Trusted Experts in Serialisation Labeling and Artwork

Dear << Test First Name >>,

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, 'Top 10 Right-First-Time Tips to Streamline and Improve Your Artwork Process' 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 4

Tip 9: Share components or packs

Shared components and packs can provide a great opportunity to increase component and pack volumes. However to make this happen it is necessary to identify markets and products that can successfully share components or packs.

There are a number of criteria that you should consider when looking to group markets for sharing. These include geography, languages, regulatory rules, regulatory approval timelines, and sale price.

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Packaging Complexity Management: Part 3

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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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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10 Tips to Accelerate your EU FMD Serialisation Strategy: Part 2

Tip 4: Understand the immature and evolving solution supply base and select appropriate implementation partners for EU FMD

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

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Executive Briefing

Top 10 Right-First-Time Tips to Streamline and Improve Your Artwork Process

We all understand that packaging and artwork still present a significant compliance risk and delivering right-first-time artwork is a complex endeavour involving many moving parts. Furthermore, being right-first-time increases speed, reduces waste and raises confidence.

From this booklet, we can see that achieving high right-first-time is doable, but there are many parts to be addressed, requiring focus and persistence. As such, right-first-time is as much a mindset as an outcome.

Tip 1: Measure your right-first-time — if you don't measure, you don't manage

Tip 2: Use codes to categorise errors, then ensure a thorough root cause analysis to eliminate source of errors

Tip 3: Make sure all of the input information is correct before starting

Tip 4: Ensure there is a comprehensive and effective end-to-end process with clear roles and responsibilities

Tip 5: Make sure the right quality of checks are undertaken by the right people

Tip 6: Ensure all people in the process have the appropriate skills, competencies and capabilities through effective training

Tip 7: Ensure there is effective cross-functional governance

Tip 8: There needs to be an appropriate and scalable suite of IT tools to support the process and people working with it

Tip 9: Ensure there is quality time and quality facilities to do quality work

Tip 10: You need to have the right culture, displayed across all teams involved in the end-to-end process to ensure success

Learn more and read the Executive Briefing

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.

Pharma recalls

Short read

Pharmaceuticals: the bad, the good and the ugly

During the month of August, everything from homeopathic medicines and a micro-stent to baby oral gels and children's pain reliever were identified on FDA's online list of voluntary recalls, market withdrawals, and safety alerts.

Click here to read the article

EU FMD

Short read

Turkish Pharmaceutical Firm Set to Meet FMD Compliance Deadline

For Istanbul, Turkey pharmaceutical company Abdi Ibrahim, its business focus centers around the “healing journey.” The company produces antianemic, antibacterial/antiviral, dermatology, endocrine, metabolism, gastrointestinal, cardiovascular, NSAI and myorelaxants, ophthalmology, central nervous system, respiratory and urogenital system products, as well as food supplements, vitamins and minerals from 13 different therapeutic areas.

Click here to read the article

US Conference

BSMA Conference – Foster City, CA

The Bio Supply Management Alliance (BSMA) will come together again on October 11th, 2018 in Foster City, California. BSMA was born for the need to create a worldwide community of operations and supply chain management leaders and professionals in the biotech, biopharma, and biomedical device industries.

Click here for details on the event

Featured Serialisation Posts

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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

Read it online

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10 Tips to Accelerate your EU FMD Serialisation Strategy: Part 2

Tip 4: Understand the immature and evolving solution supply base and select appropriate implementation partners for EU FMD

Serialisation legislation is relatively new to the pharmaceutical industry and therefore the solutions available from the supply base are correspondingly

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

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

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

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

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

Tip 6: Compare your global and local requirements for EU FMD

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

Firstly, there is a need to consider what is being standardised. There are some elements of the strategy and resultant solutions that need to be defined, built and operated at a global level so that all supply chain nodes can be supported. Other capabilities may need to have globally defined standards, but the build and implementation can be addressed locally. In other cases, it may be appropriate to direct all of the activity to local teams if

there is no network-wide impact from locally generated solutions. Typical topics where the degree of standardisation needs to be considered include:

- Policy
- Requirements
- Solution Selection
- Design
- Build
- Test/Validate
- Implement
- Operate
- Support

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

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

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

Tip 7: The need for flexibility beyond EU FMD implementation

Serialisation legislation and responses are emerging across the globe from multiple different parties. Whilst often based off standard building blocks, the detail of the requirements shows significant variation. Whilst this is frustrating

and a global set of common standards and solutions may be more cost effective, it is the reality of the situation and companies need to develop solutions to cope with it. Therefore, many companies have held back from progressing their EU FMD serialisation projects for fear of developing the wrong solutions or backing the wrong technologies.

Furthermore, capabilities required to deliver additional benefits from serialisation capabilities installed initially to meet legislative requirements also need to be considered.

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

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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Packaging Complexity Management: Part 4

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 9: Share components or packs

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

Shared components and packs can provide a great opportunity to increase component and pack volumes. However to make this happen it is necessary to identify markets and products that can successfully share components or packs.

There are a number of criteria that you should consider when looking to group markets for sharing. These include geography, languages, regulatory rules, regulatory approval timelines, and sale price.

Choosing markets to share products needs to be considered carefully as it requires close collaboration between those markets when changes are being implemented. Therefore it is better to have consistent groupings of markets rather than vary the sharing groups by different product. Standard market

groupings also simplify the ‘where used’ assessment during the change impact assessment.

A significant challenge with shared packs comes when there are different approval timelines or locally driven changes. This can result in more than one version of the shared pack being required; effectively driving you back to market specific packs.

Packaging Complexity Management Tip 10: Bundle changes

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

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.

Packaging Complexity Management Tip 11: plan for runners, repeaters and strangers

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

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.

This is the fourth 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

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Packaging Complexity Management Tip 6: Control platform sizes

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

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 you 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.

Packaging Complexity Management Tip 7: Standardise artwork templates and layouts

Are there standard templates and layouts for artworks?
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.

Packaging Complexity Management Tip 8: Minimise fonts, illustrations and graphical elements

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

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.

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