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, '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

Featured Artwork Posts

by Andrew Love

[The clock is ticking on the new EU Medical Device and In Vitro Diagnostic Device Regulations]

Following approval in March by the European Council and in April by the European Parliament, the Medical Devices Regulation (MDR) – Regulation (EU) 2017/745 – and In Vitro Diagnostic Medical Devices Regulation (IVDR) – Regulation (EU) 2017/746 – were published in the Official *Journal of the European Union* on 5th May 2017. Both Regulations entered into force on 26 May 2017, hence the new MDR rules will apply from 26 May 2020 and the IVDR rules from 26 May 2022.

Read it online

IQPC Pharmaceutical Packaging and Labelling Summit, 20 and 21 June, Zurich

I had the opportunity to attend, chair and present at the IQPC Pharmaceutical Packaging and Labelling Summit in Zurich on 20 and 21 June. Many thanks to Katherine Gordon and the team at IQPC for organising the event.

I presented on *The Implications of the New EU Medical Device Regulations on Combination Product Packaging*.

Read it online

Upcoming webinar on EU MDR compliance

Join us for this 60-minute information packed webinar on **Bridging the Gap – How to be EU MDR Labelling Compliance Ready by Using the Lessons Learnt from UDI** to discover why EU MDR will change the medical device labelling landscape globally and how to best meet the impending challenges.

Be4ward will present at this webinar **Bridging the Gap – How to be EU MDR Labelling Compliance Ready by Using the Lessons Learnt from UDI**. The webinar will take place on Thursday 20 July, 2017, at 4pm GMT / 11am EDT. We hope to see you there. For more information and to register for this webinar, click here.

Read it online

Have you developed your strategy to address the new EU MD and IVD Regulations?

The new EU Medical Device and In Vitro Device Regulations are here and companies need to be deciding how they will address them. Approved by the European Parliament in May 2017, these new regulations are the biggest change to the legislative framework for MD and IVD products in decades. As discussed in my previous blog on the subject, 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

Avoiding The Supply Risk From Serialisation With CMOs: Part 2

Key learnings 7: Make sure you have sufficient Plan Bs

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

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

Read it online

Avoiding The Supply Risk From Serialisation With CMOs: Part 3

A small number of key individuals in any project need to understand how both aspects are going to work. All too often, we see situations where nobody understands the overall picture at a sufficient level of detail, but many members of the team can identify unresolved issues. In these cases, projects typically fail, or at best, are late and over budget. A small number of key individuals in any project need to understand how both aspects are going to work. All too often, we see situations where nobody understands the overall picture at a sufficient level of detail, but many members of the team can identify unresolved issues. In these cases, projects typically fail, or at best, are late and over budget.

Read it online

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.
We hope you find this information 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.

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.

EU Falsified Medicines Directive (FMD)

Short read

Avoid supply interruption, make sure you have robust, realistic plans to address Feb 2019 EU FMD requirements

The countdown is well under way, with significantly less than two years until the EU Falsified Medicines Directive (EU FMD) serialisation compliance deadline – will your company be ready in time?

Click here to read the article

Global Serialisation

Mid read

Adapt or Die

As companies within the pharmaceutical supply chain near the November 27, 2017 deadline for the most recent phase of DSCSA compliance, contract packaging operations with comprehensive serialization implementation programs will see their business increase due to the new requirements.

Click here to read the article

EU Medical Devices Regulation

Long read

6 Things You Need to Do to Prepare for the New EU Medical Devices Regulation
When the EU's new *Medical Devices Regulation* (*MDR*) entered into force last month, it set in motion a three-year countdown to the new rules' full application in 2020. For companies marketing devices in the EU that wish to continue to do so, there is a lot to do in that relatively short time, so it is critical to begin as soon as possible. Early preparation is key. Following are six things you should be doing to get ready.

Click here to read the article

Featured Serialisation Posts

Avoiding The Supply Risk From Serialisation With CMOs: Part 2

This is the second part of my Key Learnings on Avoiding The Supply Risk From Serialisation With CMOs. To see Part 1, please click here.

Key learnings 7: Make sure you have sufficient Plan Bs

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

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

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

Key learnings 8: Ensure you have a cross-functional team on this from day 1

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

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

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

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

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

As part of their sales ‘promise’, the enterprise (Level 4/5) serialisation system vendors may lead you, or members of your team, to believe that they manage the whole CMO integration process for you. Whilst your system vendor undoubtedly plays an instrumental role in making the system interface(s) happen, the scope of any one CMO integration is far more than just connecting two IT systems. Often the interface will need additional master data to be exchanged you need to understand and agree any master data impacts.

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

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

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

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

In our experience the discussions between CMO and customers need clear leadership to make sure that you have the right person leading the discussions.

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

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

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

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

Key learnings 12: Make sure your internal RACI is clear

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

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

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

- Relationship and contractual
- Serialisation design

- Quality and validation
- Implementation timing and coordination
- Funding.

Furthermore, serialisation tends to fail in the details, as several IT systems need to be connected in near-real-time. As experience with IT probably tells you, if the details are not exactly correct, then such connections simply do not work.
This is a new area, so sorting out the RACI for decisions in a way that ensures the overall impact of any individual decision is understood and agreed is key to success. Often the team will include two 3rd party software suppliers — the customer's and the CMO — it is critical that these resources are identified in the RACI.

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can identify unresolved issues. In these cases, projects typically fail, or at best, are late and over budget.

This is the third part of my Key Learnings on Avoiding The Supply Risk From Serialisation With CMOs. To see Part 1, please click here, or to see part 2, please click here.

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

As with all projects, there are two principle aspects of a CMO integration that need to be worked out:

- How is the end-to-end final result going to work? — the 'To-Be' design.
- How are the team going to get from where they are to the end result? — the Project design.

An example of a critical area would be the integration of your quality system to those in each of your CMOs. A small number of key individuals in any project need to understand how both aspects are going to work. All too often, we see situations where nobody understands the overall picture at a sufficient level of detail, but many members of the team can identify unresolved issues. In these cases, projects typically fail, or at best, are late and over budget.

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

Ultimately, serialisation is about maintaining an information view of what is happening in the physical (product packaging, movement and consumption) supply chain. Furthermore, this information typically needs to be shared across several locations, organisations and IT systems to work correctly.

To work at all, this information and the way it is communicated needs to be entirely consistent to the finest level of detail across the end-to-end supply chain. This is not to say that individual data items or message methods need to be exactly the same across the end-to-end supply chain, as the likes of middleware can accommodate a degree of data and message format transformation. However, in order for this transformation to work successfully, the underlying data needs to be consistent and transformable using simple rules, across the end-to-end supply chain.

Unfortunately, whilst standards exist for a significant portion of these information and messaging requirements, several issues arise, including:

- Legislation requirements that are not all consistent across countries.
- Standards, when applicable, that do not cover the full scope of the problem.
- Standards, where they exist, that sometimes leave many options as to how specific processes and information communication can be done.
- Different equipment and IT solutions that have different constraints placed on the way in which information can be represented and communicated. This is particularly true in the relatively immature area of serialisation.

Key learnings 15: Ensure there are repeatable test protocols in place

Not only are there many system connections and product implementations to perform in a typical serialisation program, but there are also many changes that will be needed along the way as well.

There are not only many systems involved, but each of these systems will typically have a number of environments through which any changes need to be propagated, e.g. development, testing and production environments.

Given the relatively immature nature of serialisation and the over-stretched nature of the supply base, the opportunities for error in coordinating all these changes is plentiful.

The use of standard test protocols can go a long way to ensure that not only new changes function correctly, but also that any changes do not have unintended effects.

Key learnings 16: Separate capability implementation from product cut-over

For many organisations, there are many individual products that need to be serialised, but a much smaller number of capabilities (e.g. packing lines, CMOs, 3PLs) that need to be serialisation enabled.

Furthermore, organisations are normally well set up for implementing packaging changes on products and recognise that this, in itself, is a relatively complicated coordination activity of many moving parts.

On the other hand, serialisation capability implementation is typically the realm of the serialisation program/project teams, with an emphasis on one-off changes to significant capabilities and establishing new organisation and systems integrations. This would typically include any changes to the ongoing pack change implementation processes in an organisation.

Once these new capabilities have been established, implementing the individual pack changes should be very much ‘business as usual’ for an organisation, typically managed and coordinated from the supply chain and planning teams in an organisation.

It can be very effective to divide the responsibilities for serialisation capability implementation and subsequent individual pack change serialisation cut-over to different teams. This frees the serialisation capability implementation to focus on what they should be good at, whilst leaving the individual pack change implementation activity to the existing teams in the business who best know how to do this. It can also serve to ease some of the political

tensions that are often seen in serialisation programs at this organisational interface.

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

Each specific CMO integration will be different in a number of ways, as each CMO is a unique organisation, with its own:

- Governance
- Organisation and people
- Serialisation solutions and vendors
- Quality system(s)
- Contractual and finance requirements
- Timelines and constraints
- Culture.

Therefore, each implementation is at least one project, if not several, if a phased implementation is required. Therefore, it is sensible to treat the overall CMO integration activity as a program, ensuring that the appropriate level of program management capabilities are applied to the problem. Furthermore, successful programs tend to be those that recognise that program management skills are distinct and different to project management skills.

Key learnings 18: Recognise and cater for ongoing change

There are many reasons in the serialisation area, why what is implemented initially will need to be changed over time. Examples of these change drivers include, but are not limited to:

- Changing legislation and standards
- Changing product portfolio
- Changing product supply chains

- Changing or evolving supply chain partner capabilities.

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Featured Artwork Posts

The clock is ticking on the new EU Medical Device and In Vitro Diagnostic Device Regulations

Following approval in March by the European Council and in April by the European Parliament, the Medical Devices Regulation (MDR) – Regulation (EU) 2017/745 – and In Vitro Diagnostic Medical Devices Regulation (IVDR) – Regulation (EU) 2017/746 – were published in the Official *Journal of the European Union* on 5th May 2017. Both Regulations entered into force on 26 May 2017, hence the new MDR rules will apply from 26 May 2020 and the IVDR rules from 26 May 2022.

Billed as the most significant changes to medical device legislation in decades, these regulations seek to increase the safety and effectiveness of medical devices available in the EU market and address weaknesses in the regulations revealed in several high profile incidents. Medical device and in vitro diagnostic device manufacturers large and small who supply product to the EU market will be impacted and need to start planning now on how to transition to the new requirements.

There are a number of changes being introduced by the new regulations, some of the most significant being:

The role of economic operators: Economic operators (the collective description for manufacturers, importers, distributors, suppliers, subcontractors and EU authorised representatives) carry the ultimate responsibility for conformity to regulations. The legislation outlines the general obligations of each or these parties, explaining both what they need to do and how they need to do it.

The scope and classification of products: Whilst the classification system (Class III, Class IIa, Class IIb and Class I) is retained, some rules have been tightened. Some industry commentators anticipate this could result in some devices moving to higher classes of product. Moreover, a number of types of products that were previously exempt from the regulations are now included in scope.

Technical files, common specifications, clinical evidence, conformity assessments and product labelling: Additional requirements have been included to each of these aspects of product registration and approval. These may require further product information or testing to be provided to support approval. Transitioning arrangements for existing products or products currently undergoing conformity assessment are being clarified, but some industry experts are concerned that these new requirements could require all products to be registered as they transition to the new legislation.

Vigilance and post-market surveillance: The regulations introduce further requirements for vigilance and post-market surveillance undertaken by both the Economic Operators and the National Authorities.

Quality management system: All manufacturers and their representatives must have an appropriate quality management system.

Person responsible for regulatory compliance: The regulations require that manufacturers and authorised representatives have permanently and at their disposal at least one person responsible for regulatory compliance. This isn’t necessarily an employee, but must be accessible to the organisation. The person is responsible for ensuring the conformity of devices are checked

prior to release including that technical documents and certificates of conformity are accurate.

Notified body re-designation: The legislation includes a series of requirements for notified bodies who will be required to be re-designated as part of the regulation. It is targeted to have this complete towards the end of 2018.

Unannounced audits: Notified bodies will be required to undertake unannounced audits of manufacturers and their authorised representatives. Notified bodies will have to provide schedules of unannounced audits to their national authorities.

Medical Device Coordination Group: The legislation includes the creation of a pan-EU expert committee, The Medical Device Coordination Group (MDCG). This will comprise representatives from the member states and will assist the Commission in the implementation and operation of the new legislation.

Unique device identification (UDI): UDIs will be introduced on all medical devices. They will be placed on the label of the device, implant cards for Class III devices, and in the case of re-useable devices, potentially on the device as well. These UDIs will be used to provide traceability of use of devices.

EUDAMED database: The Commission will establish a centralised EU database for the storage of information on medical devices (EUDAMED). This will facilitate the communication of both pre- and post-approval product information between economic operators, the Commission, member states and in some cases healthcare professionals and the public. It is targeted to have this database available towards the end of 2018.

As can be seen from the above changes, the requirements for the new legislation are varied, impacting the majority of parties involved in the supply and governance of medical devices to the EU market across the entire

lifecycle of each device. The legislation is in force now so companies need to act to define their strategies for transition

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I presented on *The Implications of the New EU Medical Device Regulations on Combination Product Packaging*. I discussed how the regulations of medical devices and in vitro diagnostic devices are undergoing the most significant change in decades. I outlined the objectives that the legislation seeks to address and the challenging timelines for implementation. I also explained how the legislation impacts the whole lifecycle of medical devices

that are marketed in Europe and the complex group of actors impacted. It is clear the legislation introduces some significant changes to the way the EU-marketed MD/IVD lifecycle needs to be managed and it will present a number of packaging challenges.

The presentation can be accessed via the following link: The Implications of the New EU Medical Device Regulations on Combination Product Packaging.

Other presentations from the event included:

A Case Study: Benefits of Offshoring & Centralising – A Graphic Design Perspective
Chikkam Rama Mohan Rao, Senior Director – Global Regulatory, Novo Nordisk
Chikkam presented on the approach Novo Nordisk has taken to establish their Bangalore shared-service operation, by employing approximately 1,700 staff. The operation itself commenced in 2011 and the range of departments based in India allows communication between these departments to be very efficient. Chikkam and his team have looked for many opportunities for activities to be centralised from local operations to raise capabilities, such as renewals management.

The Bangalore operation works hand in hand with the labelling operations team in Denmark to offer an end-to-end solution across the product lifecycle. As part of the outsourcing process, Novo Nordisk did a detailed risk analysis to ensure transition risks were monitored and a set of KPIs monitor the performance of the operation. Benefits seen include a reduction in artwork backlog and improvement in right-first-time.

Get connected: Embrace the Changing Patient Journey and Strengthen Your Brand Across Physical and Digital Channels
Mike Baird, Global Business Development, ESKO
Mike explored the physical and digital challenges impacting product information and healthcare companies. Mike highlighted how patients

nowadays are very confident about searching online for information about their health condition. Keeping the physical brand image and content consistent with this digital presence is becoming ever more important.

Companies have many different types of product information stored in many locations and they need to look at how this can be rationalised with better asset management, making sure appropriate stakeholders are involved where needed. Mike also emphasised the importance of rationalised processes with built-in QA/QC.

Current Regulatory Issues and Packaging Changes: Gain Clarity and Develop Solutions

Johan Verhaeghe, FMD Project Manager, Medicines for Europe

Johan presented on Medicines for Europe's perspective on the adoption of the FMD regulations. Johan outlined the EU FMD legislation framework and the blueprint approach for the European Hub and national systems. The cost impacts on generic manufacturers, wholesalers, distributors and pharmacies and the readiness in each impacted country for establishing their national systems.

Johan discussed some of the issues facing the industry, including:

- The volume of notifications and verification
- The impact on packaging lines
- The ongoing running costs for the new capabilities being introduced.

Why Your Labelling Process is Obsolete

Askold Zimmermann, Account Executive, Global Vision

Askold presented on how the use of electronic proof reading tools can substantially change your artwork workflow by moving away from paper copy content reviews. Askold also discussed the risk with the quality of manual checks and complexities due to different language. The volumes of data and the complexities of networks results in companies needing appropriate

artwork management systems to ensure process optimisation and data management.

Packaging Sustainability: Scrutinising the Revised ISO 14001

Horst Kastrup, Senior Regulatory Advisor, MEDA Pharma

Horst presented on the requirements of ISO 14001 and the benefits to companies about being certified to the ISO and adopting sustainable packaging. Horst walked through the updates in the 2015 issue of the ISO that companies will need to meet.

Horst also explained how there are various ways packaging materials can be reused. It is also important to watch out for substances or finishes which might impede recycling. Primary packaging can be challenging to change due to registration requirements, but secondary packaging can be more feasible. Shippers should also be considered. Horst also outlined some core studies of specific products that were assessed against the ISO standard.

Avoiding Labelling Misprints: The Truth Behind the Labelling Review Process

Marc Chaillou, Account Manager, Schlafender Hase GmbH

Marc presented on the typical reasons for artwork error, outlining some of the main reasons for artwork change and the need for accurate and effective labelling and artwork. Marc's presentation looked at a case study of how an error can happen and the impacts felt. Marc then gave some tips on how to improve the proofreading process through appropriate methods and technology.

Artwork Management Systems: Strategies for Success

Suzanne Ivory, Global Head of Quality, Perigord

Suzanne presented on how to ensure you set up your artwork service for success. There are many drivers that are generating increasing volumes on artwork change putting more complexity into operations. Suzanne explained that getting clear instructions, standards and guidelines is essential to reduce ambiguity. An effective Quality Management System is key to provide the

appropriate oversight to your service, and the right measures in place to control operations and focus improvements. Suzanne also covered the benefits of outsourcing artwork operations and discussed how technology is developing and systems are becoming more integrated.

What Are the Main Challenges of Serialisation & Traceability Applications for Packaging Lines?

Julia Guedes Canicali, Project Manager, Novo Nordisk

Julia presented on some of the challenges seen with implementing serialisation in Novo Nordisk. Highlighting the issues that can arise in each of the process steps for how serialisation data flows to and from the line. Julia and her team have seen issues in preparing the lines – defining the print and IT approaches and making space for new equipment. Whilst bringing the data to the line, Novo Nordisk have had to integrate new capabilities to their MES / ERP systems. Different substrates and shapes impact the print performances and print head position. Verification is also impacted by different substrates and can impact line speed.

Master Data Management: The Missing Link in Packaging and Serialisation Initiatives

Chris Doyle, Managing Director, Genshone Transformation

Chris presented on the importance of master data in serialisation and packaging improvements. Through a number of examples, Chris outlined how supply chain effectiveness is underpinned by good data management and standardisation of master data management. Chris also shared some examples of when the product was rendered unsaleable because of errors with master data and raised the question that if this can happen, why are there so many examples of poor data management?

Strategies for Packaging Branding in Pharmaceuticals

Iñaki Remiro, Global Packaging & Design Management, Almirall

Iñaki presented on the relationship between branding and packaging. Iñaki discussed the approach on a range of products that ensured a consistent

approach to product branding across Almirall's packaging. He also emphasised the various aspects of product branding and how companies had achieved this in their packaging design.

Enterprise Serialisation: Best Practice for Global Commercial Supply in an Evolving Market

Robbie Stewart, Contract Manufacturing and Packaging Expert – Pharmaceutical & Biotech, PCI Pharma Services

Robbie presented on lessons learned from the serialisation programmes PCI have been involved in. He first talked about the latest view of the evolving legislation worldwide. Robbie highlighted the challenges serialisation is creating with artwork regarding finding appropriate space for codes and subsequently executing the required artwork changes. Due to the vast majority of PCI's customers requesting aggregation, PCI have had to introduce increasing levels of flexibility on the packaging suites to be able to meet the needs of multiple clients. This way PCI are trying to future proof their lines and seeing an impact on OEE.

Ensuring Child Safety – and Improving Anti-Counterfeiting

Stephen Wilkins, Chairman, Child-Safe Packaging Group

Stephen presented on the requirements and legislation for child restraint packaging and outlined the various standards and tests that support them. Stephen then explored the impact of child restraint packaging on aging patients and some pack designs that can be easier to use.

GS1 Standards – A Toolkit for Fighting Against Pharmaceutical Counterfeiting

Géraldine Lissalde-Bonnet, Director Public Policy, GS1 Global Office

Géraldine presented on the latest activities GS1 are involved in to help combat counterfeit pharmaceutical products. Outlining the developing serialisation and track and trace regulations around the world and how GS1 standards support the requirements. Géraldine explained how GS1 help

shape legislative responses and supports GS1 mentors in their understanding of requirements.

EU FMD Readiness – A Stage Play in Three Acts

Stefan Artlich, Director Product Tracking and Authentication, Bayer AG

Stefan presented on the development and requirements of the EU FMD legislation. Stefan talked about how the legislation evolved and some of the key decisions made during that process. Stefan also highlighted a number of key issues that still need to be addressed, even though the deadlines are close, and what potential solutions might be applied.

A Case Study: Lundbeck's Integrated Artwork and Master Data Workflow

Tina Schuleit, Senior Manager, Artwork & Master Data, Lundbeck

Tina presented on what Lundbeck have been doing to integrate artwork change and master data updates. Tina explained that this helps Lundbeck better integrate changes and manage stocks of components. Changes are executed via a workflow in SAP. Tina shared how Lundbeck's process works and the teams accountable for each step. She outlined the benefits of the capability and the areas Lundbeck were looking to further develop.

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Key Learning Objectives:

- Understand what EU MDR compliance means for your business and how it will affect your labelling 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 learn from UDI to work smarter in meeting the implementation deadlines of MDR by May 2020 and IVDR by May 2022

- Learn about a labelling 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.

Read it online

Have you developed your strategy to address the new EU MD and IVD Regulations?

The new EU Medical Device and In Vitro Device Regulations are here and companies need to be deciding how they will address them. Approved by the European Parliament in May 2017, these new regulations are the biggest change to the legislative framework for MD and IVD products in decades. As discussed in my previous blog on the subject, 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.

For companies faced with these challenges, it begs the obvious question ‘So where do we start?’

Define your strategy

The logical first step is to define the company’s strategy for how to tackle the new regulations. Typically, strategy development would include:

1. Understanding of the current and new legislation.
2. Impact of the legislation on the company’s operations, including any opportunities that might present.
3. A gap analysis of each relevant aspect of the company’s operations against the requirements of the new legislation.
4. An assessment on existing and pipeline product registrations, testing and labelling.

5. Initial high level designs of potential new processes, capabilities and IT solutions.
6. High level roadmap for re-registrations, testing or re-labelling and implementing new processes, capabilities and IT solutions.
7. Cost and resource impact estimation.
8. Plan for the next phase of activity.

Some considerations when defining your strategy
From our experience of delivering large and complex legislative-driven change, there are a number of things to think about when defining your strategy:

Take a cross functional approach: The impacts of the regulations are cross-functional so make sure that you have all relevant functions involved in defining your strategy. Avoid the temptation to 'slice and dice', allowing each function to independently develop their approach. The company needs a holistic response so develop your strategy as a true cross-functional activity. All stakeholder groups involved in the delivery of the legislation need to contribute effectively or the whole 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.

Define and agree some governing principles: Providing guidance to the team on what would be permissible or not, defining the 'rules of game' to all parties. This provides a boundary and decision-making framework for solutions being developed and should be approved and managed by the governance team.

Ensure effective cross-functional governance: Given the cross-functional and cross-organisational nature of the regulations, establishing the right inclusive leadership and governance is key to the long-term success of the activity. A cross-function governance team should therefore be established to steer the definition, establishment and ongoing delivery of your strategy.

This governance body should include membership from all the stakeholder groups involved.

Build in flexibility: The implementation of solutions to address new legislative drivers is complex, not least because through the implementation journey, the legislation evolves. Unforeseen situations and challenges will arise, timelines may change, Delegated Acts may introduce further local requirements. Therefore, solutions defined need to have sufficient flexibility to cope with further emerging requirements. This is not easy, but is a key challenge of which solution design teams must be made aware.

Look for standard approaches: In large and complex operations, it may be necessary to implement solutions at multiple locations. It can therefore be beneficial to develop standard approaches for solutions that can be replicated at each of these locations rather than 're-inventing the wheel' at each one. This provides two benefits – it can be more efficient in preparing the solutions and learnings across the organisation can be shared. However, if taking this approach, local requirements must be highlighted and built into the developed solutions.

Put a capable, dynamic and motivated leader on the problem: These regulations are complex and evolving, touching many parts of an organisation. With the challenges facing the leadership that is charged with implementing such capabilities, they need to have a broad range of skills, the drive and motivation to anticipate risks and issues, as well as ensure they are effectively managed proactively. Furthermore, there will be many technical challenges to address so the leadership of the program needs to have the technical strength and breadth to succeed in managing these.

Involve local country teams and management early: Good change management practice encourages the involvement of those impacted early in the activity. The local country teams will be key in supporting implementation and ongoing operation of solutions implemented, as well as undertaking a significant role in product re-registration and labelling updates. Involving

them early will ensure solutions are fit for purpose and that they buy into the activities you need them to do.

Refresh your strategy as appropriate: The implementation of the new regulations will take many years and requirements will probably evolve. The environment you operate in and your company will likely change in this time as well. Your strategy is therefore not a one-time activity. It needs to grow and evolve as the surroundings change. Hence you need to build in regular reviews of the strategy to ensure it remains pertinent and comprehensive.

Your strategy will help you chart your course

As can be seen from the above, developing your strategy is a key point in your journey to address the issues presented by EU MDR/EU IVDR. It will help your company understand what needs to be done and how resources will be marshalled to address those challenges. The strategy processes need to be timely, giving enough time to undertake the strategy process itself effectively but also giving enough time to subsequently implement the new requirements, and it is an ongoing process tuning the company's response as situations change. Appropriate flexibility and risk mitigation needs to be built into your solutions and deployment plans. A good strategy will help facilitate a successful response to the legislation across your organisation.

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.

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