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

In this edition,

- In the **Spotlight on Be4ward,** we will answer the question, Who is Clive Mallard, a valued member of our Team?
- Our consultants' thoughts and knowledge (via our monthly blogs) in the **Featured Blog Post** section
- We're pleased to share with you our **Executive Briefing**
- In the **Top News Picks** we share a few articles from the industry that we believe are worth a read.

We appreciate you taking the time to enjoy our news and updates. As always, we welcome your thoughts and comments. If you and your business require advice or assistance, please do not hesitate to get in touch.

Kind regards,

The Be4ward Team

Be4ward

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Spotlight on

_____Be4ward

A highly skilled and experienced program/project manager and coach, combining a broad range of firsthand Pharma/Biotech business knowledge with excellent consulting skills. Helping clients design and successfully deliver change programs/projects of all sizes and complexities

As a member of the Be4ward team for many years, coupled with his work as a business coach, Clive engages with project team members from all levels/functions, selecting tools and techniques which maximise the engagement and contribution of each team member

Clive honed his consulting skills over 8 years as an Executive Consultant at Cap Gemini in their Life Sciences and Sales & Marketing businesses

Beginning his career as a fast-track management trainee, he took on a range of general management, sales and marketing roles during his 13 years with Unilever PLC, including 3 years running the marketing function for one of their Canadian operating companies

Clive continues the part time coaching work he has done for many years as Director of Coaching for a company focusing on SME business growth.

Company Brochure

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Company Blogs

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Excellent Packaging Artwork Capabilities Part 1 - Why artwork matters and what happens when you get it wrong?

In the opening part to my new blog series examining how to create and apply excellent artwork capabilities, I look at why packaging artwork matters so much and what happens when you get it wrong. What are the far-reaching impacts of artwork error on the various stakeholders involved?

Read it online

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

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.

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

Read it online

Executive Briefing

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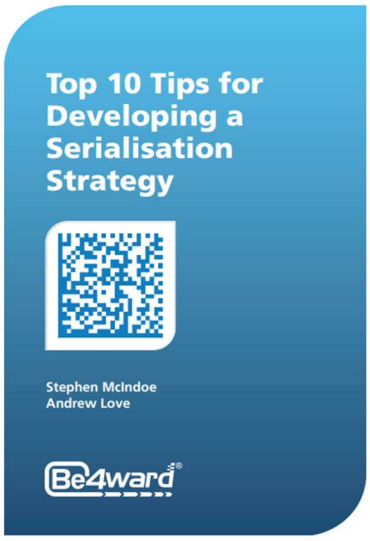

Top 10 Tips for Developing a Serialisation Strategy

Download a copy on www.be4ward.com or an offline version is available at the bottom of the email

Top News Picks

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DSCSA deadline has been pushed back a year

By Phil Taylor for **Securing Industry**

The final implementation date for the Drug Supply Chain Security Act (DSCSA) has been set back a year after the FDA responded to pleas for more time, with the new deadline set for November 27, 2024.

Dubbed a "stabilisation period" rather than the usual "enforcement discretion" holidays that have affected earlier DSCSA implementation deadlines, the delay is intended not to allow trading partners to relax – rather, it is an opportunity to "implement, troubleshoot and mature" the systems that will need to be in place next year.

Click here to read the article

Trial starts in Uzbekistan over child cough syrup deaths

By Phil Taylor for **Securing Industry**

A trial has started in Uzbekistan in connection with the deaths last year of children linked to contaminated cough syrup products.

The complaint cites 65 cases thought to have been caused by substandard cough syrup products containing diethylene glycol and/or ethylene glycol, much higher than the 18 cases cited in a World Health Organisation (WHO) alert on the incident published at the start of this year.

Click here to read the article

FDA warns distributor over ‘suspect’ HIV medicines

By Phil Taylor for **Securing Industry**

The FDA has issued a rebuke to wholesale distributor Safe Chain Solutions, which has been named in a lawsuit filed by Gilead Sciences and Johnson & Johnson accusing it of allowing falsified HIV drugs to enter the supply chain.

The June 8 letter – which was published on the FDA’s website yesterday – says that Safe Chain Solutions did not have systems in place that would allow it to comply with the verification requirements of the Drug Supply Chain Security Act (DSCSA), including the identification of ‘suspect product’.

Click here to read the article

Executive Briefing:

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Top 10 Tips for Developing a Serialisation Strategy

Stephen McIndoe
Andrew Love

Introduction

Serialisation legislation will require new capabilities to be implemented across many different functions of a typical company.

The most obvious include:

- Regulatory and legislative management and government affairs who will have to understand new emerging requirements and represent the company in external influencing and governance bodies.
- Packaging operations, where serialisation will have to be applied to the product packaging at one or more lines.

- Distribution operations, where the more complex serialisation models, this operational impact will extend into these operations in central and/or local markets, where information on individual sale and shipment transactions needs to be gathered and added to the serialisation information.
- IT, particularly for the more complex track and trace models, where significant IT capabilities will be required to manage serial numbers and tracking information related to the product and its movement.

The serialisation strategy of a company and the resultant serialisation service that delivers and maintains the capabilities required, needs to ensure that the requirements of legislation are thoroughly understood and that appropriate capabilities are defined to meet those needs. These capabilities must then be implemented effectively in a timely manner to ensure product supply is maintained. Once serialisation capabilities become available, companies can then look to leverage them for product security and other benefits that are not directly driven by legislation. The following is a series of tips for developing and implementing your serialisation strategy.

Tip 1
Identify and interpret the emerging and evolving legislation.
Serialisation legislation, particularly in its early iterations, tends to be somewhat vague, incomplete and sometimes contradictory. Interpreting the legislation and predicting its impacts can present significant challenges, requiring specific serialisation knowledge as well as new legislative relationships with local legislators.

This is further compounded when considering the timelines allowed in the legislation. History has shown that timelines are often vague and subject to change. However, when implementation dates are finally set, they often do not allow enough time for robust implementation.

Given the uncertainties in requirements and timing, organisations need to ensure there is a clear way of communicating their considered view of the legislative requirements at any particular moment. Failing to do this will

potentially result in individual functions or groups
creating their own interpretations, which at minimum is wasteful of resources, but at worst results in capabilities being implemented which do not meet the eventual requirements of the legislation.

Tip 2
Understand the full impact of these multiple pieces of legislation on the company and product supply chain

Serialisation presents a potentially broad impact on a typical organisation. It is important to engage all of the potentially impacted parties early in the impact assessment phase to ensure that comprehensive solutions can be defined.

A further challenge is that multiple pieces of evolving legislation will often impact many of the same capabilities. Understanding these potential impacts and their likely evolution over time is key to ensuring effective solutions are defined and implemented in a timely manner.

Tip 3
Define solutions and implementation plans which strike the optimal balance between ensuring product supply and the caution that is prudent with evolving legislation

There are often a number of supply chain configurations and technical options that can be brought to bear with particular serialisation legislative requirements. Short term tactical options have to be weighed against longer term strategic solutions. Some of the challenges that need to be addressed when defining optimal solutions include:

- Differing serialisation models being called for in differing pieces of legislation
- Uncertainty in the detailed technical requirements as legislation evolves.
- Evolving and competing serialisation standards being developed by standards bodies and industry groups.

- The requirement for many supply chain nodes and assets to be able to handle multiple legislative requirements simultaneously.
- Deciding on the optimal degree of integration of serialisation capabilities with existing capabilities e.g. production control systems and ERP systems.
- Uncertainty in the timing of legislation.
- Striking the optimal balance between providing new equipment versus retrofitting existing equipment.
- Agreeing interfaces and implementation timelines with third parties.

Defining the timing of implementation plans, to a large extent, needs to be considered hand-in-hand with the solutions themselves. One risk that also needs to be considered is that of the 'last minute rush', or 'Y2K effect'. By this we mean the risk that, as is so often the case with this type of legislation, everyone waits until the last minute to implement solutions, only to find that the supply base cannot cope with the peak in demand, driving up cost and forcing companies into non-compliance. This was a particular concern in 2017 when the USA, Europe and others all had legislation which became effective around that time.

Tip 4
Understand the immature and evolving solution supply base and select appropriate implementation partners

Serialisation legislation is relatively new to the pharmaceutical industry and therefore the solutions available from the supply base are correspondingly immature and in many cases evolving. Supplier selection will often be the start of a very long relationship, as solutions that are initially implemented will need to be supported and adapted to new requirements over time. There have already been several examples of suppliers that have come and gone as legislation has evolved or been delayed. Understanding the supply base and choosing the most appropriate suppliers will be critical to long term success.

Defining complete requirements covering all aspects of the solution's lifecycle and then realistically judging the supplier's ability to meet these requirements

also presents challenges.

Tip 5
Resource implementation projects with sufficient serialisation specific knowledge to minimise the risk of wasted resources, delays and implementation failure

The specific challenge during the design, build, test and implementation phases of solution projects is to resource them with sufficient serialisation subject matter skills and knowledge to avoid common pitfalls, reduce wasted effort and the risks of delay and solution failure.

Organisations need to plan for these resource requirements, build sufficient capabilities internally and secure access to sufficient external resources where appropriate.

Tip 6
Understand global versus local

The question of global versus local needs to be considered on several different dimensions.

Firstly, there is a need to consider what is being standardised. There are some elements of the strategy and resultant solutions that need to defined, built and operated at a global level so that all supply chain nodes can be supported. Other capabilities may need to have globally defined standards, but the build and implementation can be addressed locally. In other cases, it may be appropriate to direct all of the activity to local teams if there is no network-wide impact from locally generated solutions. Typical topics where the degree of standardisation needs to be considered include:

- Policy
- Requirements
- Solution Selection
- Design

- Build
- Test/Validate
- Implement
- Operate
- Support

The second consideration is where serialisation activities are to be undertaken. Again, there will be a mix of global, regional or functional or local answers to where you are doing things. For example, it may not be appropriate for all supply chain nodes to be individually tracking emerging legislation, but also packing operations are likely to stay at local supply chain nodes.

The final consideration is to what degree is the resultant capability global or local. Maintaining the number management systems is likely a global capability whereas maintaining the on-line printing and verification systems is more likely to be local.

In order to ensure that the capabilities required are appropriately specified and managed through their lifecycle, understanding and agreeing what is done globally, regionally or functionally and locally are key success factors in a serialisation strategy.

Tip 7
The need for flexibility

Serialisation legislation and responses are emerging across the globe from multiple different parties. Whilst often based of standard building blocks, the detail of the requirements shows significant variation. Whilst this is frustrating and a global set of common standards and solutions may be more cost effective, it is the reality of the situation and companies need to develop solutions to cope with it. This is why many companies have held back from progressing their serialisation projects for fear of developing the wrong solutions or backing the wrong technologies.

Furthermore, capabilities required to deliver additional benefits from

serialisation capabilities installed initially to meet legislative requirements also need to be considered.

Therefore, when developing your sterilisation strategy, you need to be thinking of not just known, but also emerging and likely requirements. Solutions designed need to have a sufficient degree of flexibility to be able to cope with these requirements. This is not easy, but is a key challenge that must be made aware to solution design teams.

Tip 8
Define and agree some governing principles

The next tip addresses developing and agreeing the key principles required to govern the lifecycle of the serialisation capability. These principles should provide guidance for teams on what is permissible or not and would be approved and managed via the governance team.

Examples of principles could include:

- A single serialisation enterprise management system will be implemented and used by all supply chain nodes for transmission and receipt of serialisation numbers.
- A single serialisation issue investigation capability will be established with a physical presence in each geographic region.
- Supply nodes must ensure they have competent local capability to support installed on-line printing and verification equipment.

The benefit of such principles is that they clearly define the ‘rules of the game’ to all parties, thus providing a boundary and a decision making framework for the development of solutions. If anyone would wish to go outside of or change a principle, they would have to gain permission from the governance team.

Tip 9
Implement effective cross-functional governance

Given the cross-functional and cross-organisational nature of the serialisation capabilities, establishing the right inclusive leadership and governance is key to the long-term success of the activity. All stakeholder groups involved in the delivery of the serialisation capability need to contribute effectively or the whole process is at risk of failure. Therefore, all parties must buy into their roles in the processes and actively contribute to them. This will rarely happen if they are simply passive bystanders in the design of the capabilities or the delivery of the resulting activities.

A cross-function governance team should therefore be established to steer the definition, establishment, ongoing delivery and development of the overall serialisation service across the multiple stakeholder groups involved. This governance body should include membership from all of these stakeholder groups involved in the processes, including, where appropriate, external service providers. Typical activities that would be included in the role of such a Serialisation Governance Team include ensuring:

A clear vision and strategy is defined and communicated.

- Decision making is taken with all impacted parties, at the right levels in each of the organisations involved.
- A ‘Target Response’ is defined that specifies what the organisation must achieve and by when, given the current state of legislation and the organisation’s considered view of how and when capabilities are required.
- Changes to the target response are carefully managed and cascaded to all impacted groups.
- Appropriate approval serialisation capability designs.
- The performance of the serialisation service is meeting business needs.
- The programme of legislative responses and improvement activities are prioritised and approved.
- Resources are in place for the serialisation service and improvement activity.
- Stakeholder group conflicts are effectively resolved.

Tip 10
Understand where to start

As a place to start, we would recommend a small focused piece of work which has the
following objectives:

- Understand the issue as it relates to your business.
- Understand the likely impact across your organisation.
- Identify, educate and mobilise an effective cross-functional governance team.
- Establish an effective legislative monitoring capability.
- Define an initial ‘Target Response’.
- Define a plan of action.
- Identify any initiatives that are currently underway and define how they should proceed.
- Understand the high level budgetary implications.

From here, a programme of activity can be implemented to effectively manage the legislative risk and oversee subsequent capability deployment.

Summary
From all of the above, there are some key learnings that should be borne in mind when defining your serialisation strategy:

- Recognise the significant supply risk and manage it accordingly, establishing senior cross functional governance early.
- Mobilise your regulatory, legal and technical teams to establish effective access to, and interpretation of, the emerging legislative and technical standards.
- Actively interpret the evolving requirements and standards for the organisation using tools such as the "Target Response".

- Establish a programme of activity to build organisational and extended supply chain capability.
- Be realistic about the emerging nature of these capabilities and build in adequate time and resource to effectively test and iterate solutions.
- Design serialisation activities to closely couple related actions to minimise the possibility for errors due to abnormal events.
- Design both the normal processes and the regularly occurring non-standard events to avoid product supply quickly grinding to a halt.
- Ensure cross-functional teams are established to carefully design the interfaces between departmental and organisational boundaries.
- Ensure adequate time is allowed for packaging design changes to be made to accommodate serialisation features required.
- Be cautious about suppliers who have little practical experience in this area.

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Excellent Packaging Artwork Capabilities Part 1 - Why Artwork Matters And What Happens When You Get It Wrong?

In the opening part to my new blog series examining how to create and apply excellent artwork capabilities, I look at why packaging artwork matters so much and what happens when you get it wrong. What are the far-reaching impacts of artwork error on the various stakeholders involved?

Packaging artwork is an often-forgotten back room process in most pharmaceutical companies, but the changing business environment has brought issues from this capability to the fore. Pharmaceutical and other healthcare companies are facing one of the most difficult periods in their history. Current products are rapidly going off patent leaving significant revenue challenges. At the same time, weak product pipelines are failing to fill the gap. Furthermore, global markets are changing rapidly. Traditional markets are stagnating and new markets are evolving at a rapid pace. Everywhere, key healthcare purchasers are putting increasing pressure on drug prices. In response to these significant challenges, pharmaceutical companies are looking to make the most out of their current assets. This often manifests itself in a drive to launch as many product variants in as many markets as possible. For the traditional molecule-based global pharmaceutical companies, this represents a significant change in strategy.

The rapid growth in the number of drugs coming off patent, together with the increasing pressure on price from the major purchasers, has led to a huge opportunity and growth for generic pharmaceutical companies. For them the challenges are very similar to the pharmaceutical companies, namely to market as many product variants in as many markets, as quickly as possible.

In today's world, all drug companies have an increasing need to develop and maintain an excellent reputation with a diverse group of stakeholders. Pharmaceutical companies are looking to develop and maintain trust with governments and purchasing groups in order to help maintain the product prices necessary to support their significant drug development spending. The increasing competition amongst generic companies means that they each need to develop and sustain their reputation in order to win business and maintain their production licences.

Maintaining this reputation whilst rapidly growing the number of products is particularly challenging when one considers that one of the largest single causes of product recall is packaging errors. In recognition of this, regulators around the world are focusing on driving improvement in all business capabilities associated with the management of packaging design and manufacture.

When launching product variants in new markets much, if not all, of the physical packaging design is already established. The text and graphics, or ‘artwork’ as it is known, that is placed on these physical components is what changes every time. It is this artwork design and maintenance capability that becomes critical to achieving and maintaining the objectives of both pharmaceutical and generic drug companies.

For a large global pharmaceutical company, developing artwork for tens of thousands of products is typically a process involving thousands of people, in over a hundred countries, from tens of different organisations. To orchestrate all this activity, the right combination of business processes, organisation design, information technology, facilities and suppliers must be managed. For smaller organisations, whilst the scale of the problem may be reduced, all of the same challenges have to be met.

So, what are the types of packaging labelling and artwork errors (which we refer to as “artwork errors”) that often occur and what are their significant and far reaching impacts? This will provide some context for later posts discussing the capabilities that need to be put in place to prevent them.

Whilst written from the perspective of a typical pharmaceutical company, we believe the points made apply equally well to other supply chain partners and other regulated industries.

What is an artwork error?

We categorise artwork errors into four groups for the purposes of discussion:

Gross errors - Where significant information is omitted from an artwork. An example would be completely missing the need to change a piece of artwork in response to a new regulatory requirement.

Context and meaning errors - Where information is presented in an ambiguous or incorrect way on the artwork. An example of this might be the inappropriate use of hyphenation causing ambiguous or incorrect meaning.

Content errors - Where there are errors and omissions in the detailed content of the artwork. An example of this would be incorrect symbols being used in the artwork.

Technical errors - Where there are errors or omissions in the technical aspects of the artwork. An example of this would be the wrong specification of barcode being used in an artwork.

The implications of an artwork error

The implications of an artwork error can be as far-reaching and serious as any other error with the supplied product. Artwork text and graphics describe the product and provide information and instruction for its safe and effective use.

Impact on patients - The bond between the patient and their medicine is deep-rooted. Patients trust that the product will make them better and expect that it has been developed, manufactured and supplied to the highest quality and ethical standards. Errors in the information provided with the product are significant and can be life-threatening. We are sure that you will agree that any risk to the patient's well-being is not acceptable and their confidence in the treatments they are taking must be maintained. Trust is easily lost and almost impossible to recover.

Impact on prescribers - All prescribers (whether doctors, pharmacists, nurses or other healthcare professionals) are busy people with a clear mission – to make the patients they treat better. They expect that the products and information they are provided with are fit for purpose, error-free and safe to use. They don't want to administer products that will make their patients more unwell. Rectifying the patient issues created by artwork errors is a burden they neither want nor welcome. Furthermore, the remedial action following an incident diverts their limited resources away from their core purpose

These healthcare professionals are often the final decision-makers when it comes to selecting the product that is prescribed or used in the future. Hence, any lack of confidence that they may have in a particular product, brand or company can have a direct impact on the products that get used. Also, it must not be forgotten that there is also a serious personal impact for some prescribers involved in incidents leading to patient harm. Indeed, some prescribers involved in such incidents subsequently go on to leave their chosen profession altogether.

Impact on regulators - The remit of the pharmaceutical regulators, amongst other things, is to set and enforce the standards by which the industry must operate to ensure patient safety. They have the authority to allow or block product use and the power to take punitive action against companies who they see fail to meet expected standards. The regulatory environment is becoming ever more complex and stringent and there is less and less tolerance for artwork error. Moreover, as we have already observed, the information age means that an incident in any country has visibility to all regulators worldwide. It is therefore understandable that regulators expect companies to be continually striving to eliminate artwork errors and take appropriate actions to reinforce that view.

Impact on pharmaceutical company staff - Two groups of pharmaceutical company staff are typically impacted by an artwork error: the team managing the recall and the operations teams who support the artwork process in which the error occurred.

The team managing the recall need to focus on the immediate and urgent tasks related to identifying the impacted product, withdrawing it from the supply-chain and reinstating adequate supply as quickly as possible. Whilst challenging, this work is often very motivating for those involved as a great deal of satisfaction can be derived from solving the immediate and significant recall problem.

The impact on the staff involved in the operation of the artwork process is somewhat different. Not only are they likely to be involved in the rectification activity, they will be heavily involved in the incident enquiry and corrective and preventative actions. Furthermore, there are the undoubted performance and morale issues that will likely need to be addressed.

Impact on the company - The impact on the company can be significant. The patient safety implications are counter to any pharmaceutical company's core values. This is compounded by the sales, reputation and sanction impacts, through unfavourable publicity, loss of customer confidence, possible loss of licence and increased regulator scrutiny and action. As we discussed earlier, in

today’s business environment, these impacts are potentially significant to the success of the company.

The cost impacts of these errors are also substantial. There are the immediate tangible costs of recall, product write-off, repacking and market re-supply. However, these can be overshadowed by the less tangible follow-on costs occurring through loss of sales and market share, customer reimbursement and litigation. In the extreme these not only impact the bottom line but can directly influence the company’s share price.

The benefits of getting it right

There are of course very tangible benefits to getting your artwork right. Achieving excellence in this area can help deliver many significant strategic benefits including:

• Increased patient safety

• Improved regulatory compliance

• Increased sales

• Improved profit margin

• Improved reputation

• Reduced cost and valuable resource absorption

In part two of this blog series I will 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’ll also discuss developing a common service culture, internally and externally across an organisation.

Ensure there is a comprehensive instruction to the translation provider

The preparation of the specification discussed in the previous section is the starting point for briefing your service provider. Key things for the service provider are an understanding of the target country, language and dialect(s),

the audience, the timelines, the formats and key instructions that you want followed. This is all part of your specification.

Keep your service provider up to date with your project and any potential changes that might happen. This allows them to prepare and be more responsive.

Organize your file submissions

To ensure the most effective use of your service provider, don't just send through all of the materials you may have. Make sure that you have organised your materials to help them. Include all the relevant files in a logical order and don't include any materials that you don't want translated. This saves the translator time and effort by not having to sift through mate-rials looking for relevant content or translating material that you don't need. If the translator has to sort your documentation it will likely delay your project.

Also provide files in a suitable format. Whilst most translation service providers can handle many formats it takes longer to translate from hard copy.

Tell the translator what it's for

Different types of document need different styles of translations. A technical article is not a travel brochure and a press release requires a different style from a legal contract. It is therefore essential to be clear to your translation provider what the translation is for and your expectations for tone, word choice, sentence length, phrasing and degree of formality.

You also need to inform your translation provider about your target audience. Different age groups and education backgrounds in your target audiences will require different approaches and tone.

If your translation is a technical subject it is important that your translation provider under-stands that subject. They need to articulate the subject accurately in a way that is clear and readable to the audience, and people familiar with the subject are likely to produce better text.

An experienced translator is likely to ask for such information and the different requirements in quality have a direct effect on the cost and completion times.

For many translations the successful expression of the meaning is more important than an exact translation of the source text, so the translation provider has to make difficult decisions on the style and meaning. As your translation provider gains understanding of your business strategy, products, audiences and preferences, the better their translations will be. If you translation provider is not comfortable with your subjects and audiences, it is time to change your suppliers. You need your foreign language text to have the maximum impact and a provider that can deliver that.

Provide all the details to your translator

The more informed your translation provider is, the better prepared they can be and the better service you will receive. The greater the clarity the translation provider has, the more chance there is of choosing a translator who has the appropriate experience in the area.

We have discussed already ensuring the translation provider knows the intended audience, use, style, etc of your translation, but you also need to think about the quality criteria that have to be met. Some of the questions you need to consider are:

Will a second translator be involved in the editing or proofreading? Is it client's responsibility, or will a separate reviewer be assigned? The quality of the translated text will be much better if it is reviewed and enhanced by a second translator and in some cases this quality control is a must. However it may cost extra or have an effect on deadlines so this must be agreed upfront with your translation provider.

Is the overseas representative for your company going to have a look at it as well? If yes, at what stage of the process would this take place? Who is responsible for managing this, the translation provider or yourself?

What will be the format of the final file (PDF, etc), and how will the translation company deliver the file? Who will ensure that all corrections are incorporated and how many revision cycles are included in the price? How do you want to communicate revision requirements to the translation provider?

Finally it is worth considering what happens to the text after it has been translated. If post-translation work, such as typesetting, is required for the project, it is possible for some translation companies to undertake this as well. Similarly if the translation is required for recorded speech, the translation company may have services to provide this.

We hope you find this information useful. We are always searching for ways to improve our work, so of you have any feedback, please do not hesitate to contact us at enquiries@be4ward.com

Read it online

Excellent Packaging Artwork Capabilities Part 2 - The Causes Of Artwork Error And The Importance Of A Service Culture

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.

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