Trusted Experts in Serialisation Labeling and Artwork

We have received lots of great customer feedback about our newsletter to include some past articles and more industry news. Therefore, along with our current Be4ward posts, we have also included a Be4ward Executive Briefing, 'Executive Briefing Avoiding the supply risk from serialisation with CMOs' compiled from previous posts. We have also selected some Top News Picks from the industry that we think are worth reading.

Click the links to go to the articles, or scroll down to find them below.

We hope you will find this Be4ward industry newsletter interesting and we would welcome any feedback.

Kind regards,
The team at Be4ward

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Featured Artwork Posts

by Andrew Love

Packaging Complexity Management: Part 6

Tip 15: Packaging design

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

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.

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Packaging Complexity Management: Part 5

Tip 12: Manage order quantities of components and finished packs

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.

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Featured Serialisation Posts

by Stephen McIndoe

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10 Tips to Accelerate your EU FMD Serialisation Strategy: Part 3

Tip 8: Define and agree some governing principles for EU FMD

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

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

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Executive Briefing

Avoiding the supply risk from serialisation with CMOS

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, with out 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 are high.

Be4ward has been implementing serialisation with Pharma companies and CMOs for many years. We have written this document to capture some of our learning throughout that journey and hope it will be useful to you, the reader.

Read the Executive Briefing to learn more

Top 3 News Picks

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

Serialisation

Medium read

Serialisation and data connectivity – the new wrinkle in your supply chain

The United States drug market is comprised of a population of more than 330 million people. In terms of its attractiveness as a market for selling pharmaceutical therapies, it is valued at $358 billion annually and represents approximately 44% percent of the total global pharmaceutical market. Pharmaceutical companies operating in the United States are now expected

to have taken initial steps in securing their supply chain, complying to the Drug Safety and Supply Chain Act (DSCSA) effective November of 2017. The US Food and Drug Administration provided a grace period, opting to defer enforcement of penalty for noncompliance until the fast approaching date of November 2018.

Click here to read the article

Labeling and packaging

Short read

Brexit will impact drug packaging, and many pharma firms are unaware

If drug makers change their drug's batch release site or have to reapply for a marketing authorisation, they will need to repackage their drug making this Brexit's biggest impact on pharma companies, said Lynne Byers, Executive Director of NSF International's pharma biotech services.

Currently, new drugs are approved in the EU by a mutual recognition procedure (MRP) whereby a single EU country assesses the product and awards a marketing authorisation , which then holds for all EU countries.

Click here to read the article

Counterfeit

Short read

Global crackdown seizes £10m of counterfeit medicines

UK authorities have intercepted more than a million doses of drugs worth £2million as part of a global crackdown on fake drugs and medical devices.

The UK confiscations were part of Interpol's Operation Pangea initiative involving 116 countries. Between October 9 and 17 the Medicines and Healthcare Regulatory Agency (MHRA) and UK partners found falsified and unlicensed medicines and medical devices in the UK including the sedative diazepam, modafinil, a drug to treat narcolepsy, and dermal fillers.

Click here for details on the event

Featured Serialisation Posts

10 Tips to Accelerate your EU FMD Serialisation Strategy: Part 3

Tip 8: Define and agree some governing principles for EU FMD

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

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

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

Tip 9: Implement effective cross-functional governance for EU FMD

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

A cross-function governance team should therefore be established to steer the definition, establishment, ongoing delivery and development of the overall serialisation service across the multiple stakeholder groups involved.

This governance body should include membership from all of these stakeholder groups involved in the processes, including where appropriate, external service providers. Typical activities that would be included in the role of your EU FMD Serialisation Governance Team include ensuring:

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

Tip 10: Understand how to start planning your EU FMD serialisation strategy

As a place to start the planning your EU FMD serialisation strategy, I would recommend a small focussed piece of work which has the following objectives:

- Understand the issue as it relates to your business.
- Understand the likely impact across your organisation.

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

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

Summary

I hope you found these 10 tips on accelerating your EU FMD serialisation strategy both useful and helpful. Here are some key learnings that should be borne in mind when defining your EU FMD serialisation strategy:

- Recognise the significant supply risk and manage it accordingly, establishing senior cross functional governance early.
- Mobilise your regulatory, legal and technical teams to establish effective access to, and interpretation of, the emerging legislative and technical standards.
- Actively interpret the evolving requirements and standards for the organisation using tools such as the ‘Target Response’.
- Establish a programme of activity to build organisational and extended supply chain capability.
- Be realistic about the emerging nature of these capabilities and build in adequate time and resource to effectively test and iterate solutions.
- Design serialisation activities to closely couple related actions to minimise the possibility for errors due to abnormal events.

- Design both the normal processes and the regularly occurring non-standard events to avoid product supply quickly grinding to a halt.
- Ensure cross-functional teams are established to carefully design the interfaces between departmental and organisational boundaries.
- Ensure adequate time is allowed for packaging design changes to be made to accommodate serialisation features required.
- Be cautious about suppliers who have little practical experience in this area.

It is crucial that your company has a comprehensive, robust and realistic plan in place to deliver EU FMD serialisation and avoid product supply issues. If you don't have such a plan in place, act now – contact Be4ward to understand how we can help deliver your strategy and plan quickly, with minimal impact to your team. Should you have any questions about the EU FMD legislation, or would simply like to request a copy of any of our serialisation booklets, please don't hesitate to contact me at Stephen.McIndoe@be4ward.com

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Featured Artwork Posts

Packaging Complexity Management: Part 6

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.

In this blog series I will describe key features of a complexity management capability in an easy to digest format. I hope you find this information useful. We are always searching for ways to improve our work, so if you have any feedback, please do not hesitate to contact me at Andrew.Love@be4ward.com.

Packaging Complexity Management Tip 15: Packaging design

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

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.

Packaging Complexity Management Tip 16: Build flexibility into packaging equipment

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

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 re-equip 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.

Packaging Complexity Management Tip 17: Reduce line change-over time

Have you maximised your opportunities for fast changeover?

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 start-up, 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.

This is the sixth of a series of 7 blogs giving a view of methods to deal with packaging complexity. Should you have any questions about this or any of my other blogs, or would simply like to request a copy of my booklets, please don't hesitate to contact me directly on my email.

Andrew.love@be4ward.com

Read it online

Packaging Complexity Management: Part 5

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.

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Packaging Complexity Management Tip 12: Manage order quantities of components and finished packs

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

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.

Packaging Complexity Management Tip 13: Postponement

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

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 into 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.

Packaging Complexity Management Tip 14: Late customisation

Can you late customise components and products?
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 pre-glued) 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?

This is the fifth of a series of 7 blogs giving a view of methods to deal with packaging complexity. Should you have any questions about this or any of my other blogs, or would simply like to request a copy of my booklets, please don't hesitate to contact me directly on my email.

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