See the latest business and pharma industry news from Be4ward.
Featuring: Serialisation | Packaging | Labelling & Artwork | Supply Chain

Welcome to our first Be4ward newsletter of 2020, our opportunity to share with you our most recent articles, along with our company and wider industry news.

This year we celebrate Be4ward's 10th anniversary. We will be marking this significant milestone with some exciting new marketing developments, including fresh web content and the launch of our brand new company brochure. Watch this space for further news.

In this issue, we share our Consultant's thoughts and knowledge via a series of articles from the VP blogs, finishing our look at **Avoiding the Supply Risk from Serialisation with CMOs** and **Managing Clinical Trials Artwork** and beginning a new blog series on the topic of **Excellent Packaging Artwork Capabilities**. 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: ***Top 20 Packaging Complexity Management Tips*** where we present the top 20 things you should consider to drive maximum value out of your packaging portfolio.

We have also selected some 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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Go to Executive Briefing

Go to Top News Picks

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CONFERENCE NEWS

Where the Pharmaceutical Industry M

We're delighted to be supporting Making Pharmaceutical Conference 2020 this year with four excellent talks on the following subjects:

- Developing and Sustaining Excellent Packaging Labelling and Artwork Capabilities
- Pharmaceutical Packaging in the Digital Age
- Serialisation in 2020 – Delivery and Challenges
- Making Pharmaceutical Packaging that is Easy for Elderly People to Open

The Making Pharmaceuticals conference programme is free to attend, with 5 parallel conference streams, giving visitors a huge choice of topics. Most sessions run in parallel so you can move between the 5 different conference rooms, creating your own tailored conference programme to suit your interests and professional information requirements.

The full conference agenda will be available 10th February. You can register your attendance and keep up to date with speaker notifications here.

Featured Blog Post

by Stephen McIndoe

Avoiding The Supply Risk From Serialisation With CMOs: Part 3

Stephen McIndoe -VP of Be4ward

Be4ward has been implementing serialisation with Pharma companies and CMOs for many years. We have created this guide to capture some of our learnings throughout that journey.

Here in part 3, VP Stephen McIndoe examines the final six learnings, focusing on internal teams, template models and protocols, programme management and preparing for future change.

>> Read it offline

Read it online

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

Stephen McIndoe -VP of Be4ward

In the opening part to a new blog series examining how to create and apply excellent artwork capabilities, VP Stephen McIndoe looks 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 offline

Read it online

Featured Blog Post
by Andrew Love

Managing Clinical Trials Artwork Part 4 – How to develop your process

Clinical trials are a vital endeavour for a pharmaceutical company, the success of which is dependent on the effective design of the trials and their underpinning artwork process. In the concluding part of his blog series, VP Andrew Love examines the activities required to develop your clinical trials artwork process.

>> Read it offline

Read it online

Top 20 Packaging Complexity Management Tips

Top 20 things to consider to drive the maximum value out of your packaging portfolio

Stephen McIndoe
Andrew Love

Be4ward

Executive Briefing

Andrew Love
Stephen McIndoe

Stock Keeping Unit (SKU) and packaging component portfolio control is a critical activity for organisations. Ensuring the correct balance between a commercially advantageous portfolio, whilst minimising unnecessary pack and component variants is a challenge faced by many healthcare product companies as they grow their product range and expand into new markets. Therefore ensuring there are decision making processes in the organisation to manage required levels of complexity is a key aspect of effective pack management. This publication takes the popular Top 20 Tips format to describe key features of a complexity management capability in an easy to digest format.

Read the Executive Briefing to learn more

>> Read it offline

Top 3 News Picks

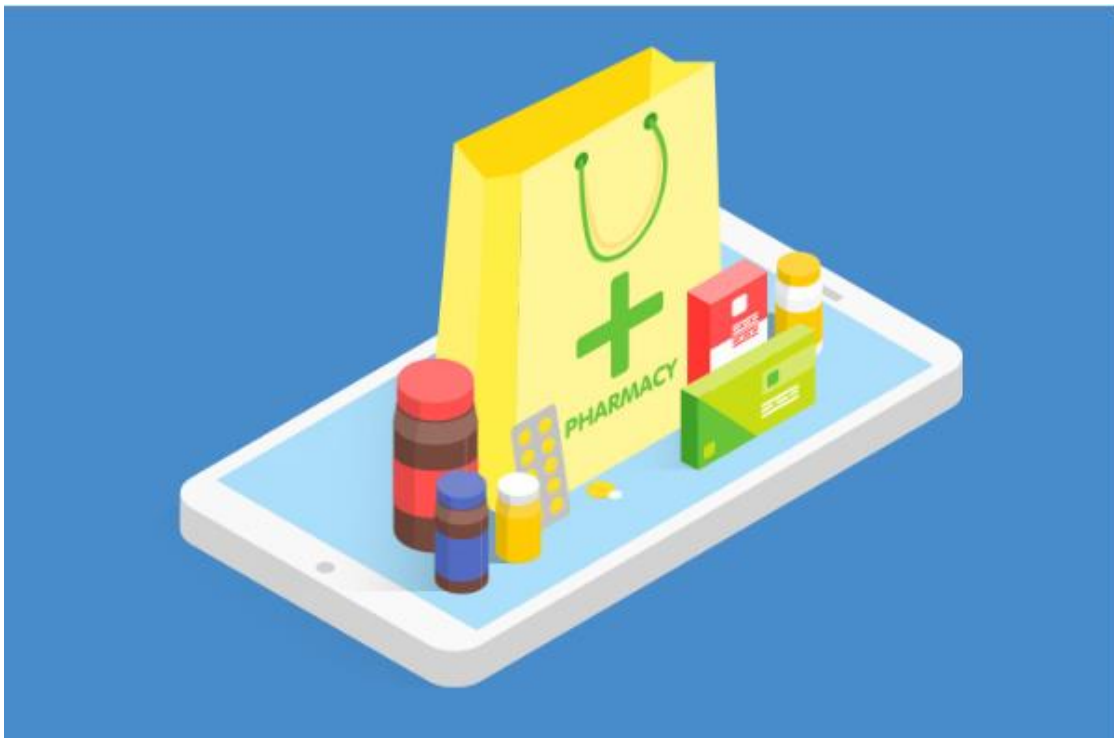
We share some of the latest worldwide news picks, on topics related to Serialisation, Artwork, Proofreading, Packaging and Supply Chain Optimisation. Here are three links from the many recently shared articles in the industry that we think are worth your time.

Drug delivery and packaging trends for 2020 revealed

By Victoria Rees for *European Pharmaceutcial Review*

Pharmaceutical industry experts have highlighted the key trends for the coming year for drug delivery and packaging.

Click here to read the article



Top 10 regulatory issues affecting pharmacy industry

By Susan Hunneyball for *PharmaField*

With 2019 almost over and 2020 rapidly approaching, Susan Hunneyball offers her top 10 regulatory issues affecting the pharmacy sector.

Click here to read the article

"This year will bring continual shifts in how healthcare is delivered"

Wholesalers: Supply could come under unprecedented pressure in 2020

By Martin Sawer for *Chemist + Druggist*

The UK must not miss out on EU initiatives to help ease medicine supply pressures after Brexit, says HDA executive director Martin Sawer

Click here to read the article

Executive Briefing: read offline

Top 20 Complexity Management Tips

Stephen McIndoe
Andrew Love

Why does Packaging Complexity occur?

Many healthcare product companies have broad product portfolios that they are selling in multiple markets. Beyond the US and big five European markets, sales volumes can drop dramatically for individual SKUs. Even within those markets, portfolio expansion and specialised products can result in low volumes. These effects result in an explosion of packaging components of ever decreasing volumes, creating a significant overhead cost (often referred to as a 'hidden factory') to manage and maintain, and reducing run times on packaging lines. We have seen healthcare product companies where >50% of their SKU portfolio have daily sales volumes of less than 30 packs, yet where packaging batches supply years of stock. So why does this happen? We suggest four main root causes:

1. Maximising the sales value of the portfolio

As margins are squeezed and new blockbusters are becoming increasingly difficult to find, healthcare product companies are focusing their attention on maximising the value that they can extract from their current assets. One of the significant ways they can achieve this is to create and launch as many existing product variants, in as many markets, through as many channels as possible. For many companies this represents a significant change of strategy as traditionally they would have focussed their attention on a few large products in the larger volume markets.

2. The move to higher value, lower volume products

Many new products coming to market are for treating more complex conditions with increasingly tailored therapies. Whilst these products may be very high value, the product volume is typically much lower than traditional pharmaceutical products. Moreover they often have complex dosing regimes, devices or combination products that require specialist and complicated packaging.

3. Legislation and regulation drivers

Legislative and regulatory requirements are continually becoming more stringent, e.g. Braille, font size, authentication, tamper evidence etc. The requirements and development of this legislation is not harmonised across all of the different legislators globally, and in some cases it could appear that any effort to harmonise is met with a counter requirement for differentiation. This not only results in added complexity through new features having to be added to the packaging, but those requirements being necessary for some markets but not others (yet a product may be packed for all markets on the same packaging line).

4. Local requirements and preferences

Requirements here can fall into two groups – necessary requirements to meet the needs of the market e.g. language, and local marketing and historical preferences e.g. a 28 or 30 tablet blister count. Some of these are captured in local regulation and it can be difficult to differentiate between what is a ‘must have’ and what is a ‘nice to have’. But even where it is not a mandated requirement, it can be very difficult to shift a local preference

Packaging complexity creates a number of consequences for healthcare product companies and their customers. These include:

1. Compliance issues

It is essential that the correct products and components are supplied to the

correct markets with the latest approved product information. With an ever-increasing portfolio complexity, exercising appropriate jurisdiction control over what is supplied where and when gets ever more difficult. Also, many companies have tried to overcome the complexity of supply to the smallest markets with standard ‘general export’ type packs, only to find unexpected and uncontrolled local repacking or over labelling activity e.g. where standard leaflets are replaced with locally sourced local language ones. These sorts of practices obviously present an unacceptable compliance risk if not managed effectively.

2. Lost commercial opportunities and product unavailability

Sometimes the financial trade-off between the supply of a unique variant to a specific market versus the cost of supply doesn’t merit selling that product in that location. Whilst that may be considered a victory in minimising complexity, it is a lost opportunity due to an unsuitable supply chain and there are patients in that country that don’t have that product or product-form available to them. It is therefore a bit of a hollow victory, and if the company had more cost effective capabilities to supply and maintain such variants, this could have been avoided.

3. Manufacturing inefficiencies

Small volumes obviously mean small pack runs and lots of change-overs. This is generally counter to the objectives of a packaging operation, whom are measured on cost of goods, production efficiencies and line utilisation. We have seen many examples where the packaging line spends more time being changed over than actually producing product. Complexity can also create needs for specific additional tooling, equipment and hand finishing.

4. Support function inefficiencies

In addition to manufacturing 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, increased volumes of artwork change, more purchasing activity, more warehouse space. This is often invisible and not considered in the cost of supply.

5. Obsolescence

There are two main types of obsolescence (where materials are no longer fit for use) that we would consider; packaging components and finished product. Economic order quantities can mean that the volumes of packaging components purchased have a disproportionate amount of forward cover versus the typical rate of change of those components. Therefore high amounts of materials can be written off when components are changed. Similarly, high inventories of low sales volume finished pack stock, caused by minimum packaging line order quantities risks obsolescence due to shelf life expiry, causing either product write-off or repacking.

So why is packaging complexity necessary? We would suggest there are two main reasons:

• Market access: you cannot sell the product in this market without meeting these specific requirements, whether they be legislative or not.
• Commercial advantage: providing these features gives an advantageous position in the market and the incremental impact on cost of goods is outweighed by the commercial benefits obtained. So some complexity may be considered ‘good complexity’ because it presents value in terms of the financial return from the sale of the product. The key is to learn how to cope efficiently with this ‘good complexity’ whilst developing methods to control the other type of complexity – the ‘bad complexity’. Unfortunately there does not seem to be any ‘golden bullet’ that will help you to do this easily. Rather, there are a series of techniques that can be applied across the portfolio to manage the complexity and create an optimal portfolio. In the following

pages we will outline a series of tips for how to do this. These are broken into two sections:
Part 1: Techniques to control non added-value complexity and, Part 2: Techniques to cope with added-value complexity

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?

Discussion: 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 the product will be marketed in
• Competitor activity and the competitive environment
• Commercialisation strategies for the product
• Market positioning and product cost profile
• Product lifecycle, 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.

2. Understand the portfolio, volumes and lifecycle of SKUs

Is the portfolio, volumes and lifecycles of your SKUs understood?
Discussion: 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 lifecycle; are volumes increasing or decreasing. Typically, products go through a standard lifecycle: launch, growth, maturity, and tail off. The value of portfolio complexity often varies through this lifecycle. Therefore, it is important to understand where a product is on its lifecycle as products where the volumes are likely to increase need to be considered differently from tail products where the volumes are declining.

3. Clear approval and control processes for portfolio changes
Do you have clear approval and control procedures for adding and removing SKUs from your portfolio?
Discussion: 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?

4. Prune the portfolio regularly

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

Discussion: The performance of the portfolio is dynamic, changing due to many environmental and lifecycle 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, contributing the majority of revenue, where sales effort should be focussed 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.

5. Control brand variation

Do you have a process to control the brand image and prevent unnecessary or undesirable proliferation of brand designs?

Discussion: It is not uncommon for companies to have a range of brand images that have arisen historically:

• Locally generated brand names and brand images.

• Response to local market regulations requiring unique local naming or branding.

• Legacy brand images from acquired companies who once marketed the product in a specific country.

• 2nd brands or co-marketed products. If standard brand images and packaging artwork designs can be maintained, it presents the opportunity to take a template approach to artwork, improving efficiency and reducing risk or error. This is discussed further in Tip 7. Many companies now exercise strict control over brand images and packaging designs at a global or regional level, to ensure they present a common identity to consumers. It is extremely difficult to rationalise brand images after the event due to regulatory constraint and consumer resistance and therefore clearly defined and mandated brand guidelines are an important tool in controlling brand variation up front.

6. Control platform sizes

Do you define and maintain a set of standard platform sizes?

Discussion: Components can come in multiple sizes and shapes and the challenge is how these can be controlled to an optimum number. Your approach to this will be heavily impacted by your supply chain design.

• If you have a few global or regional factories, rationalisation can be targeted at a local level.

• If you have a high number of factories supplying multiple dose forms to many markets, you will be presented with a significant number of inter-dependencies making rationalisation more challenging.
• If you purchase finished products from 3rd parties, you may be restricted to each supplier's standards.

Many companies will have combinations of all of the above, so your approach may be global, regional or by product/supply chain. For printed packaging components, the challenge is to reduce the range down to the smallest practical number of profiles. This gives less profiles to manage and will aid line change-overs. It is also a pre-requisite for most types of late customisation. Platform sizes are normally driven by the size of primary components and so it is often best to start with a rationalisation of primary component sizes and shapes to reach an optimum range of platforms. For other components, such as spoons and measuring cups, try to rationalise to the minimum number of variants.

7. Standardise artwork templates and layouts

Are there standard templates and layouts for artworks?

Discussion: Standardising the brand image, packaging artwork design and component sizes, permits the use of standard artwork templates and layouts. In this approach, global or regional templates can be created including all of the standard design content. Areas for specific market or regional content can be provided on the artwork and these can be populated when specific local variants are required, either creating market specific artworks or as part of an on-line printing activity with semi-finished components. This saves having to create a completely new artwork every time, which has obvious compliance benefits. It also ensures that areas such as overprint areas are always in the correct locations. Furthermore it facilitates using tools to automatically add content to the template and automatically create the artwork.

8. Minimise fonts, illustrations and graphical elements

Are there defined standard fonts, illustrations, and graphical elements?

Discussion: Artwork content such as fonts, illustrations and other graphical content can provide hidden sources of complexity. It is common for companies to build large ranges of content that needs to be stored, maintained and updated. Proliferation of fonts may not seem significant, but licenses need to be managed and fonts need to be assured to ensure accurate replication across different platforms and machines. It also results in dilution of the brand image. To control fonts, a defined house style set of fonts should be mandated within the corporate and brand guidelines with clear processes for the introduction of new fonts. Similarly, illustrations and graphical elements should be held in controlled libraries with standard images for particular uses.

9. Share components or packs

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

Discussion: 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.

10. Bundle changes

Are you maximising the opportunities to combine changes to minimise the frequency of changes to components?

Discussion : The concept of ‘bundling changes’ is the grouping of multiple different changes affecting the same pack or component together to change the pack only once. An analogy that many of us are familiar with is that of road repairs. How often does the water company dig the road up one week, for the gas company to come and dig it up again a week later? The purpose of bundling changes is to minimise the frequency of change to components by coordinating changes together. To be able to do this, you need to have an understanding of all of the parts of the organisation where changes can be triggered from, and a single shared forecast of required pack changes for each product. This is often maintained by the product strategy team, giving visibility of who wants to change what and when. It is also necessary to understand which changes have mandatory timelines and which changes have latitude in timing so that they can be combined. One of the biggest challenges in managing bundled changes is keeping dependencies aligned, particularly if some of the deliverables are outside of your control. To assess how well you are managing to bundle changes, measure the frequency of change for each brand, country, SKU and component type to look for opportunities to improve.

11. Plan for runners, repeaters and strangers

Do you have capability to supply product with different order and volume profiles – runners, repeaters and strangers?

Discussion: Products can be classified into three groupings:

• Runners: products that are produced very regularly.

• Repeaters: products that are produced or packed frequently, but not every

week or month.

• Strangers: products that are produced very infrequently.

The concept of runners, repeaters and strangers provides an excellent method for production scheduling and supply chain management. Runners typically provide the bulk of the stable packaging volume permitting high line run times and often dedicated equipment. Repeaters don't justify dedicated equipment, but occur frequently enough to allow scheduling with runners and still packaged in reasonable batch sizes. Strangers present a greater challenge as their infrequent nature and small overall volume make them challenging to build into the production schedule, produce in economic batch sizes and manage component supplies. Supply sites will normally have to produce products for all three groupings, and increasingly an individual brand can have all three types of product. It is therefore necessary to have the capability to schedule and pack all three. The application of many of the techniques in this booklet to minimise variation, increase pack or component sharing, or introduce postponement or late customisation techniques can assist in managing the disruption created.

12. Manage order quantities of components and finished packs

Have you got processes to effectively manage order quantities of components and finished packs?

Discussion: Considering the previous tip on runners, repeaters and strangers, it is important to consider how volumes of components and finished products are managed through the supply chain. Packaging operations are under high degrees of pressure to maximise efficiency. Where high volume runner products are present it is easy to produce in economic batch sizes and purchase commercially advantageous volumes of components. However with stranger products, the preferred packaging batch sizes can often result in high levels of inventory of finished packs which are at risk of obsolescence through shelf life expiry. Often this results in repackaging activity to move product from one market to another prior to

expiry. In addition the economic order quantities of packaging components can often result in high stock levels of components that have to be written off when a pack change is required. It is therefore important to manage two dynamics to minimise the risk of obsolescence:

1. Maximise the order volumes through pack or component sharing or postponement or late customisation techniques to increase stock turns.
2. Consider the whole activity cost in setting economic batch and order sizes and thus reduce the batch and order volumes.

13. Postponement

Can you postpone customisation to as late as possible in the supply chain?

Discussion: There are a number of definitions of postponement, but the one we will use here is the delaying of customisation of a product until as late as possible in the packaging operation. There are many examples of this:

• Filing blank bottles or cans for stock and labelling when fulfilling a specific order.
• BIB/BOB (blisters in boxes, blisters out of boxes) e.g. producing standard blisters for stock and packing into cartons at a later stage to create market specific packs.
• Assembling different combinations of standard components to create a unique pack variant for a specific market.

In all cases it can be seen that the goal is to keep the product as standard as possible for as far through the packaging operation, and then only make it market specific at the latest possible operation, perhaps against a specific market order. This can present a number of challenges for most operations:

• Additional quality system control to manage intermediate handling and subsequent further packaging operations.
• With fill and pack lines it can be necessary to remove the product part way through the operation and then run it down the line again at a later time to complete the packaging.
• Hand packing can be required for the final assembly of small batches.

• The design and characteristics of some products and components makes it very difficult to avoid making market specific until late in the process.

14. Late Customisation

Can you late customise components and products?

Discussion: Our definition of late customisation is the physical modification of standard components and products to add features or information, making them product or market specific. Examples would include on-line printing of content and over-labelling and may be undertaken downstream of the packaging facility. On-line component printing is becoming increasingly common, but depends upon the type of component and information required:

• On-line printing of foils and labels is often undertaken, particularly if only requiring black ink.

• Equipment for near-line short-order printing of leaflets and booklets is becoming available.

• On-line printing of multi-colour cartons (particularly preglued) is more complex with fewer examples, although digital presses are increasingly used at print suppliers for short runs. Over-labelling can vary between simple printed labels (pharmacy labels) to complex labels (e.g. including sealed pouches for leaflets). A few considerations with late-customisation and over-labelling:

• How do you assure the quality of print for all components? A missing decimal point could have significant consequences.

• How do you ensure the line speeds are not significantly impacted? Is near-line printing a better option?

• Do on-line printing machines require different artwork files or formats? Where are these files stored and how does that impact your artwork process and system uptime?

• Can your MRP system provide the necessary breakdown of SKUs and components?

15. Packaging design

Have you designed your packaging to maximise the opportunities to deal with complexity?

Discussion: All of the different techniques we have discussed in these tips offer opportunities for dealing with low volume products and managing complexity but they may not be feasible with your existing packaging designs. It may therefore be necessary to revisit some of the structural or artwork elements of the design to exploit specific techniques. These can include:

• Changing component artwork to make it standard across multiple countries (or even removing all market specific information).
• Grouping all market specific information on certain areas of the artwork (like the EU blue box concept).
• Providing space on components and artwork for on-line printing requirements or application of labels.
• Reducing colours to make on-line printing easier.
• Changing component size to provide more printing space.
• Providing pockets or flaps on cartons for attaching leaflets and booklets.
• Standardising sizes, platforms, layouts and templates.
• Using colour coding, poke-yoke and pharmacodes or data matrix codes to aid control of assembly operations.

It is therefore important to ensure that a holistic approach to packaging design is taken, ensuring effective design for manufacture.

16. Build flexibility into packaging equipment

Have you got the right type of packaging equipment that provides suitable levels of flexibility?

Discussion: It is often tempting when specifying equipment to specify the fastest packaging lines. Indeed, due to being pressured for ever increasing levels of efficiency, most packaging operations would love to be producing high volumes of few variants as fast as possible. However, as we have

discussed, the healthcare marketplace is increasingly not like that, as volumes are decreasing and complexity is increasing. It is therefore important when specifying packaging equipment to ensure that the correct criteria for how the portfolio needs to be supplied are defined and agreed. Trends are driving this to much more flexible machinery that can be easily changed for different pack formats, with the ability to insert specific modules when required (e.g. serialisation printing modules), or the ability to split fill and pack lines to permit part packing. Due to the capital costs required, it is unlikely to be feasible to reequip packaging facilities at a later date. Therefore, making the right choice of equipment to support your expected portfolio and supply strategies is a critical strategic decision.

17. Reduce line change-over time

Have you maximised your opportunities for fast changeover?

Discussion: Line change-overs are non-productive time and in a world of increasing complexity and product variants, the amount of changeovers increases and so lines can spend significant amounts of time not producing product. This reduces capacity and increases cost. There are three parts to a changeover; clean-down, set-up and startup, and all can be improved through the application of operational excellence techniques and product and equipment design. There are four steps to consider and many opportunities with each: Eliminate non-essential operations: for example standardise component sizes, reduce the range of tooling, equipment modifications like adjusting only one guard rail instead of two. Perform external setup: for example have all of the change-over materials and equipment ready before you start, use pre-assembled modules. Simplify internal set up: for example use quick couplings, scribe marks, jigs, hand knobs rather than nuts and bolts. Measure and improve: continue to look for opportunities, hone your process and keep training. A changeover should be like a racing car pit stop.

18. Supply Chain design and Hubs

Have you optimised your supply chain to provide required levels of variation and customisation?

Discussion: In coping with complexity, it is necessary to think not just of what must be done and how, but also where. To minimise obsolescence the goal should be to make products and components market specific as late in the supply chain as possible. To achieve this, a different approach to the design of the supply chain may be required. Postponement and late customisation activities are production activities and therefore must be undertaken with appropriate GMP processes and facilities. You therefore need to ensure that such operations are being undertaken with appropriate levels of control and therefore undertaking such tasks within warehouse operations may not be appropriate. Conversely, as most markets are supplied from many packaging facilities providing the local market specific requirements from each factory can be an unwelcome complexity burden at each factory. Ensuring that activities are undertaken at the appropriate points in the supply chain is therefore another key part of managing complexity. The concept of regional hubs can help provide appropriate solutions, where the hub supplies a group of local markets with market-specific product created from a stock of standard and customised components supplied from the factories.

19. Outsourcing

Have you considered outsourcing the things you are not best equipped to do?

Discussion: Another facet of the design of your supply chain is the ‘make or buy’ decision. It may be tempting to try to keep all of the volume in house, but considering the concept of runners, repeaters and strangers, you may not be best equipped to deal with all. If you have a high volume facility, it may be better to outsource the strangers to a packaging third party who can cope with an unpredictable product and infrequent orders. Alternatively you may want to keep all of the specialist and unusual product in house and outsource the standard and repetitive volume. Also, considering the overall

supply chain design, there may be geographic areas where you want to customise product but don't have internal facilities available locally. An outsourced partner may be able to provide an appropriate regional hub. The important consideration is that you don't have to do everything yourself and external partners may be better suited to solving the challenges you are faced with.

20. Plan for future legislation

Are you already planning for how you will introduce required future legislation

Discussion: No matter how well you manage your current portfolio, there will always be new challenges to drive further complexity. New aspects of legislation will arise, requiring new solutions to provide. At the time of writing these included:

• QR codes
• Serialisation
• Tamper evidence
• Temperature monitoring

It is therefore worthwhile planning ahead for future legislative drivers and considering: • How well are you sensing what is likely to happen in the future?

• What changes do you want to influence and how are you engaged in that influencing?
• How early do you mobilise to start introducing new capabilities?
• What alliances and partnerships do you need to establish to develop new solutions and supply strategies?
• How do you integrate necessary changes into normal business to avoid the incremental workload?
• How do you ensure packaging design activities are cognisant of potential future requirements?
• How do you track progress to ensure compliance is achieved?

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Featured Blog Posts : read offline

AVOIDING THE SUPPLY RISK FROM SERIALISATION WITH CMOS: PART 3

By Stephen McIndoe - VP of Be4ward

Welcome to part 3 of my *Key Learnings on Avoiding The Supply Risk From Serialisation With CMOs*. In part 2, I looked at processes and resource within the Pharma company. Here in part 3 I consider the final six learnings, focusing on internal teams, template models and protocols, programme management and preparing for future change.

Key learning 13: Make sure everyone understands how this is going to work

As with all projects, there are two principle aspects of a CMO integration that need to be worked out:

• How is the end-to-end final result going to work? — the 'To-Be' design
• How are the team going to get from where they are to the end result? — the Project design

An example of a critical area would be the integration of your quality system to those in each of your CMOs. A small number of key individuals in any project need to understand how both aspects are going to work. All too often, we see situations where nobody understands the overall picture at a sufficient level of detail, but many members of the team can identify

unresolved issues. In these cases projects typically fail, or at best are late and over budget.

Key learning 14: Ensure there is a clear data and messaging model in place

Ultimately, serialisation is about maintaining an information view of what is happening in the physical (product packaging, movement and consumption) supply chain. Furthermore this information typically needs to be shared across several locations, organisations and IT systems to work correctly.

To work at all, this information and the way it is communicated needs to be entirely consistent to the finest level of detail across the end-to-end supply chain. This is not to say that individual data items or message methods need to be exactly the same across the end-to-end supply chain, as the likes of middleware can accommodate a degree of data and message format transformation. However, in order for this transformation to work successfully, the underlying data needs to be consistent and transformable using simple rules, across the end-to-end supply chain.

Unfortunately, whilst standards exist for a significant portion of these information and messaging requirements, several issues arise including:

• Legislation requirements that are not all consistent across countries
• Standards, when applicable, that do not cover the full scope of the problem
• Standards, where they exist, that sometimes leave many options as to how specific processes and information communication can be carried out
• Different equipment and IT solutions that have different constraints placed on the way in which information can be represented and communicated. This is particularly true in the relatively immature area of serialisation

Key learning 15: Ensure there are repeatable test protocols in place

Not only are there many system connections and product implementations to perform in a typical serialisation programme, but there are also many changes that will be needed along the way as well.

There are not only many systems involved, but each of these systems will typically have a number of environments through which any changes need to be propagated, e.g. development, testing and production environments.

Given the relatively immature nature of serialisation and the over-stretched nature of the supply base, the opportunity for error in coordinating all these changes is plentiful.

The use of standard test protocols can go a long way to ensure that not only new changes function correctly, but also that any changes do not have unintended effects.

Key learning 16: Separate capability implementation from product cut-over

For many organisations, there are many individual products that need to be serialised, but a much smaller number of capabilities (e.g. packing lines, CMOs, 3PLs) that need to be serialisation enabled.

Furthermore, organisations are normally well set up for implementing packaging changes on products and recognise that this in itself is a relatively complicated coordination activity of many moving parts.

On the other hand, serialisation capability implementation is typically the realm of the serialisation programme / project teams, with an emphasis on one-off changes to significant capabilities and establishing new organisation and systems integrations. This would typically include any changes to the ongoing pack change implementation processes in an organisation.

Once these new capabilities have been established, implementing the individual pack changes should be very much ‘business as usual’ for an organisation, typically managed and coordinated from the supply chain and planning teams in an organisation.

It can be very effective to divide the responsibilities for serialisation capability implementation and subsequent individual pack change serialisation cut-over to different teams. This frees the serialisation capability implementation to

focus on what they should be good at, whilst leaving the individual pack change implementation activity to the existing teams in the business who best know how to do this. It can also serve to ease some of the political tensions that are often seen in serialisation programmes at this organisational interface.

Key learning 17: Treat this as a program (unless you only have one CMO)

Each specific CMO integration will be different in a number of ways, as each CMO is a unique organisation, with its own:

• Governance
• Organisation and people
• Serialisation solutions and vendors
• Quality system(s)
• Contractual and finance requirements
• Timelines and constraints
• Culture

Therefore, each implementation is at least one project, if not several, if a phased implementation is required. Therefore, it is sensible to treat the overall CMO integration activity as a program, ensuring that the appropriate level of program management capabilities are applied to the problem. Furthermore, successful programs tend to be those that recognise that program management skills are distinct and different to project management skills.

Key learning 18: Recognise and cater for ongoing change

There are many reasons in the serialisation area, why what is implemented initially will need to be changed over time. Examples of these change drivers include, but are not limited to:

• Changing legislation and standards
• Changing product portfolio

• Changing product supply chains
• Changing or evolving supply chain partner capabilities.

Any serialisation programme therefore needs to recognise these drivers, and have a way to understand and manage their impact and adapt accordingly.

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 at Stephen.McIndoe@be4ward.com

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

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 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.

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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Managing Clinical Trials Artwork Part 4 – How to develop your process

Andrew R Love

In the part three of this blog series, I discussed some pitfalls to consider if using the commercial artwork process as a base-on for the clinical trials artwork process, and how it is essential to understand these sensitivities to ensure a suitable capability is provided.

In this, the final post in the series, I will discuss the activities required to develop your clinical trials artwork process.

The first step we would suggest is a thorough capture of the current (as-is) processes and activities involved in the creation of existing clinical trials artworks. This should include all required scenarios and process variations for different products, suppliers, geographies or any other changeable parameters.

Once the as-is process has been determined, the status of relevant supporting capabilities should be considered. This should include, but is not limited to, how the process is controlled, how workload is forecast and projects planned, how people are organised and service providers managed, how performance is monitored and governed, and how are supporting

systems provided and operated. This will indicate the level of maturity for each capability.

The final step of the as-is analysis is the commercial artwork process, again mapping the end-to-end process and any variants and determining the status of supporting capabilities. When pulled together these assessments should provide a comprehensive picture of the as-is situation for both the clinical trials and commercial artwork processes.

Moving on to develop the future (to-be) design, the first step would be to determine the output requirements and success criteria for the clinical trials artwork process – what does the process need to deliver to meet the requirements of your business? How is this going to be measured and how will you assure success? From there, we would suggest you consider the key decision gates that are required along the process. Referring back to the second post in this series, this may be similar to:

High level process step
1. Define the text required
2. Define the change required
3. Create the artwork
4. Approve the printer proof (if required)
5. Implement the change

Decision gate outcome
1. An approved text
2. An approved change or brief
3. An approved artwork
4. An approved printer proof (if required)
5. A final packaging component available

These five steps illustrate the summary high level (level 1) process design. From there, each process step should be further divided into sub-steps at an activity (level 2) and then task (level 3) level. This gives the detail of each step required to meet the requirements of the decision gate. Inputs and

outputs, roles and responsibilities, information flows, key features and documentation requirements can then be described for each step.

Once the process has been described in detail, the to-be requirements for the underpinning capabilities can be defined. It is important to then test the design against defined scenarios and through design reviews with key stakeholders to ensure an appropriate and all-encompassing proposal has been developed.

From here the next step would be an impact of change assessment against the as-is clinical trials and commercial artwork processes and capabilities to define what changes will be required, the implications of those changes and what aspects of the commercial artwork process and capabilities can be exploited to support clinical trials artwork development. This will then permit the development of implementation plans, system user requirements and funding applications as required by the change and your company's governance.

From the above it can be seen that the development of a clinical trials artwork process follows a methodical path utilising standard process design methodologies. It is important that this activity is undertaken with all of the required knowledge and input from the various parties within and outside your organisation who participate in the process, and the design considers future business requirements as well as meeting today's challenges.

This concludes this series of blog posts on this topic. I hope you have found the content useful. If you require any help, advice or assistance with any aspect of your finished good supply chain process, please get in touch with us at Be4ward.

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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