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 20 Packaging Complexity Management Tips' 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

IQPC Combination Products Forum, 24 and 25 October, Munich

I had the opportunity to attend, chair and present at the IQPC Combination Products Forum in Munich on 24 and 25 October. Many thanks to Romy Tuin and the team at IQPC for organising the event.

I presented on *The Implications of the New EU Medical Device Regulations on Combination Products*. I discussed how the regulations of medical devices and In vitro diagnostic devices are undergoing the most significant change for 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 challenges to products that are within scope.

Read it online

Is Your Quality Management System Compliant with the New EU MDR and EU IVDR Regulations?

A brief overview of the EU MDR and EU IVDR regulations

Following approval in March 2017 by the European Council and in April 2017 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 5 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

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- Preparing for the digitalisation trend in combination product use and design
- Understanding how adjacent legislation will affect the already confusing regulatory pathway
- Determining how to improve mechanisms and usability of combination products as new technologies evolve
- Integration of medical apps for your new device.

Read it online

Featured Serialisation Posts

by Stephen McIndoe

Join Be4ward at BSMA USA Supply Chain Management Forum, taking place on October 12, 2017 in Foster City, CA

‘Driving Innovation and Technology in the Bio-pharma Supply Chain’

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. As Affiliate Members of BSMA, Be4ward are proud to attend the 10th Annual Supply Chain Management Forum, taking place on October 12, 2017 in Foster City, CA. It would be great to meet you there.

Read it online

10 Tips to Accelerate your EU FMD Serialisation Strategy: Part 1

The countdown is well under way, with significantly less than 18 months until the EU Falsified Medicines Directive (EU FMD) serialisation compliance deadline – will your company be ready in time? With 32 countries across Europe being affected by this legislation, in this blog series I will discuss 10 tips to consider whilst developing and implementing your EU FMD serialisation strategy. Avoid supply interruption, make sure you have robust, realistic plans to address February 2019 EU FMD requirements.

The EU FMD legislation will require new capabilities to be implemented across many different functions of a typical company.

Read it online

Join our Webinar on EU Falsified Medicines Directive: How to Develop a Comprehensive Plan with Rapid Implementation

The countdown to EU FMD compliance is underway. Join us and be prepared.

Getting ready for Falsified Medicines Directive (FMD) compliance can be a complex process. Avoid supply interruption. Make sure you have a robust, realistic plan to meet the February 9, 2019 EU FMD compliance deadline.

Less than two years remain — will you be ready in time? With 32 countries across Europe being affected by this serialisation legislation, the entire industry must prepare. This webinar will help ensure you have a solid, comprehensive strategy and implementation plan in place before it is too late.

Read it online

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

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

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

Read it online

Executive Briefing

Top 20 Packaging Complexity Management Tips

Stock Keeping unit (SKU) and packaging component portfolio control is a critical activity for organisations. Ensuring the correct balance between a commercially advantageous portfolio, whilst minimising unnecessary pack and component variants is a challenge faced by many healthcare product companies as they grow their product range and expand into new markets. Therefore ensuring there are decision making processes in the organisation to manage required levels of complexity is a key aspect of effective pack management.

This booklet takes the popular Top 20 Tips format to describe key features of a complexity management capability in an easy to digest format.

We hope you find this information useful. We are always searching for ways to improve our work, so if you have any feedback, please do not hesitate to contact us at enquiries@be4ward.com.

Part 1: Techniques to control non added-value complexity

Tip 1 Understand the product/therapy strategy and value of complexity

Tip 2 Understand the portfolio, volumes and lifecycle of SKUs

Tip 3 Clear approval and control processes for portfolio changes

Tip 4 Prune the portfolio regularly
Tip 5 Control brand variation
Tip 6 Control platform sizes
Tip 7 Standardise artwork templates and layouts
Tip 8 Minimise fonts, illustrations and graphical elements
Tip 9 Share components or packs
Tip 10 Bundle changes
Part 2: Techniques to cope with added-value complexity
Tip 11 Plan for runners, repeaters and strangers
Tip 12 Manage order quantities of components and finished packs
Tip 13 Postponement
Tip 14 Late Customisation
Tip 15 Packaging design
Tip 16 Build flexibility into packaging equipment
Tip 17 Reduce line changeover time
Tip 18 Supply Chain design and Hubs
Tip 19 Outsourcing
Tip 20 Plan for future legislation

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.

Webinar Invite

Short read

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

Join us, Optel Group and Verify Brand for a free webinar on November 14 about EU FMD and how to develop a comprehensive plan with rapid implementation. Stephen will be giving 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 will also cover the key elements of successful EU FMD planning and execution.

Click here to read the article

Global Serialisation

Mid read

Serialisation Track and Trace Map 2017

IQPC are a partner that we work with and support on a regular basis, contributing to articles and attending and chairing their events. The global pharmaceutical industry is moving towards a serialised world. In over 40 countries, regulatory mandates to secure

the supply chain are already in place or in development. Download IQPC's printable map to see an overview of various nations' progress in their serialisation journey.

Click here to read the article

EU Medical Devices Regulation

Long read

White Paper: EU MDR Labeling Compliance: Learning The Lessons From UDI

The European medical device industry is in the grip of the biggest changes the market has seen in decades. Significant new rules to ensure the safety of medical devices became active in June 2017, imposing major new requirements on anybody involved in the design, manufacture, approval and commercialization of devices that are sold in the EU.

Read our whitepaper "EU MDR Labeling Compliance: Learning the Lessons from UDI " to find out the significant ramifications the regulation will have on labeling operations.

Click here to read the article

Featured Serialisation Posts

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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.

Over the last nine years, the 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.

In addition to keynote addresses, presentations, and industry panels, a technology showcase (Multi-Track Break-Out Sessions) will be 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

For more information, follow the link to the event organizer website.

This event will be attended by Be4ward. We hope to see you there.

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The EU FMD legislation will require new capabilities to be implemented across many different functions of a typical company. The most obvious include:

- Regulatory and legislative management and government affairs who will have to understand new emerging requirements and represent the company in external influencing and governance bodies.
- Packaging operations, where serialisation will have to be applied to the product packaging at one or more lines.
- Distribution operations, where the more complex serialisation models, this operational impact will extend into these operations in central and/or local markets, where information on individual sale and

shipment transactions needs to be gathered and added to the serialisation information.

- IT, particularly for the more complex track and trace models, where significant IT capabilities will be required to manage serial numbers and tracking information related to the product and its movement.

The serialisation strategy of a company and the resultant serialisation service that delivers and maintains the capabilities required, needs to ensure that the requirements of the EU FMD legislation are thoroughly understood and that appropriate capabilities are defined to meet those needs. These capabilities must then be implemented effectively in a timely manner to ensure product supply is maintained. Once serialisation capabilities become available, companies can then look to leverage them for product security and other benefits that are not directly driven by the EU FMD legislation. The following is a series of tips for developing and implementing your EU FMD serialisation strategy.

Tip 1: Identify and interpret the emerging and evolving EU FMD legislation

Serialisation legislation, particularly in its early iterations, tends to be somewhat vague, incomplete and sometimes contradictory. Interpreting the legislation and predicting its impacts can present significant challenges, requiring specific serialisation knowledge as well as new legislative relationships with local legislators.

The situation is no different in Europe as each of the National Authorities, National Medicines Verification Organisations and local supply chain stakeholders agree how each local model is going to work in detail.

Given the uncertainties in requirements and timing, organisations need to ensure there is a clear way of communicating their considered view of the legislative requirements at any particular moment. Failing to do this will potentially result in individual functions or groups creating their own

interpretations, which at minimum is wasteful of resources, but at worst results in capabilities being implemented which do not meet the eventual requirements of the legislation.

Tip 2: Understand the full impact of the EU FMD legislation on your company and product supply chain

Serialisation presents a potentially broad impact on a typical organisation. It is important to engage all of the potentially impacted parties early in the impact assessment phase to ensure that comprehensive solutions can be defined.

A further challenge is that multiple pieces of evolving legislation will often impact many of the same capabilities. Understanding these potential impacts and their likely evolution over time is key to ensuring effective solutions are defined and implemented in a timely manner.

Tip 3: Define solutions and implementation plans which strike the optimal balance between ensuring product supply and the caution that is prudent with the EU FMD legislation

There are often a number of supply chain configurations and technical options that can be brought to bear with particular serialisation legislative requirements. Short term tactical options have to be weighed against longer term strategic solutions. Some of the challenges that need to be addressed when defining optimal solutions include:

- Differing serialisation models being called for in differing pieces of legislation.
- Uncertainty in the detailed technical requirements as legislation evolves.
- Evolving and competing serialisation standards being developed by standards bodies and industry groups.
- The requirement for many supply chain nodes and assets to be able to handle multiple legislative requirements simultaneously.

- Deciding on the optimal degree of integration of serialisation capabilities with existing capabilities e.g. production control systems and ERP systems.
- Uncertainty in the timing of legislation.
- Striking the optimal balance between providing new equipment versus retrofitting existing equipment.
- Agreeing interfaces and implementation timelines with third parties.

Defining the timing of implementation plans, to a large extent, needs to be considered hand-in-hand with the solutions themselves. One risk that also needs to be considered is that of the 'last minute rush', or 'Y2K effect'. By this I mean the risk that, as is so often the case with this type of legislation, everyone waits until the last minute to implement solutions, only to find that the supply base cannot cope with the peak in demand, driving up cost and forcing companies into non-compliance. This is a particular concern in the 2018 – 2019 timeframe as the USA, Europe and others all have legislation which becomes effective around this time.

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Read it online

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Without an effective plan, you risk facing significant product supply issues once the deadline is enforced. Join Be4ward, OPTEL and Verify Brand for this informative webinar –

Learn how to:

- Develop an effective strategy for EU FMD compliance with low risk to your business
- Implement your EU FMD plan with minimal impact to your resources
- Identify key solutions, specially designed for rapid implementation

To find out more about the webinar, click here.
Register Today!
November 14, 2017 1PM GMT

REGISTER NOW!

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

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

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

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

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

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

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

Firstly, there is a need to consider what is being standardised. There are some elements of the strategy and resultant solutions that need to be defined, built and operated at a global level so that all supply chain nodes

can be supported. Other capabilities may need to have globally defined standards, but the build and implementation can be addressed locally. In other cases, it may be appropriate to direct all of the activity to local teams if there is no network-wide impact from locally generated solutions. Typical topics where the degree of standardisation needs to be considered include:

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

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

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

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

Tip 7: The need for flexibility beyond EU FMD implementation

Serialisation legislation and responses are emerging across the globe from multiple different parties. Whilst often based off standard building blocks, the detail of the requirements shows significant variation. Whilst this is frustrating and a global set of common standards and solutions may be more cost effective, it is the reality of the situation and companies need to develop solutions to cope with it. Therefore, many companies have held back from progressing their EU FMD serialisation projects for fear of developing the wrong solutions or backing the wrong technologies.

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

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

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Featured Artwork Posts

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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:

Beyond the Molecule – Optimising Combination Product Development Using the E-Health Wave

Steve Dew, Associate Director Combination Products and Medical Devices, Biogen

Steve presented on how digital health is expanding and how this needs to be built into the development of your combination products. Some of the topics covered included:

- Data and connectivity are providing added value for patients and healthcare providers.
- Adding electronics to products is a growing trend – both for clinical trials and commercial products.

- Patient-centric solutions will drive the integration of devices, pharmaceuticals and technology.
- Combination products can make products more convenient and easier to use.
- Connected medical devices can collect data to demonstrate health outcomes, compliance and persistence.

Steve also presented a number of examples of combination products being developed by healthcare providers.

Platform Technologies For Antimicrobial and Potential Next-gen Ophthalmic and Cancer Fighting Drug-Devices

Drew Rogers, Global Director for Healthcare & Medical, Trelleborg Sealing Solutions and Mark Paulsen, President, Silicone Consulting LLC

Drew and Mark presented on the use of silicone in the medical device industry. They talked about the use of implantable silicone devices impregnated with drug product to support different applications. They provided an overview of two studies they have been involved in, testing the effectiveness of impregnating silicone tubes with various drug products to help enhance the effectiveness of the impregnation process.

MHRA Perspective: Understanding The Regulatory Landscape For Combination Products

Dr Stefania Ragone, Pharmaceutical Assessor Licensing Division, MHRA

Stefania presented on the regulatory environment for combination products in Europe. She drew attention to two significant aspects of the European regulations:

- Medical devices are certified by Notified Bodies whereas pharmaceutical products are registered by the Competent Bodies.
- There is not a definition for combination products in Europe (as there is in the US).

Stefania discussed the requirements of the regulations and, through a number of examples, some of the pitfalls to avoid when preparing submissions.

Using Design Control to Aid in the Development of Combination Products

Margaret Kelly, Device Development Project Leader, Novartis

Margaret presented on the use of design controls in a medical device development process. She walked through a typical development process to show how this would fit to a design control framework and how you can use the design history file to collate the information gathered in the development of the device. This led to a conversation on how the device and drug development processes interlink and how they should be managed.

Cockpit's Guided Compliance For Medical Device And Combination Product Development

Edwin Schumacher, Managing Partner, Synergio

Edwin demonstrated Synergio's guided compliance tool for product development – Cockpit.

Edwin provided an overview of the product's key features and benefits and, by way of a specimen project, demonstrated the functionality of the system.

Optimising and De-risking Device Development of Combination Products

Peter Czuczman, Global Project Leader Drug Device Product Development, BTG

Peter presented on the work he is undertaking in BTG to de-risk device development for combination products. Initially Peter gave an overview of the legislative environment and the implications presented for product development. He then discussed how you can take the regulatory frameworks to develop your drug and device development processes, de-risking the processes by making sure the regulatory requirements are built in.

To conclude, Peter explained which standards support which parts of the development process and how a suite of standard tools can underpin the process and make it more repeatable.

Applying The TRIZ Methodology To Medical Device Innovations

René Dathe, Head of Quality Medical Devices Shared Function, Novartis

René's presentation covered the use of the TRIZ methodology in Novartis and how it can be applied to medical device innovation.

The TRIZ methodology is an alternative problem-solving methodology that was originally developed in Russia and can be applied to technology driven problems.

René explained a case study they used to test the methodology using an auto-injector product design.

Harmonizing the Integration of Drug Developments and Device Approaches

Lori-Ann Woodard, Senior Manager Quality Compliance Combination Products, Teva Pharmaceuticals

Lori-Ann presented on how to align the legislative requirements for devices and drug products. In particular Lori-Ann looked at what you need to do to have one comprehensive QMS in your company, depending on whether you base your QMS on the requirements for drug products or devices.

Lori-Ann also looked at how key milestones in the drug products and device development methodologies can be aligned to give one seamless development approach.

Navigating the Different Regulatory Pathways for Combination Products Across the EU and US

Lars Hyveled-Nielsen, Regulatory Project Director, Regulatory Affairs, Zealand Pharma

Lars' presentation focussed on which regulations apply to medical devices and drug products in the EU and US.

Lars explained how single-use devices and multi-use devices have different regulatory approaches in the EU. Lars explained the different requirements for each.

Lars also explained the regulatory requirements for combination products in the US and how these differ from the EU.

Human Factors Engineering for Combination Products

Heidi Manijeh Mehrzad, Principal Human Factors Specialist, HFUX Research

Heidi provided a comprehensive and wide-ranging presentation on the requirements for human factors studies in medical devices. Heidi explained the requirements for such studies and how they fit into the overall device development process.

Heidi highlighted the benefits from a well-thought-out human factors study approach and discussed numerous best practices to consider, in defining your human factors study approach.

How to Compile a Clinical Evaluation for Combination Products

Florian Tolkmitt, Independent Regulatory Affairs and Clinical Evaluation Expert

Florian talked about the clinical evaluation requirements for combination products. Florian provided an overview of the requirements for clinical trials in the new EU MDR regulations.

Florian outlined the processes and documentation requirements that companies will need to apply to their clinical evaluations through the new regulations and discussed a number of challenges that companies will need to meet.

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The requirements for a quality management system as defined in the regulations

Article 10(9) of the EU MDR regulations and Article 10(8) of the EU IVDR regulations state that:

'Manufacturers of devices, other than investigational devices, shall establish, document, implement, maintain, keep up to date and continually improve a quality management system that shall ensure compliance with this Regulation in the most effective manner and in a manner that is proportionate to the risk class and the type of device.

The quality management system shall cover all parts and elements of a manufacturer's organisation dealing with the quality of processes, procedures and devices. It shall govern the structure, responsibilities, procedures, processes and management resources required to implement

the principles and actions necessary to achieve compliance with the provisions of this Regulation.'

The article then lists a series of aspects that the quality management system (QMS) shall address.

To achieve product certification under the new regulations, companies will need to be compliant with these new requirements.

For some companies, particularly those where their products have been incorporated into the new regulations but were not subject to previous versions of the legislation, a QMS may be a completely new requirement. This can be a significant undertaking and must be planned accordingly.

ISO 13485 and the implications on the regulations

ISO 13485 Quality Management for Medical Devices was updated in 2016 and contains new requirements and more emphasis on a risk-based approach to the overall QMS process. Previous versions of this document have outlined the standard that many organisations have used as the basis for their QMS. The requirements of ISO 13485 and the new regulations have some overlapping provisions but for companies wishing to retain ISO certification, compliance with both will be necessary. At the time of writing this article it was anticipated in the industry that the ISO standard and the new regulations would be harmonised.

However, in the short term, this presents a situation where regulatory and quality professionals need to ensure that their QMS is updated for both the requirements of ISO 13485 and the new regulations.

What do you need to do to meet the requirements?

From the above it can be seen that companies will have to review and update their QMS to meet the new requirements. The first step might be to

have an independent audit readiness assessment of your QMS to determine how effective your current capability is.

From there, the next logical step would be to define your approach to your QMS. Typically, this would include:

1. Assess the audit readiness gaps with your existing QMS
2. Understand the requirements for quality management systems in the new regulations.
3. A gap analysis of each relevant aspect of the company's QMS against the audit findings and new requirements.
4. Initial high level designs of potential new processes, capabilities and IT solutions.
5. High level roadmap for implementing new processes, capabilities and IT solutions.
6. Cost and resource impact estimation.
7. Plan for the next phase of activity.

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

It is important to consider in your implementation activities that your goal should not just be to have your new QMS **in-place** but also ensure that it is fully **in-use**. This latter condition is often the most challenging, necessitating significant change management activity across your organisation. However, without ensuring in-use, you cannot consider that your QMS is audit ready.

Summary

As can be seen from the above, ensuring your QMS is compliant with the new regulations is not an insignificant activity. Your updates need to be timely to meet the needs of both ISO 13485 and the new regulations and could have significant impact across your operations. A well thought out implementation approach 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.

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- Preparing for the digitalisation trend in combination product use and design
- Understanding how adjacent legislation will affect the already confusing regulatory pathway
- Determining how to improve mechanisms and usability of combination products as new technologies evolve
- Integration of medical apps for your new device.

This is the only conference in Europe that is dedicated to ensuring your teams can comply with the multitude of regulations governing the development of combination products.
This event will be attended by Be4ward and I will be taking the opportunity to present. We hope to see you there.
For more information, follow the link to the event organiser website.

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