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, '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

Featured Artwork Posts

by Andrew Love

Right-first-time tips 8 and 9: Ensuring appropriate IT support, quality time and quality facilities to do quality work

I believe right-first-time is a key metric and mindset for your artwork process and in this article, I continue my series on top tips to improve it, looking at tip 8, ensuring there is an appropriate and scalable suite of IT tools to support the process and the people working with it, and tip 9, ensuring there is quality time and quality facilities to do quality work.

Read it online

Right-first-time tip 10: Ensuring you have the right culture to succeed

In this, the last article in the series, we will look at the importance of Culture and then summarise the series. Looking first at tip 10 on culture, you need to ensure you have the right culture, displayed across all teams involved in the end-to-end process, to ensure success.

Read it online

Featured Serialisation Posts

by Stephen McIndoe

Be4ward Answer Crucial Questions Surrounding EU Falsified Medicines Directive (FMD) Pharma Artwork Compliance in Visual E-Guide

The global pharma market faces unprecedented complexities and pressures regarding the packaging and labelling of medicinal products. This guide examines the changes required for pharmaceutical packaging to meet the

requirements of EU Falsified Medicines Directive (FMD) and the crucial questions to ask in order to achieve compliance. This guide includes areas such as; EU FMD packaging related requirements, broader organisation and supply chain implications, unique identifiers (UID), anti-tampering solutions and artwork design implementation guidance.

Read it online

Avoiding The Supply Risk From Serialisation With CMOs: Part 1

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.

Read it online

Executive Briefing

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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.

Key learning 1 Be realistic about the real flexibility the CMOs have
Key learning 2 Be realistic about what CMOs are really going to pay for
Key learning 3 Understand the CMO's decision making process
Key learning 4 Be realistic about your CMOs view of your importance to them
Key learning 5 Use risk management to focus resource application
Key learning 6 Make sure you assess each CMOs capability and capacity to deliver
Key learning 7 Make sure you have sufficient Plan Bs
Key learning 8 Ensure you have a cross-functional team on this from day 1
Key learning 9 Don't believe that the software vendors can sort this out for you
Key learning 10 Standard ways of working are valuable, but only guidance for wise men
Key learning 11 Make sure that there is enough of the right resource engaged on

the problem

Key learning 12 Make sure your internal RACI is clear

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

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

Key learning 15 Ensure there are repeatable test protocols in place

Key learning 16 Separate capability implementation from product cut-over

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

Key learning 18 Recognise and cater for ongoing change

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.

EU MDR Update

Short read

Final EU MDR, IVDR Texts Published, Countdown to Implementation Begins

The final texts of the new European medical device and in vitro diagnostic (IVD) regulations were published on Friday in the Official Journal of the European Union, setting in motion the timeline for implementation of the new regulations to commence on 25 May.

Click here to read the article

Global Serialisation

Mid read

New Research Shows Companies Could Miss Serialization Deadlines

New industry research reveals that 36% of pharmaceutical manufacturers and contract packagers are not currently preparing for global serialization requirements, despite impending deadlines.

Click here to read the article

EU FMD Artwork Compliance

Long read

EU FMD Artwork Compliance Visual E-Guide: Crucial Questions

The global pharma market faces unprecedented complexities and pressures regarding the packaging and labelling of medicinal products. Ahead of the 2017 Packaging and Labelling Summit, this guide examines the changes required for pharmaceutical packaging to meet the requirements of EU Falsified Medicines Directive (FMD) and the crucial questions to ask in order to achieve compliance.

Click here to read the article

Featured Serialisation Posts

Be4ward Answer Crucial Questions Surrounding EU Falsified Medicines Directive (FMD) Pharma Artwork Compliance in Visual E-Guide

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This guide was recently published by Pharma Logistics IQ for IQPC's Pharmaceutical Packaging and Labelling Summit, 19 – 21 June 2017 in Zurich, Switzerland. Be4ward led the creation of this guide, in partnership with Schawk and Patheon. Stephen McIndoe, lead author of this guide and Serialisation Practice VP at Be4ward explains, 'We wanted this guide to be

useful to companies who are still looking for help with their EU FMD serialisation project. This guide is aimed to provide an awareness of the crucial questions companies should be asking.'

Download your free copy of the EU FMD Artwork Compliance Guide here

Be4ward advises companies on how to accelerate the process to meet the fast approaching EU FMD Artwork Compliance deadline. If you would like specific help on preparing for and/or implementing EU FMD Artwork Compliance in your company, please contact Stephen McIndoe on email at Stephen.mcindoe@be4ward.com or visit Be4ward's corporate website at www.be4ward.com

Be4ward has helped many pharma and biotech companies and their supply chain partners to define and implement end-to-end serialisation capabilities to both meet legislative requirements and deliver other business benefits. Be4ward also specialise in the areas of labelling and artwork. Be4ward deliver value to their clients through a combination of deep subject matter expertise and excellent consulting skills.

Be4ward's serialisation services include:

- Strategy development
- Ongoing legislation understanding and impact assessment
- Requirements development
- Independent solution supplier selection
- Detailed design
- Supply chain partner integration management
- Implementation support
- Validation services
- Support model design and implementation
- Project and program management

Be4ward is a niche consultancy company helping pharmaceutical, biotech and medical device companies and their supply base improve their

serialisation, labelling and artwork capabilities. Be4ward help clients define the most efficient business processes, organisation design and, being completely independent, help them select and implement the most appropriate service providers and IT systems to meet their needs.

If you would like to discuss your particular situation with regard to aggregation, or other aspects of serialization, please do not hesitate to contact me at Stephen.McIndoe@be4ward.com

Read it online

Avoiding The Supply Risk From Serialisation With CMOs: Part 1

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 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.

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

CMOs, like all organisations, have many constraints, both internal and

external, 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 immature 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 comes by 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 requirements-focused, Pharma companies are probably better to assume they will have to adapt to a number of different and relatively inflexible CMO serialisation models.

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

CMOs are relatively low margin businesses when 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 learnings 3: Understand the CMO's decision-making process

Following on from our discussion 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 learnings 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, often culturally, 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 learnings 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 program 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 learnings 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 leaner 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.

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

Read it online

Featured Artwork Posts

Right-first-time tips 8 and 9: Ensuring appropriate IT support, quality time and quality facilities to do quality work

I believe right-first-time is a key metric and mindset for your artwork process and in this article, I continue my series on top tips to improve it, looking at tip 8, ensuring there is an appropriate and scalable suite of IT tools to support the process and the people working with it, and tip 9, ensuring there is quality time and quality facilities to do quality work.

Looking first at tip 8 the need for appropriate and scalable IT tools.

There are a range of tools available to support artwork operations

I am not going to go through every tool in this blog but instead highlight some of the key types.

Document management and workflow tools allow you to manage your documents in a controlled electronic environment and route them to key users to perform the process tasks necessary. These tools sometimes also permit planning of artwork projects. Document review and approval tools allow users to view, comment and approve documents electronically (usually with an electronic signature). These above tools are the typical functionality of Artwork Management Systems.

Electronic proof reading tools allow you to electronically check text, graphics, barcodes, Braille and, depending on the package, other artwork elements. Artwork and drawing tools are typically used by artwork operators to generate artwork and engineers to create the profiles and templates for components.

Technology helps right-first-time

Two of the ways technology can assist with right-first-time is to automate activities and reduce opportunity for human error. A frequent source of error in a manual process is mistakes with document versions. An electronic

document management system can avoid this as they typically provide closed loop version management, automatically version-numbering iterations of a document and ensuring it is obvious which is the most recent version.

Human error is always a challenge when proof reading large documents which require long periods of focused attention. Electronic proof-reading tools can assist here by providing an electronic means of proofing that is consistent and accurate.

Technology presents some downsides that need to be considered

We often hear the same thing when we engage with a client that has undertaken a major technology project – 'We have implemented a new system but our right-first-time performance has not improved – why?'. The answer to this is pretty simple – application of technology is part of the solution, not the whole solution. If you look back through this set of articles, there are many things that need to be done to raise performance beyond technology: addressing process, people and organisational issues. Missing these means that you are unlikely to achieve an holistic outcome.

Another downside is that technology costs money, both in the initial cost of the tool and in implementation, maintenance and support requirements. We often find that people trying to implement systems look only at the initial license costs, which once you have considered project resource and validation costs and ongoing running costs, are a small part of the total lifecycle cost of a system. This total cost is often a surprise.

Finally, technology is used by people, and in the case of artwork systems, many of those people may use the system only occasionally (think of the regulatory staff in your different countries). So even a technology project is really about people, as you have to give them the motivation and capability to change and the education and training to be able to use the tools correctly.

Choose a strategy that fits with your needs

Therefore, in defining how to move forward with technology you need to consider the needs of your individual company. As a broad generalisation, the technology needs become greater the larger the size of your company. We typically measure this in the number of artworks required. If you have 360,000 artworks to manage you need some sophisticated capabilities. If you only have three, your approach can be much simpler. But remember that technology takes time to implement, so if you are growing fast you need to be thinking ahead.

Now let's turn to my ninth tip which is to make sure there are quality time and quality facilities to do quality work.

Leadership needs to take accountability for the performance of their function

Reviewing the right-first-time figures at the governance meeting, with sufficient root-causing activity, should highlight areas where the process just seems to 'get stuck'. Each representative then needs to work to resolve issues that have arisen in their areas of responsibility, in the interests of the whole artwork supply chain.

Quality time for quality work

We talked early in this series about the 'concertina' effect in artwork projects, where numerous rounds of rework occur but the deadline is fixed so work gets continually squeezed into faster and faster rework cycles. This is a downward spiral as the increasing pressure likely results in either shortcuts being taken or more errors being made. How often have you seen the situation where an artwork has to be sent out at 5pm on a Friday followed by a phone call asking if you have approved it yet?

One of the greatest benefits of achieving a high right-first-time is to get out of this whirlwind of rework and chasing. Schedules become more stable and

outcomes become more predictable. People get the quality time to do the quality work required because they don't have to do it again and again.

We often hear, 'Let's get the artwork started now because is takes forever'. Invariably this means starting without knowing all of the information – this is just a guaranteed way of generating rework. Surely the better way is 'Let's get all of the information together and correct and then do the artwork really quickly – ONCE!'

Quality facilities – a tidy desk is a tidy mind

Line clearance procedures in pharmaceutical packaging facilities are a critical quality process. Why? To avoid the risk of cross contamination of products or components from one batch to another.

The principle also applies to artwork. A routine source of error is when source information gets mixed up and the wrong documents are compared. This can be a particular risk when there are a number of strengths of a product being compared against a number of reference documents – it can be easy to be looking at a wrong combination. A clean-down of the workspace between each artwork should be undertaken.

Think about workplace design

Most artwork activity is desk-based in offices, but there are some specific facility requirements that should be considered. Proof reading and artwork review needs good lighting, space to lay out large documents and quiet areas. Many of the roles need two screens so they can be looking at an artwork and a set of instructions, or comparing two artworks.

Think about the facility and equipment needs of the people who undertake the tasks in your processes. If they don't have what they need, they will be unlikely to be able to do quality work.

In my next article, I will look at the last tip in this series, tip 10 looking at culture and then some summary points to conclude this series.

Read it online

Right-first-time tip 10: Ensuring you have the right culture to succeed

In this, the last article in the series, we will look at the importance of Culture and then summarise the series. Looking first at tip 10 on culture, you need to ensure you have the right culture, displayed across all teams involved in the end-to-end process, to ensure success.

Why think about culture?

So what do we mean when we talk about culture in the context of the workplace? Culture is a facet of the way people engage and behave towards each other. It is prevalent in the way people respond to instructions and rules. It affects the way people respond to different types of recognition and reward. Workplace culture is influenced by the different national and geographic cultures present in the workplace.

Culture could be considered as the informal rules in the workplace or 'the way things get done around here'. Therefore if you want certain behaviours from your team, you need to make sure you have a culture that promotes those behaviours.

What would define a winning culture?

There are lots of ways you could define your target culture. We typically use nine parameters as a starting point:

- Accountability
- Commitment and values
- Sharing of knowledge
- Team working
- Customer focus
- Continuous improvement

- Decision making
- Working under pressure
- Recognition

This list is not exhaustive but covers the key elements we consider most important. However, this isn't necessarily a list you can just lift and use. Many companies have culture and value statements at a corporate, if not also functional, level and so your target culture needs to align with these. This may impact the parameters you chose or the language you use.

Once you have agreed your parameters, you need to decide what good would look like for each. If you were displaying a successful outcome for each parameter, how would that manifest itself? How would it look at feel? Could you measure it? It is best doing this as a team exercise to build buy-in to the desired outcomes.

How do I get the right culture?

Once you have defined your target culture you can look at how you can achieve it. What is different from today and what will need to change to make that happen? Changing mindset and behaviours is difficult and takes time and perseverance. Do you need to change any management processes? Do you need to do team working training? Do you need to change the way people are measured? How do you reward for people who are doing what you want and what do you do about people who are not?

Your culture will not change automatically – you need to define the actionable steps that you will take to make it happen. Again, work with your team on this transition plan to build their buy-in..

The role of leaders in attaining the right culture

Leadership is key in realising and sustaining cultural change. Leaders need to express, model and reinforce the new culture you want to achieve. They need to role model the new behaviours – if they don't, people will not believe it is real. They need to be seen to actively promote the culture you want,

recognising teams and individuals who are displaying your new culture and behaviours. Therefore your target culture needs to align with the expectations of your governance, so you need buy-in from leadership as well as the teams involved.

Series summary

In this series of articles, we have covered a number of tips for how to improve your right-first-time. Summarising these, we have discussed:

Tip 1 – Measure your right first time.
Tip 2 – Use codes to categorise errors, then ensure a thorough root cause analysis to eliminate the 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 is 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 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.

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 series, 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 is as much a mind set as an outcome

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

Read it online

Be4ward® Trusted Experts in Serialisation Labeling and Artwork

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