenance and support requirements. We often find that people trying to implement systems look only at the initial license costs, which once you have considered project resource and validation costs and ongoing running costs, are a small part of the total lifecycle cost of a system. This total cost is often a surprise.

Finally, technology is used by people, and in the case of artwork systems, many of those people may use the system only occasionally (think of the regulatory staff in your different countries). So even a technology project is really about people, as you have to give them the motivation and capability to change and the education and training to be able to use the tools correctly.

Choose a strategy that fits with your needs

Therefore, in defining how to move forward with technology you need to consider the needs of your individual company. As a broad generalisation, the technology needs become greater the larger the size of your company. We typically measure this in the number of artworks required. If you have 360,000 artworks to manage you need some sophisticated capabilities. If you only have three, your approach can be much simpler. But remember that technology takes time to implement, so if you are growing fast you need to be thinking ahead.

In the fourth and final part of this right-first-time blog series we examine the benefits of quality time and quality facilities and how to create a winning culture in the workplace.

To help you in your Artwork Improvement Programme, you can also find useful information in my 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 my booklets, please don't hesitate to contact me directly on my email: stephen.mcindoe@be4ward.com

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