Managing Regulatory Requirements as the MedTech Sectors Sees Unprecedented Growth

Amplexor's Barbara Peralta on how and why MedTech manufacturers must adopt a more joined-up and better co-ordinated means of refining technical content in order to manage increasing regulatory requirements.

One of the fastest growing sectors within the broader pharmaceutical market is that of global medical devices. Known in the industry as 'MedTech', it is a market expected to be USD 613 billion by 2025. As the value of the market increases, so does the volume and complexity of the associated regulated information that needs to be managed.

In May 2021, the EU Medical Device Regulation (MDR) came into force across EU member states, and the equivalent *In Vitro* Diagnostic Regulation (IVDR) will follow in May 2022. It is a similar story of increased regulatory requirements in the rest of the world. Other regions are heading in a similar direction to the EU, with health authorities keen to make devices more traceable and enforce more consistent monitoring of device safety, prior to products entering the market and once they are in use.

This all means that organisations must define and implement a clear and robust content strategy to meet global requirements and to reap their own business benefits from them. Manufacturers will need to decide how they will optimise processes, manage resources and fill any gaps in their current skill sets.

Although regulatory compliance can feel onerous, increased information and process rigour can positively affect any MedTech business.

Removing content siloes

Organisations in many industries commonly store content across repositories. This siloed approach also exists in MedTech, which exacerbates this by adopting a relatively 'loose' approach to change management. This includes amending labelling, quality, and marketing content in a siloed manner rather than scheduling the updates centrally.

To stay on the right side of the new regulations, to maintain the highest level of patient safety, and to take advantage of economies of scale, manufacturers need to adopt a more joined-up and co-ordinated means of refining technical content. This should involve looping market feedback back into product lifecycle and labelling management and a holistic and systematic approach to planning and scheduling content updates.

This establishes good practice for any immediate requirements and readies them for increased regulatory measures in other major regions worldwide as and when they evolve.

Adopt a realistic timescale and plan of action

No company can do everything at once, so to understand the scale of work and the priorities, MedTech firms should begin with a gap analysis. This allows them to prioritise and plan much more effectively.

Each MedTech company's situation will differ depending on their product portfolio, device classes, current CE marks and their time to expiry, and what it will take to make each product compliant with the new requirements under MDR or IVDR. Regulatory experts will be able to help with these assessments and with regulatory planning.

The next logical step is to assess what it will take to bring content into a compliant state and how to do this efficiently and economically, aligned with other change requirements – especially if there are high volumes of technical and quality documents or labels to update. There are no shortcuts to doing this properly, so a long-term plan will be required.

Ensure content is managed centrally

Up to now, each team in an organisation has pursued its own agenda, without much thought to combined efficiency or consistency of content or its presentation. Quality, Regulatory Affairs and Marketing all hold their own information and content, and all work with it in different ways.

The MDR and IVDR focus on clinical evaluation and post-market surveillance, means that MedTech manufacturers will be able to more efficiently manage changes and updates, as they develop a co-ordinated content management and translation strategy that spans and consolidates common information sources. It should drive higher quality, greater content control and streamlined change management across the board – serving the needs of Quality and Marketing as well as regulatory compliance from a single, master source of truth.

Being strategic about all of this will enable companies to start capitalising on the wider benefits of holistic content management. These include new scope for structured content authoring/automated publishing, dynamically calling up and re-using agreed fragments of content/topic-specific information to create content for Regulatory, Quality, or Product Labelling requirements.

Selecting the right solution

There are many content management and authoring systems for MedTech firms to choose between. Once they have a good grasp of their starting point and where they need to get to, medical device manufacturers can begin their search for the right system for their particular circumstances.

Some tools are more technically complex, requiring retraining, which might feel a step too far. Other systems look and feel more like Word while still delivering the XML output needed to support dynamic search and structured authoring/automated publishing.

A good partner will be able to help with a pilot project and ROI modelling to show the savings that will be possible from adopting a particular approach and system. As a rule of thumb, companies should allow 1-3 months for the assessment and pilot and another 3–6 months for the phased transition to the new way of managing content, labelling and document publishing. So while the MDR/IVDR deadlines are looming – there is still time to make this strategic change and reap the long term benefits from it post-deadline.

Retaining content control

As combination products – those combining devices and drugs – continue to multiply, and as these products become smarter and more sophisticated, maintaining high levels of content control will become more important too.

The evolving role of combination treatments in diabetes care highlights the more embedded role MedTech is playing in patients' everyday lives. First, home kits were used simply to test for glucose levels following a pin-prick blood test. This scenario progressed to continuous monitoring using patches or implants, and now the latest MedTech innovation goes one step further – automatically administering glucose once a lower threshold has been crossed. The more invasive and safety-critical the role of the device, the more important regulatory rigour – close monitoring and reporting of their efficacy, safety and reliability – becomes.

Content is one of the most important assets any MedTech firm has at its disposal. But it needs to be managed effectively in order for organisations to reap the most benefit from it. This is true now and will be even truer in the future when regulatory compliance requirements become even greater. Therefore, any MedTech manufacturer should begin this process of change sooner rather than later.

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