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

Join our Webinar, EU MDR Labeling Compliance: Learn the Lessons from UDI

Join us 5-6 December 2017 for MedTech Digital Week, a 2-day series of live educational webcasts and downloadable resources on the latest EU MDR, IVDR and Emerging Market Regulation updates.

EU MDR is being viewed as an extension of the FDA's UDI (Unique Device Identification), but also a 'step up'. However, it's more detailed and more complex due to the local language requirements needed for Europe.

Read it online

Are you an Economic Operator as defined by EU MDR and IVDR? Do you understand your obligations under the legislation?

The new EU Medical Device and In Vitro Diagnostic Device regulations were approved by the European Parliament in May 2017. One aspect of the new legislation is the definition of an Economic Operator. This definition impacts a number of organisations involved in the supply of medical devices and the clarification of the obligations of each of these Economic Operators.

The new regulations are the biggest change to the legislative framework for MD and IVD products in decades. The impact on device manufacturers and other Economic Operators is significant, with new or changed requirements across the entire product lifecycle. Companies will need to implement many new or enhanced capabilities to meet these obligations.

Read it online

Featured Serialisation Posts

by Stephen McIndoe

Key Insights for Bio-Pharma Supply Chain at BSMA's 10th Annual Supply Chain Management Forum

'Driving Innovation and Technology in the Bio-pharma Supply Chain'

BSMA really are 'driving innovation and technology' with their latest conference. This year, the 10th Annual Supply Chain Management Forum took place in Foster City, CA on 12 October 2017. As a member of BSMA I had the opportunity to attend this excellent event. With more than 200 attendees, it was a great networking opportunity for supply chain thought leaders, supply chain managers and suppliers alike. Many thanks to Pam Gardner, Dave Malenfant, Devendra Mishra and the team at BSMA for organising this event.

Read it online

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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.

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.

Read it online

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.

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.

On-Demand Webinar

On-demand webinar

EU Falsified Medicines Directive: How to Develop a Comprehensive Plan with Rapid Implementation

Have you considered this in your 2018 plans? Join us, Optel Group and Verify Brand for an on-demand webinar about EU FMD and how to develop a comprehensive plan with rapid implementation. Stephen gives an overview of the EU FMD legislation -- where we are now, the implications of EU FMD on an organisation, and complex implementation scenarios pharma organisations may encounter. Stephen also covers the key elements of successful EU FMD planning and execution.

Click here to download the on-demand webinar

EU Medical Device Regulation

On-demand webinar

EU MDR Labeling Compliance: Learn the Lessons from UDI

Watch our on-demand webinar with Prisym ID, EU MDR Labeling Compliance: Learn the Lessons from UDI. As part of MedTech Digital Week, Be4ward joined the 2-day series of live educational webcasts and downloadable resources on the latest EU MDR, IVDR and Emerging Market Regulation updates. Specifically, on this webinar we discuss how EU MDR will change the medical device labeling landscape globally and how to best meet the impending challenges.

Click here to watch the on-demand webinar

Medical Devices

Article

3D Printing: FDA Finalizes Guidance for Medical Devices

The US Food and Drug Administration (FDA) have finalized guidance on medical device additive manufacturing, also known as 3D printing. The guidance finalizes the draft version from May 2016 and largely keeps intact the recommendations and considerations laid out in the draft.

Click here to read the article

Featured Serialisation Posts

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BSMA really are 'driving innovation and technology' with their latest conference. This year, the 10th Annual Supply Chain Management Forum took place in Foster City, CA on 12 October 2017. As a member of BSMA I had the opportunity to attend this excellent event. With more than 200 attendees, it was a great networking opportunity for supply chain thought leaders, supply chain managers and suppliers alike. Many thanks to Pam Gardner, Dave Malenfant, Devendra Mishra and the team at BSMA for organising this event.

As an example of one of the many successful moments at this conference, Kite Pharma – now owned by Gilead Sciences – won the Supply Chain Achievement Award for a very innovative supply chain. Congratulations to Kite on this well-deserved recognition. Kite is an industry leader in the emerging field of cell therapy, which uses a patient's own immune cells to fight cancer. Kite have developed a patient-manufacture-patient closed supply chain, a remarkable achievement considering the complete process takes between 14 – 16 days. To do this, they not only had to compress many manufacturing steps, but they also had to leverage many connected Information Technology systems to allow real time visibility and management of the end-to-end supply chain.

Overall this conference was a professional gathering of supply chain strategists and I look forward to attending future BSMA events. The next

event is currently being organised by BSMA Europe, taking place 25 May 2018, in Lausanne, Switzerland. Click here to keep up to date with the latest details.

Here's a list of other highlights from the latest US BSMA conference:

There were keynote addresses, presentations, and industry panels, a technology showcase (Multi-Track Break-Out Sessions) were presented by experts in the following areas:

- Blockchain: The Playbook for Life Sciences and Healthcare
- Offshoring for Lower Total Cost of Ownership
- Integrated Clinical Supply Chain Systems
- Cold Chain and Temperature-controlled Logistics
- Data Analytics for Bio-pharma Industry Transformation
- Digitalization and Cloud Technology for Healthcare
- Packaging for Clinical and Commercial Drugs

Bio Supply Management Alliance (BSMA) supports continuous learning and improvement of bio supply management professionals and the enhancement of the efficacy of the supply chain of the industry through collaboration. For 10 years, BSMA, the first industry initiative dedicated to bringing together the stakeholders of the global biotech industry supply chain, continues to foster its mission to accelerate the profitable growth of companies by developing, advancing, and disseminating best practices, knowledge, and research through collaboration and networking. This conference has been recognized to be the most informative, interactive, technology-enabling and solution-sharing event in the bio-pharma space where drug manufacturers lead, academia provide research and suppliers/service providers support.

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

serialisation, labelling and artwork capabilities. We 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. Be4ward helps these companies improve patient safety and drive additional value from their product range.

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

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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:

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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

Featured Artwork Posts

Join our Webinar, EU MDR Labeling Compliance: Learn the Lessons from UDI

Join us 5-6 December 2017 for MedTech Digital Week, a 2-day series of live educational webcasts and downloadable resources on the latest EU MDR, IVDR and Emerging Market Regulation updates EU MDR Labeling Compliance: Learn the Lessons from UDI

EU MDR is being viewed as an extension of the FDA's UDI (Unique Device Identification), but also a 'step up'. However, it's more detailed and more complex due to the local language requirements needed for Europe.

The introduction of UDI requirements into the EU is good news for organizations that are already along the pathway of adopting systems and processes to support FDA UDI compliance. However, for those that aren't – and indeed those that may have made only basic adjustments to their labeling infrastructure in response to the regulations – there are five key learnings that have emerged from the UDI experience that may help inform best practice adoption with EU MDR.

Join us for this 60-minute information packed webinar to discover why EU MDR will change the medical device labeling landscape globally and how to best meet the impending challenges.

Key Learning Objectives:

- Understand what EU MDR compliance means for your business and how it will affect your labeling processes
- Develop an understanding of the market's perceptions of EU MDR
- Recognize what the biggest labeling compliance challenges ahead are and how to proactively overcome them
- Embrace the lessons from UDI to work smarter in meeting the implementation deadlines of MDR by May 2020 and IVDR by May 2022
- Learn about a labeling system that can adapt to regulations that will be following for other countries that are not part of the US or EU, so that any new regulation does not have a similar size impact

Overview

Title: EU MDR Labeling Compliance: Learn the Lessons from UDI

Date: Tuesday, December 05, 2017

Time: 03:00 PM Greenwich Mean Time

Duration: 1 hour

Attend

This presentation will begin on Tuesday, December 05, 2017 at 03:00 PM Greenwich Mean Time.

Audience members may arrive 15 minutes in advance of this time.

REGISTER NOW

Speakers

Andrew Love
VP Capability Development
Be4ward

Andrew Love is a multi-award-winning packaging and artwork management strategist, leader and author. Andrew spent 10 years as head of global packaging design operations at GlaxoSmithKline, the world's second largest pharmaceutical company at the time. During his time there he oversaw the transformation of the global artwork management activities into a world-class, award-winning capability. Andrew is one of the founders of Be4ward which helps pharmaceutical, biotech and other healthcare companies and their supply base to improve patient safety and drive additional value from their product range. He now develops products for, and works with, a number of pharmaceutical and healthcare companies in achieving these aims. Andrew, a professional engineer and MBA with over 20 years of experience, has worked with many of the world's largest life-sciences companies.

Mark Cusworth
VP Research and Development
PRISYM ID

Mark Cusworth has over 15 years of experience heading up a team providing off the shelf and tailored solutions to Life Science companies. During this time, he has seen many changes to the industry including

significant tightening of regulations and challenges of globalization. His primary objectives are to target the ongoing investment in research, development and quality effectively and to lead the company in-house research and development to maintain the market leading position of PRISYM ID's world class label management software.

Be4ward is a niche consultancy company helping Pharmaceutical, Biotech and Medical Devices companies and their supply base improve their serialisation, labelling and artwork capabilities. Be4ward help clients define the most efficient business processes, organization design and, being completely independent, help them select and implement the most appropriate service providers and IT systems to meet their needs. Be4ward helps these companies improve patient safety and drive additional value from their product range. Corporate website: www.be4ward.com Contact: enquiries@be4ward.com

Read it online

Are you an Economic Operator as defined by EU MDR and IVDR? Do you understand your obligations under the legislation?

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The new regulations are the biggest change to the legislative framework for MD and IVD products in decades. The impact on device manufacturers and other Economic Operators is significant, with new or changed requirements

across the entire product lifecycle. Companies will need to implement many new or enhanced capabilities to meet these obligations.

Who are the organisations that are classed as Economic Operators?

Article 2 of the new regulations define an Economic Operator as:

'A manufacturer, an authorised representative, an importer, a distributor or the person referred to in Article 22(1) and 22(3)'

Article 2 then defines these four groups of organisations as:

''Manufacturer' means a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark.'

''Authorised representative' means any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer, located outside the Union, to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligations under this Regulation.'

''Importer' means any natural or legal person established within the Union that places a device from a third country on the Union market.'

''Distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting into service.'

Obligations of Economic Operators

Chapter 2 of the regulations includes a series of articles that detail the general obligations of:

- Manufacturers (Article 10)
- Authorised Representatives (Article 11)
- Importers (Article 13)

- Distributors (Article 14)

These articles set out, in a series of statements, the expectations of each of these Economic Operators with regard to the regulations. Organisations need to review these statements to determine if they, and their partners, will be in compliance with the new regulations, or if new or enhanced capabilities will be required.

Other types of Manufacturer

There are some further sub-categories defined within the scope of 'Manufacturer' over and above the traditional device manufacturer:

- Repackaging activities undertaken by Importers and Distributors (Article 16)
- Reprocessing of single use devices (Article 17)
- Providers of systems and Procedure packs (Article 22)
- Parts suppliers (Article 23)

Dependent upon the specific activities being executed by suppliers of any of the above, they could be subject to some or all of the obligations of manufacturers. To be compliant it is important to understand how your operations are affected by these requirements and what further actions you may need to take.

What do I need to do from here?

From the above it can be seen that companies will have to review the general obligation statements in relevant articles against their operations. The first step is likely to be a gap analysis of the requirements including:

1. Understand the general obligation statements from relevant articles in the new regulations.

2. A gap analysis of each relevant aspect of the company's operations against these statements.
3. Initial high level designs of potential new processes, capabilities and IT solutions.
4. High level roadmap for implementing new processes, capabilities and IT solutions.
5. Cost and resource impact estimation.
6. Plan for the next phase of activity.

This will then allow you to resource and execute the updates required.

It is important to consider the impacts on partner organisations as well as your own. Are there significant changes that they may need to make that can put supply of your products to customers at risk? May you need to change some suppliers to ensure your value chains remain compliant?

Summary

As can be seen from the above, it is essential to ensure you meet the general obligations from relevant articles in the new regulations. This needs to be a holistic approach considering which articles impact your operations and also where there are impacts on external partners. A detailed assessment and action plan will help ensure a successful outcome for your organisation.

References

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April on Medical Devices

About Be4ward

Be4ward has many years of experience in delivering large and complex legislative-driven change. We have written this document to capture some of our learning throughout that journey and hope it will be useful to you, the reader.

We hope you find this information useful and helpful. We are always searching for ways to improve our work, so if 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

GS1 The Global Language of Business | ISPE | Institute of Packaging Professionals | Institution of Mechanical Engineers Improving the world through engineering | IET The Institution of Engineering and Technology

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