Trusted Experts in Serialisation Labeling and Artwork

Welcome to our final Be4ward newsletter of 2019, our opportunity to share with you our most recent articles, along with our company and wider industry news.

During November Be4ward VP Stephen McIndoe had the pleasure of co-presenting a webinar, along with Navitas Life Sciences, asking: **Will you be ready to comply with DSCSA Verified Router Services?** Meanwhile VP Andrew Love had an article on Packaging Complexity published in the *Chimica Oggi Chemistry Today* magazine.

In other news, Be4ward has been recognised for outstanding work in Pharmaceutical Packing Supply Chain having been awarded the 2019 GHP Manufacturing and Packaging Award for our work in this area. We are also delighted to announce that we will be attending Making Pharmaceuticals 2020 conference in the spring, with four fantastic speaker slots on a variety of topics.

We've continued to share our Consultant's thoughts and knowledge via a series of articles on the VP blogs, on the topics of **Avoiding the Supply Risk from Serialisation with CMOs** and continuing our look at **Managing Clinical Trials Artwork.** 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:

Reducing Packaging Recall Risk, where we draw on our extensive experience of designing, implementing and managing global packaging artwork capabilities to help you understand how to minimise the risks of recall due to packaging artwork error.

We have also selected some Top News Picks from the industry that we think are worth a read.

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

Kind regards,

The team at Be4ward

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Go to Executive Briefing

Go to Top News Picks

Be4ward Company News

AWARD WINNING CONSULTANCY

We're delighted to have been awarded the Global Health and Pharma (GHP) 2019 award for

Best Pharmaceutical Packaging Supply Chain Experts 2019

GHP carry out extensive research and their judging process is driven by merit meaning that awardees must demonstrate expertise within a given field, dedication to customers service, and commitment to excellence and innovation.

Their research was centred around an in-depth evaluation of skills and services on offer. The wider market reputation of each nominee was also taken into consideration.

WEBINAR NEWS

Navitas Life Sciences and Be4ward On-Demand Webinar:

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

Stephen McIndoe - Vice President, Be4ward
Govind Srinivasan - Vice President, Navitas Life Sciences

Join serialization experts as they explore the VRS requirement and discuss strategies and activities companies can take to comply with the guideline as well as future-proof their supply chain for any future serialization regulatory requirements.

This webinar examines:

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

Thank you to all those who joined us for this webinar co-presented by VP Stephen McIndoe. If you were unable to join us for the live event please use this link to the watch back

PUBLISHING NEWS

Packaging Complexity: How to Cope with increasing numbers of small volume SKUs

Read VP Andrew Love's article in the monographic special issue **PHARMA SUPPLY CHAIN** of **Chimica Oggi – Chemistry Today (Sept/Oct) 2019.**

Click the article below to read online.

ANDREW R. LOVE
Bexward Ltd., London, United Kingdom

Packaging complexity

How to cope with increasing numbers of small volume SKUs

KEYWORDS: Packaging complexity, product portfolio, packaging facility, packaging operations, product packaging, labelling and artwork.

ABSTRACT

Portfolios are becoming increasingly complex due to four main drivers:
- Maximising value from current assets
- New products for complex conditions
- Local market requirements
- Commercial advantage

Within the packaging facility, outdated equipment and packing lines down to each module need to be examined, along with line specification versus product requirements, the physical layout of the facility and the effectiveness of supporting business operations.
Packaging techniques such as late stage customisation and postponement may have specific requirements for structural and artwork design, and these might require different solutions to those typically applied.
There are consequences to a company when complexity is not managed appropriately: namely compliance issues, lost commercial opportunities and product unavailability, packaging inefficiencies, support function inefficiencies and obsolescence.

Pharmaceutical packaging operations are generally labour and capital intensive and often a source of senior management frustration:

- They can be expensive in terms of either labour or capital investment, and sometimes both.
- They can often provide non-optimal levels of service, for example long lead times or inappropriate minimum order quantities.
- They can be inflexible with poor utilisation.

To offset these issues, supply chains are forced to either offer poor service levels or carry excessive stock, with the associated issues of high working capital, ageing stock and high write-offs.
A key underlying issue is balancing the demands of the product portfolio to be packed with the capabilities of the packaging facilities utilised. Portfolio complexity is very necessary for many businesses and there are numerous factors that drive increasing complexity, including different legal requirements, increasing customer service demands and product differentiation.
There are ways to effectively address these challenges:

- Assessing the portfolio complexity, ensuring it is appropriate
- Optimising the packaging facility design, to deliver optimal service levels at minimum cost
- Assessing the product packaging, ensuring its suitability for the optimised portfolio and facility

In this article we will consider these three topics and look at how you may approach a process of improvement for each in turn.

ASSESSING THE PORTFOLIO COMPLEXITY

Portfolios are becoming increasing complex. Many companies have broad product portfolios sold in multiple markets which can provide significant advantage for that business. We see four main drivers increasing portfolio complexity:

1. **Maximising value from current assets**: launching as many product variants, into as many markets, through as many channels as possible.
2. **New products for complex conditions with increasingly tailored therapies**: these products may be very high value, but 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. **Local Market requirements**: you cannot sell the product in a certain market without meeting specific market requirements, whether they be legislative or local preferences.
4. **Commercial advantage**: providing certain features gives an advantage in the market and the incremental impact on cost of goods is outweighed by the commercial benefits obtained.

Beyond the US and big five European markets, sales volumes can drop dramatically for individual SKUs (Stock Keeping Unit). Even with the large markets, portfolio expansion and specialised products can result in very low individual SKU volumes. The result is an explosion of packaging components of ever decreasing volumes. We have seen companies where more than fifty percent of their SKU portfolio have daily sales volumes of less than 30 packs and minimum order quantities of packaging batches supply years of stock.
These are the key steps to addressing your product portfolio complexity:

1. Understand the product / therapy strategy and value of complexity
2. Understand the portfolio, volumes and lifecycles of SKUs
3. Have clear approval and control processes for portfolio changes
4. Prune the portfolio regularly
5. Share components or packs where possible

OPTIMISING THE PACKAGING FACILITY DESIGN

Often the first issue within the packaging facility can be the packaging equipment itself. Old, unreliable equipment that is slow to change over might just need to be upgraded. However, it may not be the whole line that is the issue. Packing lines consist of numerous components, each doing part of the packaging process. The overall reliability and speed of the line is a function of the reliability and speed of each component. Replacing one part may beneficially impact the overall line performance.
It is also worth considering the line specification versus the product requirements to be packed. We often see complex, high speed, automated and highly integrated packaging machinery being used for low volume short run packaging batches and can also see manual lines being used to pack larger volume SKUs. A more flexible line may be more appropriate.
Facility layout can also impact productivity. Many packaging facilities evolve over time. How is the flow of materials in your facility? Is there unnecessary handling or waiting? Where are there bottlenecks? Where are you wasting time and effort?
Finally, consider the effectiveness of business processes supporting packaging operations. Are processes optimised and efficient? Moreover, are the collective cross-functional processes tuned to work in unison or do dependencies between processes promote delays wasting time and effort?
These are the key steps to optimising your packaging facility:

1. Plan for runners, repeaters and strangers: products with different order and volume profiles
2. Effectively manage order quantities of components and finished packs
3. Postpone customisation to as late as possible in the supply chain
4. 'Late Customise' components and products
5. Build flexibility into packaging equipment
6. Reduce line changeover time
7. Utilise regional hubs for market-specific product creation
8. Consider outsourcing the things you are not best equipped to do

ASSESSING THE PRODUCT PACKAGING

There are many competing requirements to be considered when designing the product packaging. It must be easy to use, meet regulatory requirements, protect the product and be robust for shipping operations. It also must play its part in ensuring the most appropriate packaging solutions can be used.
Packaging techniques such as late stage customisation and postponement may have specific requirements for structural and artwork design, and these might require different solutions to those typically applied. Packaging engineers and artwork designers need to consider the overall packaging supply system when developing their designs to ensure they are fit for different solutions that may be applicable for different volume profiles.
These are the key steps to assessing the product packaging:

1. Control brand variation between markets
2. Define and maintain a standard set of platform sizes
3. Standardise global and regional artwork templates and layouts
4. Minimise and centralise fonts, illustrations and graphics
5. Revisit structural and artwork elements of existing packaging designs
6. Plan ahead for future legislation

THERE ARE CONSEQUENCES FOR A COMPANY WHEN COMPLEXITY IS NOT MANAGED APPROPRIATELY

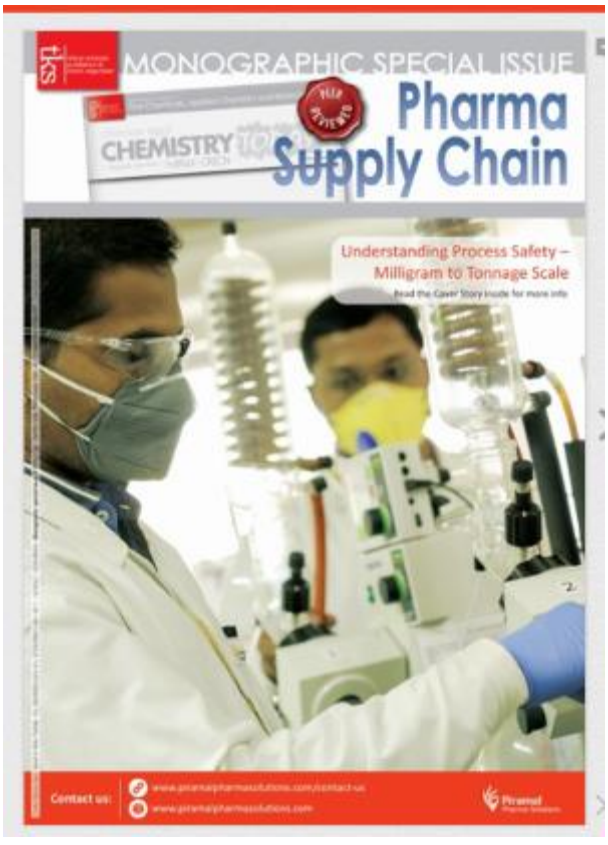
Packaging complexity creates some consequences for companies and their customers, including:

- Compliance issues: Correct products and components must be supplied to the correct markets with the latest approved product information. With ever-increasing portfolio complexity, exercising appropriate jurisdiction control over what is supplied and to where, gets more difficult. Many companies have tried to overcome this complexity by supplying smaller markets with standard 'general export' type packs, only to find unexpected and uncontrolled local repacking. This practice obviously presents an unacceptable compliance risk if not managed effectively.
- Lost commercial opportunities and product unavailability: Sometimes the financial trade-off between supplying a unique pack variant to a market versus the cost of supply doesn't merit selling that product in that location. That may be considered a victory in minimising complexity, but it is a lost commercial opportunity leaving patients in that market unable to benefit from that product being made available to them. It is therefore a hollow victory that could be avoided if the company had more cost-effective capabilities to supply such variants.
- Packaging inefficiencies: Small volumes mean small pack runs and lots of changeovers. We have seen examples where the packaging line spends more time being changed over than packing product. Complexity can also create needs for specific additional tooling, equipment and hand finishing.
- Support function inefficiencies: There is a whole 'hidden factory' in the support functions supporting the product and component range e.g. additional regulatory staff maintaining licenses and product information or more purchasing activity. This is often invisible and not considered in the cost of supply.
- Obsolescence: There are two relevant types of obsolescence: packaging components and finished product. Economic order quantities result in purchased volumes of packaging components that have a disproportionate amount of forward cover, causing high amounts of write-off when components change. Similarly, high inventories of low volume finished pack stock, caused by minimum packaging order quantities, risks either product write-off or repacking due to shelf life expiry.

In conclusion, complexity is an underlying cause of inefficiency in packaging operations. Some complexity may be considered 'good' because it presents value as financial return from 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 operation to manage the complexity and optimise your operations.

ABOUT THE AUTHOR

***Andrew Love** is a multi-award-winning packaging and artwork management strategist, leader and author. He spent 10 years as head of global packaging design operations at GlaxoSmithKline, transforming their global artwork management activities into a world-class, award-winning capability. He is one of the founders of Bexward which helps pharmaceutical, biotech and other healthcare companies and their supply base to improve patient safety and drive additional value from their product range. Andrew, a professional engineer and MBA with over 20 years of experience working with many of the world's largest life-sciences companies.*



Click the cover to read the e-version of *Pharma Supply Chain - Special Issue*

CONFERENCE NEWS

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.

Watch this space for further news on the Be4ward room and timings.

Featured Blog Post

by Stephen McIndoe

Avoiding The Supply Risk From Serialisation With CMOs: Part 1

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 1, VP Stephen McIndoe examines 6 essential learnings related to the uniqueness of the working relationship between Pharma companies and CMOs.

>> Read it offline

Read it online

Avoiding The Supply Risk From Serialisation With CMOs: Part 2

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.

In part 1, VP Stephen McIndoe introduced the first six learnings, looking at the unique relationship between Pharmas and their CMOs. Here in part 2 he considers six more learnings, focused on processes and resource within the Pharma company.

>> Read it offline

Read it online

Featured Blog Post

by Andrew Love

Managing Clinical Trials Artwork Part 2 – Opportunities to Leverage the Commercial Artwork 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 part 2 of his blog series, VP Andrew Love examines six further considerations in the clinical trials artwork process, focusing on processes and resource within the Pharma company.

>> Read it offline

Read it online

Managing Clinical Trials Artwork Part 3 – The Pitfalls to Avoid

In developing a clinical trials artwork capability, particularly when exploiting

aspects of the commercial artwork tools and capabilities, there are a number of pitfalls to be aware of and avoid. In part 3 of his blog series, VP Andrew Love explores 7 important pitfalls to avoid in developing clinical trials artwork.

>> Read it offline

Read it online

Executive Briefing

Andrew Love
Stephen McIndoe

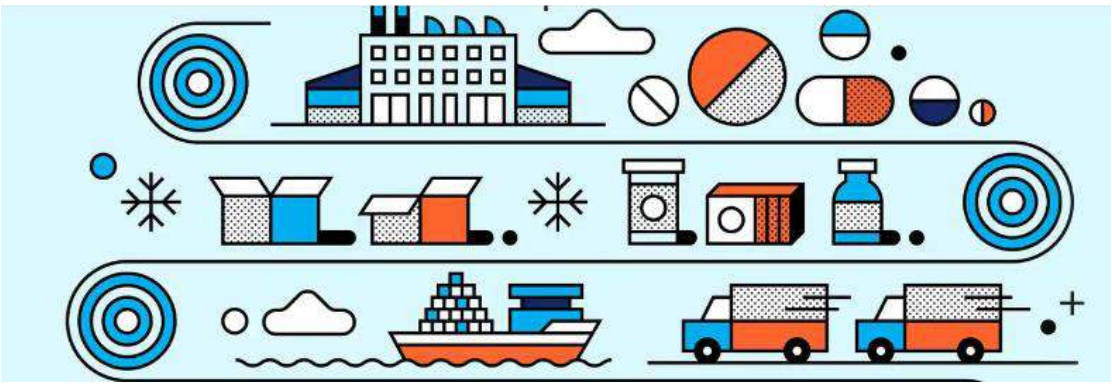
Packaging artwork is a complex but often overlooked aspect in the design of pharmaceutical products. Unfortunately, packaging artwork errors are one of the main causes of product recalls. Many factors are driving companies to increase their product range. This brings with it a corresponding increase in the risk of artwork related recalls and near misses. In this Executive Briefing we draw on our extensive experience of designing, implementing and managing global packaging artwork capabilities to help you understand how to minimise these risks.

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.



From falsified medicines to storage mishaps: the fragile state of drug supply chains

By Duncan Jefferies for *The Guardian Labs*

The increasingly complex production and distribution of medications can have a big impact on people's health in low-income countries. So how can we ensure the right drugs reach those in need on time?

Click here to read the article

General Election manifesto for UK pharmaceutical industry launched

An article for *Health Europa*

The Association of the British Pharmaceutical Industry has launched its General Election 2020 Manifesto for Medicine.

Click here to read the article

Defining the ‘New World Order’ of supply chain security

By Allan Bowyer for *European Pharmaceutical Review*

Now that prominent compliance deadlines are nearing in the US, Saudi Arabia and Russia and with the Falsified Medicines Directive (FMD) now in force in Europe, what is going on around the world with serialisation? Allan Bowyer provides a rundown of current events and shares insights into the challenges businesses are facing to meet compliance.

Click here to read the article

Executive Briefing: read offline

Reducing Packaging Recall Risk

Stephen McIndoe
Andrew Love

Executive Summary

Packaging artwork is a complex yet often overlooked aspect in the design and supply of pharmaceutical products. Unfortunately, when something goes wrong with package information or design, the impact is felt across many parts of a company and can have a significant effect on the company's reputation with patients, prescribers, and regulators. Yet despite these risks, packaging artwork is often regarded as an afterthought. The artwork department is often considered the 'Achilles Heel' of the organisation and close scrutiny is avoided. As the complexity of portfolios increases due to line extensions and market expansion, more and more companies are feeling pain in their artwork operations. This is normally due to the cross-functional nature of the work and reliance on paper-based processes and individual knowledge. Many companies are now discovering that there are process, organisational and technology solutions to these problems, and that dramatic improvements can be made.

1. Packaging Artwork Errors:
A Significant Liability In the global pharmaceutical industry, packaging artwork errors are considered to be one of the main sources of product recall. Whilst getting a true global picture is challenging, some estimates indicate that artwork error causes 30% of all recalls. An individual recall can cost millions of dollars in direct costs. Such costs include customer reimbursement, product write-off, shipping and returns costs, litigation, payments to victims and their attorneys, and costs of product packaging redesign. The indirect costs of recalls can also be very significant. These include management and staff time devoted to solving the problem, loss of immediate sales, loss of market share due to unfavourable publicity, loss of consumer and physician confidence, and increased regulator action. Packaging Artwork Definition By artwork, we mean the graphics and text that is included on the materials that make up a pharmaceutical

product.

Typically these include:
• Product primary packaging including blisters, bottles, syringes
• Product secondary packaging, typically:
− Product cardboard carton
− Product information leaflet
− Product prescribing leaflet
− Shippers, typically cases and pallets

There are two primary types of artwork error that create the need for recall. Some examples include:

Errors of fact or detail:
λ Product strength is incorrect, or different on different parts of the packaging.
λ Incorrect characters, spaces, and symbols.
λ Text hidden beneath tables or illustrations, which then get revealed unintentionally in subsequent changes.

Errors of omission:
λ Parts of changes omitted altogether.
λ Changes on some artwork(s) are missed when the same change impacts multiple components/products.
This white paper describes how these errors occur and what can be done to minimise them. We also look at other drivers for improving the overall artwork process.

2. Excellence is Within Reach
Our team has developed award-winning global artwork design capabilities in some of the world's largest pharmaceutical companies. Improvements in performance have been dramatic:
λ 90% reduction in recalls due to artwork
λ 24 hours artwork change turnaround
λ 50% reduction in process execution cost

Furthermore, benefits have resulted in related areas:

λ Improved product range management

λ Reduction in packaging component complexity

λ Opportunities to use the performance improvements to enhance company reputation

3. The Causes of Packaging Artwork Error

Packaging artwork design is the drawing together and integration of information from many sources, both across the business and from outside of the business. Typically, a pack will have information on it from more than 10 sources. Therefore the business process which coordinates this information flow needs to be cross-business and cross-organisation in span and control.

Traditionally, pharma companies have put more emphasis on ensuring that the product is right and less on ensuring the packaging is right. Therefore, once companies have got their product development right, packaging and artwork design presents a great opportunity to reduce recalls and compliance near-misses. Typically, a company's artwork capability starts in small pockets of activity attached to secondary manufacturing facilities and in individual regulatory offices in different countries. At this initial stage of their evolution, the processes and knowledge are often held in the heads of key individuals. As well as often being very much a part-time activity for these individuals, the loss of any of them can present a significant business continuity risk. As the business grows and complexity increases, the capability typically grows organically, often in an uncoordinated fashion. It is not long before the risk of error in the end-to-end process becomes unacceptable. The artwork area is complex, has its own language, and tends to be inwardly focused. When incidents do happen, the attention the area gets is often not conducive to longterm improvement. Systemic improvement is often overlooked in favour of expedience and short-term fixes. Elimination of the root causes is often not feasible due to a lack of detailed technical understanding. The cross-functional nature of the process means that there are many opportunities for the confusion of responsibilities and misunderstanding. Procedures are often defined in functional silos, with inadequate information flow across these boundaries. Accountability for the end-to-end process is seldom defined and made clear to those involved.

4. The Increasing Risk

As the regulatory environment becomes increasingly stringent and other pharma companies address their artwork recall risk, there is less tolerance for artwork error.

External drivers of increased risk include:

λ Regulatory requirements for ever-increasing amounts of product information on packs.

λ New labelling requirements such as the addition of Braille.

λ New product coding and serialisation requirements.

λ More stringent approaches being adopted by government regulatory agencies.

Senior management should also be aware that many of the internally driven improvement activities in the business are also contributing to increased risk from artwork-related incidents:

λ Expansion in product range and markets as companies seek to extract maximum value from their existing molecules.

λ Restructuring, portfolio optimisation, mergers, acquisitions, divestments, supply chain reengineering, multiple branding, and joint ventures are increasing the frequency and volume of change.

λ Supply chains becoming ever more complex and virtual, requiring communication between new and changing partners to deliver each artwork design.

λ Innovations in packaging and artwork design to increase sales of products.

λ Increased sensitivity of pharmaceutical companies to recalls in order to ensure patient safety.

Furthermore, a world-class artwork design capability is a key enabler to helping pharmaceutical companies achieve growth and product launch strategies.

5. Key Principles to Drive Improvement

Our experience has shown that by systematically applying a number of key principles, an effective, agile, and cost effective cross-functional artwork design capability can be established.

The key principles:

λ Establish cross-functional governance and sponsorship for the process. Only in this way can roles and responsibilities and end-to-end process performance be managed effectively.

λ Capture the knowledge & activities in carefully designed cross-functional business processes which are well documented.

λ Ensure that the basic process revolves around two fundamental steps. Firstly, define and agree upon what is required, the ‘Brief’. Secondly, execute the change and verify

that what has been done conforms to the Brief.

λ Make sure that complex tasks are based on standard work and that simple checklists are used to verify all activities have been completed.

λ Be wary of introducing multiple checks in a process being performed by different individuals. This often leads to complacency that others are performing those checks and ultimately the risk of error can increase.

λ Ensure specific individuals are identified to carry out each change and then manage any variance to this plan.

λ Ensure that all individuals are clear on their accountabilities within the process.

λ Ensure that all individuals are competent to carry out the activities required of them.

λ Ensure that individuals have the right tools and environment to perform their tasks. This is particularly important for activities such as proof reading and artwork creation.

λ At each of the critical control points, ensure that the individuals involved in the change sign their approval.

λ Establish a continuous improvement culture that values errors as a learning opportunity to improve the existing process. A critical part of reducing recalls in this area is identifying, learning from and designing out the more minor errors and near misses.

λ Establish a small number of Key Performance Indicators to manage the risk, e.g. percentage artworks right first time.

Artwork effort has a very clear and visible impact on patient safety, which is clearly understood by the people who work in this space and is a motivator to generate a zero-error culture.

Case Study: Top Global PharmaCo

Situation

The company wanted to reduce its recall rate due to packaging artwork errors, whilst at the same time be able to understand and reduce the complexity of its pack range and associated components. The company's packaging and artwork design capability had evolved over many years into a complex, disparate global collection of operations that made the task almost impossible to achieve.

How We Helped

Initially, members of our team ran a strategy development project that delivered the following:

• Full understanding of the complex current situation.
• Future state operating model, including a global service centre network.
• IT architecture to support the new operations.
• Change program design to deliver the new capabilities.
• Buy-in from more than 300 stakeholders across the world to the recommendations.
Subsequently, members of our team ran the significant global change program to implement the strategy:
• New global process design for 2,500 users in >100 locations.
• New organisation design including a small number of global service centres.
• New enterprise Product Lifecycle Management and artwork desktop IT capability design.
• New governance model.
• Phased implementation of the change, including closure of many existing operations.
• Pack range rationalisation program.

The Results

The new capability has reduced the recall rate due to artwork errors by 90%, improved speed to market and reduce the cost of its packaging. The change program and the capabilities have won a number of awards for innovation and excellence.

6. Capabilities

Required to Manage Packaging Artwork Design Whether in-house or out-sourced, there are key capabilities that need to be in place to effectively manage the packaging artwork design process.

Brief Creation

The Brief needs to be considered as the Work Order to the artwork operator and any opportunity for confusion will likely result in error. Ensuring individuals have the necessary skills, knowledge, tools and facilities to perform this task is critical to the success of this process. Briefs need to be clear, unambiguous and repeatable. The individuals who define the brief need to be skilled at ensuring requirements are articulately captured, accurate, and comprehensive.

Artwork Creation

Artwork creation for packaging requires a combination of graphic design skills and knowledge of pharmaceutical regulatory requirements. Ensuring individuals have the

necessary skills, knowledge, tools and facilities to perform this task is critical to the success of this process. Opportunities should be taken to work with print suppliers to construct artwork in a way which requires no change by the print supplier. Companies also need to consider the emerging automated artwork creation capabilities, which are becoming available in the market place.

Proof Reading

There are two elements to proof reading: checking the content and checking the context.

λ Content: checking that the artwork meets the brief—the character-by-character check for accuracy.

λ Context: checking that the syntax and language are correct—does the text say what it is meant to say.

Proof reading capability is often home-grown, and ensuring individuals are competent is challenging. It must also be recognised that proof reading is carried out by a number of different functions in a typical artwork process. As with artwork, companies must consider the use of emerging technologies to electronically assist the proof reading process.

Packaging Technology

Considering the technical impacts of the required change on the packaging design, manufacturing, distribution and use, e.g. Braille.

Product Coding and Marking

To ensure machine-readable coding is created and verified correctly, e.g. barcodes and datamatrix codes. Many organisations are currently struggling to understand how and where new requirements such as serialisation should be managed.

Project Management

To ensure that all the necessary parties are involved in each change and that they are properly coordinated to ensure an effective and timely result.

Document Management

To ensure accurate and effective version control and archiving.

Information Technology

See the next section for details on the many ways information technology enables this process. In addition to the above, capabilities to ensure that continuous improvement and more significant change can be carried out effectively need to be in place.

7. The Role of Information Technology as a Key Enabler

Even in the smallest of businesses, IT plays a key role in enabling this business process. Indeed, many of the improvements we discuss here would not be possible without it.

Document Management

It almost goes without saying that modern electronic document management capabilities are the foundation of an effective and compliant artwork change process. However, this is not to say that an artwork change process needs to be based on a dedicated document management system. There are many applications that include appropriate document management capabilities, e.g. Product Lifecycle Management systems.

Pack Catalogue

An enhancement of document management capabilities enables the creation of a ‘pack catalogue’, through which the organisation has access to all information associated with the company’s packaging. This has proven to have great benefits both within and outside the artwork process. For example, purchasing departments gain easy access to packaging component information which enables them to negotiate better supply deals.

Electronic Workflow

Electronic workflow tools and electronic signature capabilities help to further reduce the risk of errors by ensuring that all the mandatory tasks are performed and approved by the relevant people.

Timely Global Information Access

Today’s supply chains are geographically dispersed and are subject to rapid change. IT plays a key role in ensuring that all participants in the artwork process have timely access to all the necessary and up-to-date information to perform their role in the process.

Collaborative Design

Furthermore, the ability of today's IT tools to facilitate collaborative design and approval activities (see collaborative approval diagram) is a significant contributor to reducing the end-to-end cycle time of artwork changes.

Artwork Desktop

A controlled artwork desktop ensures that artwork documents are maintained an updated in a standard environment. Without this, errors can occur due to subtle differences in the configuration of different computers, e.g. the use of different font libraries.

Error Free WISIWIG

Indeed, the tight control of all applications that support the specification, review and approval of artwork changes is key to eliminating errors. It is critical that all applications and printing equipment involved in the compliant parts of the artwork change process are validated to provide error-free WISIWIG output. The use of virtual desktops has made this requirement significantly easier in recent years.

Work Planning and Tracking

Work planning and tracking tools ensure that individuals and management are able to plan work, understand when work needs to be completed, and have visibility of the status of activities. This capability becomes critical as the number of pack changes increases. Even small organisations can quickly find themselves having to manage many hundreds of artwork changes every year. This is a situation that can quickly get out of control without the right tools.

Inform and Alert

An enhancement of the planning and tracking capabilities is the ability to automatically inform individuals of tasks which need to be performed and alert the organisation to take action when plans go off track. This capability is very valuable in ensuring work progresses to plan across the different functions involved in the artwork change process.

Resource Management

Finally, the resource management capabilities of modern applications enable management to ensure that the right level of resources is in place to carry out forecast work. Furthermore, if work is dynamically allocated to available resources, the optimal

throughput of work can be achieved. Furthermore, the ability of today's IT tools to facilitate collaborative design and approval activities (see collaborative approval diagram) is a significant contributor to reducing the end-to-end cycle time of artwork changes. Collaborative Approval Collaborative Design Error-Free WISIWIG

At one end of the spectrum, organisations use bespoke artwork change management systems provided by external artwork service providers. At the other end of the spectrum, a number of companies use the integrated capabilities of Product Lifecycle Management (PLM) applications to great effect as the primary tool to manage this process.

Case Study: Mid-Sized PharmaCo

Situation
This mid-sized pharma company had undergone significant growth and was projecting a further dramatic increase in product portfolio and new market presence. Existing pack management processes had evolved over time and had multiple process variants depending on geography, supply chain, and product. A number of incidents and nearmisses highlighted vulnerability and business risk.

How We Helped
Our team has helped this company develop its strategy in this area and define a global project to transform its capabilities. The project includes establishment of the following elements:
• Governance model
• New end-to-end business processes
• Modified internal organisation
• Selection and integration with an external artwork provider
• Migration from existing artwork provision arrangements to the new model

The Results
The project has been approved and members of our team are currently assisting the company in the implementation of this project.

8. Principal Levers for Cost Reduction
We find that the principal levers for cost reduction lie in the following areas:

λ Reducing recall and near-miss costs.

λ Dramatically improving right-first-time at all stages of the process to reduce wasted recycling.

λ Developing an optimal standard process that reduces waste.

λ Economies of scale from concentrating key resources.

λ Improving schedule adherence to minimise packaging obsolescence.

9. Where to Start

Be4ward offer a simple diagnostic tool to assess your current situation and make recommendations on improvements. Alternatively, we would welcome the opportunity to discuss other assistance or advice you may need.

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AVOIDING THE SUPPLY RISK FROM SERIALISATION WITH CMOS: PART 1

By Stephen McIndoe - VP of Be4ward

For many Pharma companies, the use of contract manufacturing organisations (CMOs) to package commercial product is an integral part of their supply chain. Indeed for virtual companies, it may be the only way their products are packaged.

Serialisation legislation in the US, EU and many other countries means that, without the successful and timely implementation and integration of CMO serialisation capabilities, Pharma companies will no longer be able to supply product.

The complex, evolving, immature and increasingly resource-constrained area of serialisation means that the risk of significant supply interruptions is high.

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 1, I will examine 6 essential learnings related to the uniqueness of the working relationship between Pharma companies and CMOs.

Key learning 1: Be realistic about the real flexibility that CMOs have

Like all organisations, CMOs have many constraints both internally and externally, that limit what they can practically offer. It is all too easy for Pharma companies to assume that, as they are the customer, a CMO will be able and willing to accommodate any requirement they have. Unfortunately, in the area of serialisation at least, this is not the case at all.

Serialisation is an ever-developing area, with new and evolving legislation and standards. Equipment and information technology (IT) solutions are also evolving and maturing rapidly. Furthermore, the whole supply base is capacity-constrained as the demand for equipment, IT systems and consulting services has outgrown the limited pool of skilled resource.

Most CMOs have to deal with many different customers and, from a serialisation perspective, must implement packaging line and IT capabilities and interface them to each of their customers. It is impractical for them to do this and achieve time, cost and quality customer requirements without some compromise.

This compromise often results in the CMOs having to define a limited operating model, within which customers must conform, in order for the CMO to be able to effectively manage the situation. In many cases the equipment and IT solutions they are using will impose constraints on them that they have no realistic way of avoiding in the current environment.

Therefore, rather than expecting CMOs to be infinitely flexible and customer-serialisation-requirement-focused, Pharma companies are better to assume they will have to adapt to a number of different and relatively inflexible CMO serialisation models.

Key learning 2: Be realistic about what CMOs are really going to pay for

CMOs operate as relatively low margin businesses compared with most Pharma companies. Indeed, one could argue that this is due to the Pharma companies doing a good job of ensuring they only pay a reasonable price for the services they receive.

Therefore, CMOs do not typically make the profit margins that would allow them to absorb the very significant costs of implementing serialisation.

We have seen a number of clients waste a lot of time and effort trying to negotiate for a CMO to absorb the cost of serialisation when, in reality, this was never going to be a practical option. CMOs may be able to fairly share the cost of serialisation between customers, but to absorb the costs is unrealistic in many cases.

Therefore, Pharma companies should budget to pick up their fair share of the CMO serialisation implementation and ongoing operation costs and negotiate with their CMOs accordingly.

Key learning 3: Understand the CMO's decision-making process

Following on from our learning about being realistic about what CMOs are going to pay for, Pharma companies also need to understand the key decision-making processes within a CMO and how this will impact their own activities.

As an example, understanding the funding approval processes within a CMO can be key to ensuring a timely serialisation implementation. How a CMO makes its funding commitment decisions and what commitments they need from their customers along the way, should shape a Pharma company's engagement plan. All too often, a project will encounter unexpected and sometimes unexplained delays because the funding and commitment processes of the Pharma company and CMO are not aligned.

Key learning 4: Be realistic about your CMOs' views of your importance to them

Pharma companies would all like to think that every CMO treats them as a critical and highly important customer. However, this is just not realistic for most Pharma-CMO relationships. Certainly, you may be in the fortunate position of being a priority customer for a small number of your CMOs, but it is unlikely to be the case for all of them.

This is particularly true if, as is sometimes the case, a CMO is in fact a Pharma company themselves. In this situation, there may be two issues playing against you as the customer:

- As a contract supply product, your supply is often low margin and low priority for the supplying Pharma company.

- Pharma companies are typically not well set up with respect to serialisation and more so to service a model where they are the CMO, as this is different to a model to where they are the customer.

Planning on the basis of a realistic expectation of the CMO's view of your business will help avoid unnecessary supply risks.

Key learning 5: Use risk management to focus resource application

It is unlikely that you will have enough of the right resource to manage all CMOs in the same way and mitigate all risks entirely. Therefore, managing the portfolio of CMO-integration projects using a risk-based approach will give you an effective way to focus resource where it will pay the highest dividends.

Different companies will measure business risk in different ways, but the principle of applying most resource to mitigate the highest business risks is likely a sensible approach. However, it must also be recognised that this approach comes with a downside. Such a focusing of resource will mean that some areas of the programme will have a higher probability of some degree of failure. Management need to recognise this and work with their teams to ensure they understand where compromise is acceptable.

Key learning 6: Make sure you assess each CMO's capability and capacity to deliver

Our experience suggests that just because a CMO claims they can deliver, the Pharma company customer should not take this at face value, unless failure does not matter in the bigger scheme of supply risks.

The majority of CMOs are stretched to achieve serialisation and are relying, in a large part, on the same over-stretched supplier base as everyone else.

Furthermore, CMOs being lower-margin businesses than the typical Pharma company, are run much more leanly than the typical Pharma company. This typically exposes Pharma companies to delivery risk levels that may not be acceptable to them.

An assessment of any CMO's likely ability to deliver can be made to help understand this risk and actively decide if and how to mitigate it. Areas of assessment can include:

- Overall approach and plans
- Key skills
- Subject matter expertise

- Project management
- Quality and validation
- Supplier capability
- Internal and external resource capacity

In part 2 I will share six further learnings, relating to the considerations Pharmas must make to their own processes and resources when working with CMOs.

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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AVOIDING THE SUPPLY RISK FROM SERIALISATION WITH CMOS: PART 2

By Stephen McIndoe - VP of Be4ward

Welcome to part 2 of my *Key Learnings on Avoiding The Supply Risk From Serialisation With CMOs*. In part 1, I introduced the first six learnings, looking at the unique relationship between Pharmas and their CMOs. Here in part 2 I consider six more learnings, focussed on processes and resource within the Pharma company.

Key learning 7: Make sure you have sufficient Plan Bs

Given the immature and evolving nature of serialisation and the over-stretched supply base, things are undoubtedly going to go wrong.

Any successful CMO implementation programme is going to rely on one or more alternative solution in order to get to the finish line successfully. Some of these alternatives will likely be tactical in nature and require subsequent projects to make them good.

A Pharma company would be well advised to plan key mitigation options ahead of time, as these may require specific capabilities being put in place ahead of time. Furthermore, there needs to be a clear and timely decision process in place to trigger the implementation of any ‘Plan B’, adapted plans and redeploy resources accordingly.

Key learning 8: Ensure you have a cross-functional team on this from day one

There are many interdependent decisions to be made and multi-functional activities which need to be done for any single CMO implementation to be successful. This is a cross-functional activity, typically including representatives from a number of groups, including:

- External manufacturing
- Serialisation
- Key serialisation vendors
- Packaging engineering and technology
- Supply chain management and planning
- Regulatory affairs and artwork management
- Quality
- IT Technical to create/manage technical interfaces
- Computer system validation
- Procurement and legal
- Finance

Making sure that all these stakeholder groups within your organisation are engaged early and understanding their role and the resource levels that will be required is key to success. Then, for each individual CMO integration project, the identification of the cross-functional teams from each organisation need to be agreed, as well as how they will effectively communicate with each other.

Key learning 9: Don’t believe that the software vendors can sort this out for you

One of the things that must be done for serialisation to be successful is the interfacing of two or more IT systems. Your serialisation system(s) must talk to each CMO system(s) in near-real-time.

As part of their sales ‘promise’, the enterprise (Level 4/5) serialisation system vendors may lead you, or members of your team, to believe that they manage the whole CMO integration process for you. Whilst your system vendor undoubtedly plays an

instrumental role in making the system interface(s) happen, the scope of any one CMO integration is far more than just connecting two IT systems. Often the interface will need additional master data to be exchanged and you need to understand and agree any master data impacts.

Furthermore, even if the scope was just limited to connecting two IT systems, the decisions that go into the underlying business processes and information passed between the systems has implications far beyond IT alone.

Key learning 10: Standard ways of working are valuable, but only guidance for wise men

Given that there is a significant amount of repeat work involved with integrating multiple CMOs, there is no doubt that having a standard, template model for the way in which you intend to deal with each CMO is an excellent starting point.

However, given that each company involved in this endeavour has their own set of external and internal constraints, the actual way of working with each CMO needs to be adapted to suit the particular situation. The project teams need to recognise this and tailor ways of working and plans to deliver the best compromise for all involved.

In our experience the discussions between CMOs and customers need clear leadership, making sure that you have the right person leading the discussions.

Key learning 11: Make sure that there is enough of the right resource engaged on the problem

Projects are only successful if there is enough of the right resource available at the right time. Serialisation is certainly no different.

Furthermore, because of the different organisations involved in each CMO integration and the immature and evolving nature of serialisation, it is likely that repeat activity will show some improvement in efficiency however, perhaps not as much improvement as might otherwise be expected.

The other significant issue with serialisation over the next few years is the fact that the experienced serialisation resources and the equipment and IT system vendors will be highly stretched to meet the demand.

Key learning 12: Make sure your internal RACI is clear

For the purposes of this discussion, by RACI we mean ensuring that everyone understands who has: *Accountability*, to make sure a decision happens; *Responsibility* for doing the work; those who must be *Consulted* before decisions can be taken and finally those that must be *Informed* when a decision has been taken.

There have been many years of industry practice and often internal experience to agree how the typical external supply decisions are made and captured. Serialisation is an area where everyone is learning as they go along and therefore, there is no commonly understood ‘playbook’.

Decisions associated with a serialisation integration will fall in to a number of areas, including:

- Relationship and contractual
- Serialisation design
- Quality and validation
- Implementation timing and coordination
- Funding

Furthermore, serialisation tends to fail in the detail, as several IT systems need to be connected in near-real-time. As experience with IT probably tells you, if the details are not exactly correct, then such connections simply do not work.
This is a new area, so sorting out the RACI for decisions is a way of ensuring that the overall impact of any individual decision is understood and agreed and this is key to success. Often the team will include two third party software suppliers — the customer’s and the CMO — it is critical that these resources are identified in the RACI.

In the third and final part of this blog series I will look at the final six learnings from our experience of working with CMOs, relating to your internal teams, template models and protocols, programme management and preparing for future change.

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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Managing Clinical Trials Artwork Part 2 – Opportunities to Leverage the Commercial Artwork Process

Andrew R Love

In part 1 of this blog series, I discussed some key considerations in the development of an artwork process to support clinical trials. The clinical trials artwork process needs to deliver accurate and repeatable artwork in a fast changing and dynamic environment. The need for both rigour and flexibility provides challenging requirements for the process.

A clinical trials labeling capability is often developed in isolation, however most pharmaceutical companies have a complementary process and associated capabilities for managing commercial artwork for marketed products. There are opportunities to leverage aspects of this commercial process and capabilities in the development of the process and capabilities for clinical trials.

Firstly, considering the design of the clinical trials artwork process, where the company has developed an end-to-end commercial artwork process, this can be used as a base-on for the design of the clinical trials artwork process. At a high level, the basic steps and outcomes from associated decision gates are similar:

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

An effective commercial artwork process brings benefits in terms of rigour, data management and version control, however in the detail there are a number of things that would need to be considered in order to adapt it for clinical trials:

• Is the format of the text provided specific to clinical trials (rather than the Company Core Datasheet or approved regulatory text) and sourced from different teams?
• The clinical trials process may not be covered by the company change control process so approval requirements may differ. If so, how would the requirements for the change be communicated and could existing briefing documents be used?
• How are clinical trial packaging component numbers managed?
• Where local or on-line printing of components is undertaken, is there a requirement for a printer proof? If some printed components are purchased and a printer proof required, how is that process variant incorporated?
• How is the final component inspected before use?
• Who are the approvers of the text, the change, the artwork and the components?

The likely outcome is a set of specific clinical trials workflows to execute the various clinical trial artwork process scenarios that are similar, but not identical, to the commercial artwork workflows.

Beyond the process, there are also opportunities to exploit the IT capabilities underpinning the commercial artwork process:
• Data management, workflow and performance management tools can all be used to support the clinical trials workflows providing higher levels of control, secure communication and effective document control and version management. However it needs to be remembered that moving into a more controlled and rigorous environment can impact flexibility.
• Specialist tools for artwork creation, proof-reading and component verification can also be beneficial, providing company standards solutions and automating manual tasks. Any tool used needs to be compatible with the file formats required for any local or on-line printing.
• Portals provided for communication with external partners allow secure communication to clinical trials partners.

In all cases the benefits of the use of IT tools in providing more control need to be considered against the restrictions, maintenance and user change involved in operating in such an environment.

From the above it can be seen that there are benefits in using the commercial artwork process as a base-on for the clinical trials artwork process, but it is essential to understand the differences required and design the processes and supporting tools to ensure these differences are catered for. There isn't a 'one size fits all', but there are enough similarities to permit some leveraging of tools and capabilities.

In my next post I will discuss some of the pitfalls to avoid in developing your clinical trials artwork process.

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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Managing Clinical Trials Artwork Part 3 – The Pitfalls to Avoid

Andrew R Love

In part 2 of my blog series, I discussed some key considerations in using the commercial artwork process as a base-on for the clinical trials artwork process. In doing this, it is essential to understand the differences required as there isn't a 'one size fits all' process, but there are enough similarities to permit some leveraging of tools and capabilities. However, in developing a clinical trials artwork capability, particularly when exploiting aspects of the commercial artwork tools and capabilities, there are a number of pitfalls to be aware of and avoid.

The first pitfall to consider is the **design of the packaging artwork**. Commercial artwork includes graphic design for brand logos etc. whereas clinical trials artwork tends

to be a simpler artwork design with a very plain box. It is important that artwork operators appreciate the reasons for the differences.

The second pitfall concerns the process rigor inherent in the **commercial artwork process**. As discussed before, this can bring benefit in increased accuracy and repeatability, but can often be at the cost of speed and flexibility. It is important to ensure that the process performance requirements are clear, designed-in and achievable, particularly with the required change volume and turnaround speed. These differences will likely require slightly different workflows designed into your processes and IT systems which will require management. Introducing change to these workflows will be more complex in the highly controlled environment required for the commercial artwork process. It is therefore important to ensure that the appropriate mechanisms for process lifecycle management are clearly defined and capable of maintaining the required levels of process effectiveness and compliance.

In some cases it may be most appropriate, where sharing IT tools with the commercial artwork process, to create the clinical trials artwork process in an independent instance of the IT tool. This will depend on the design requirements of the artwork processes, the functionality of the tools and the infrastructure design.

The next pitfall to consider is where **on-line printing** is being used, as the artwork may have to be specifically laid out to suit the requirements of the printer by the artwork operator and held in different file formats. Furthermore, it may be necessary to interface to the on-line systems to transfer the print files.

Management of required workload is the next pitfall to consider. The visibility of required artwork change volumes in the commercial artwork process is always a difficulty, but in clinical trials this is even more acute. It is therefore essential that sufficient capacity is available in all impacted teams, to process the volume of changes required. There is an added degree of complexity where teams are shared between the commercial and clinical trials artwork processes, as capacity will be required for both and appropriate prioritisation and dispute resolution processes will be needed. This is further compounded where external service providers are used and service level agreements must reflect the performance requirements of both processes.

Performance requirements raise another pitfall to consider as the performance requirements of the commercial and clinical trials artwork processes will likely be similar but subtly different. It is therefore essential that the defined KPIs and targets reflect the requirements of each process.

The **organisational scope** of the clinical trials artwork process introduces the final two pitfalls to consider.

Firstly, the process will involve new groups and people independent to the commercial artwork process, both inside and outside of your company. The requirements for education and training, IT system access, competency assessment and ongoing refresher training and updates all bring a maintenance overhead and cost.

Secondly the involvement of these groups will require changes to governance and leadership to ensure these new parties are appropriately represented in decision making and issue resolution.

From the above it can be seen that there are pitfalls to consider if using the commercial artwork process as a base-on for the clinical trials artwork process, and it is essential to understand these sensitivities to ensure a suitable capability is provided.

In my next post in this series, I will discuss how to develop your clinical trials artwork process.

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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