GLOBAL REGULATORY INTELLIGENCE:

EVALUATING THE DEVELOPMENTS TO THE EU MDR

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Michael Santalucia, Vice President of Global Regulatory Affairs for Terumo BCT, is responsible for managing the global regulatory affairs function regarding the development and execution of product submission strategies for the company's medical devices, regulatory compliance requirements, and industry advocacy.

As medical device companies face large regulatory challenges to comply with the new European Union Medical Device Regulation (EU MDR), we sat down with Michael Santalucia to learn how Regulatory Affairs organizations are evolving along with global regulations, what Terumo BCT has been doing to comply with EU MDR, and how members of the medical device industry can stay informed.

Michael will be joining us at the American Medical Device Summit in October, where he will speak on the same topic.

As a VP of Global Regulatory affairs, how important is it to be aware of and adhere to the new EU MDR?

The EU MDR is arguably the most important legislation to affect our industry in the last two decades. Because of the impact this will have for any firm with CE marked devices, it is essential to have someone in the organization that can provide the company with advice and guidance to the requirements that have been established and those that are yet to evolve. For Terumo BCT, the executive team has made it clear that they are looking to the Regulatory Affairs organization for the leadership, guidance, and recommendations needed to prepare for this legislation. We have assured our entire organization and made everyone aware of the important impact the EU MDR will have not only to the portfolio but also to the way we will conduct our

business in the future from a financial, process and cultural perspective. As a global company with a commitment to a culture of compliance, we are focused on implementing the necessary actions to meet the obligations of the new EU MDR.

In your opinion, what will be the biggest challenge surrounding the EU MDR impact?

The biggest challenge will be to manage the additional educational and cultural shift necessary for organizations to understand, prepare, and participate in this major regulatory change. Because the MDR changes the way the EU will regulate medical devices, and it will affect countries that recognize the CE mark, meeting the new expectations will require a significant change to the process and systems most firms have in place to get their products into the global market. Firms should be well on their way to educate their associates at all levels of the organization to the requirements of the EU MDR, how this will change the way they do business, the scope of the impact and how their organizations will support and prepare to comply.

How has Terumo BCT adapted to meet the EU MDR?

Terumo BCT began our journey to meet the EU MDR over a year ago by reviewing the legislation and understanding the difference between the MDD and new EU MDR. Based on that review, we developed a gap analysis between current practices and the requirements of the MDR. Rather than keeping this understanding within our Regulatory Affairs team, an important first step was to inform our senior managers of the new legislation as well as the impact and timing for implementation. Core departments in our company, such as Law, R&D, Commercial, Operations, and Quality, were informed of the new legislation requirements and their contribution. For broader awareness, a series of short educational programs were developed and placed on our intranet and the expectations were raised that this was a company-wide program with everyone contributing. In addition to education, teams were established to address specific areas in the legislation with cross-functional teams. We expect that as we learn more and start to develop systems to meet the MDR, these teams will continue to adapt and our organizational education will evolve.

How has your role in the global regulatory landscape evolved?

I believe the role for all Regulatory Professionals has evolved along with the global regulatory environment. Regulators have adapted their thinking around applying regulatory systems. We continue to see countries implementing new regulatory controls, adopting the use of harmonized standards and moves towards electronic submissions. As the regulated environment changes, my role has changed with an emphasis on developing global regulatory strategies, implementing internal processes that can efficiently share data with our global RA and business teams, developing systems to understand the changing requirements and educating others in the organization. The EU MDR challenges us to rethink how we look at the systems and processes that will be implemented and how we can leverage the MDR requirements into the compliance systems for other countries. One phrase that I think sums up our current and future state is "today is the least regulated we can expect to be."

What do you look forward to most in the regulatory field in the next five years?

Like all of us, I am excited to see what new technologies and conveniences will be applied to the practice of Regulatory Affairs. We will continue to see the regulatory field change and adapt as new approaches to submission requirements are developed by regulators and as new technologies are developed. I fully expect that the adoption of harmonized standards will increase for data development and manufacturing compliance. I look forward to the evolution of regulatory practices as we increase the collaboration between industry experts and regulatory agencies in the areas of personalized medicine, using real-world evidence and the use of more post-market data. With the growing tension between increasing or changing regulatory requirements and the business pressure to do more with fewer resources, I would like to see the future development and adoption of Regulatory Systems that utilize Artificial Intelligence to help manage internal process more efficiently to allow us to use our human capital in other ways.

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What advice do you have for current regulatory leaders?

The regulation of medical products will continue to change and adapt to the needs to the user, patient, regulator, and industry. The need to be engaged as informed regulatory affairs professionals will continue to be an important factor to make important new medical products available. Staying fully engaged will be important as new requirements are implemented. I encourage my colleagues to be involved with the various trade associations that affect their businesses, engage in important educational forums to share information and mentor others in this profession to continue the development of talent.

Michael Santalucia will speak about "Global Regulatory Intelligence: Evaluating the Developments to the EU MDR" at the 2018 American Medical Device Summit.

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Are you prepared?

To hear more from Michael, join us at the American Medical Device Summit!

[View the Program]