Adapting to a New Regulatory Environment MedTech Boardroom - Genesis 2017

The MedTech Boardroom allowed for a small group of delegates to gather around a table at Genesis in December. The small group format encouraged strategic and operational best practice debate, providing key insights, tips and advice to those executives developing their successful strategies in the MedTech field.

Sponsored by:

Attended: Tamsyn Frost (Chair, IDEA Regulatory), Morris Berrie (TTS), Tony Sedgwick (The Thought Disruptor), Sorrin Popa (Stent Tek), Phil Smith (Cardinal Health) and Nadia Shivji (One Nucleus)

Context

Early in 2017, the new Medical Device Regulation and In Vitro Diagnostic Device Regulation was launched to introduce more stringent laws. This created new challenges for companies trying to introduce new and existing devices into the healthcare sector. This boardroom discussed some of the challenges Regulatory Affairs professionals face.

Points for Discussion:

1. The biggest changes for Medical Device and IVD Developers in Europe
2. Clinical Evidence - identifying and engaging the best clinical trial sites
3. Is your Quality Management System fit for purpose?
4. Regulatory submissions and post market surveillance - can MedTech learn from Pharma?

As the discussion started, it was clear around the table that not much was known by companies present about regulatory affairs so the discussion commenced by describing the challenges faced by those operating in this field.

Challenges:

- BioPharma companies have a tendency to engage with regulatory affairs too late in the development pathway, only thinking of them when preparing for clinical trials. But regulatory affairs does not just affect clinical trials, it is also about validating the processes and products along the pathway. It impacts every stage of product development, both in MedTech and BioPharma. Companies often do not know the process of involving regulatory affairs and at what stage, so thousands of pounds, and hundreds of hours are lost in companies just because regulatory affairs are brought in too late.
• How can we change this thinking? Does the message have to come from the investors? Do the problems stem from academia, where regulatory affairs is barely even thought about? Does more work need to be done with universities? IDEA are involved in some Horizon 2020 grants to start bringing an understanding of regulatory affairs to PhD students, is this something we need to do more of?

• Regulatory affairs covers so many aspects and varieties of products that it is difficult to educate companies on the right process. The processes differ between companies, depending on the type of products they are making, and their exit strategies, one size does not fit all.

• Other industries work with regulations from the beginning. For example, car manufacturers would never manufacture a tyre that does not comply with standards. This attitude needs to be built into the healthcare sector.

• Regulatory affairs consultants can produce documented development plans to show to investors when money is being raised. Investors like that you are fully prepared and have taken regulatory requirements and milestones such as scientific advice, into consideration. There is then a higher chance of them investing in you

1. The biggest changes for Medical Device and IVD Developers in Europe

Quality Management Systems don’t exist in the same way in Pharma as in MedTech. While MedTech companies are used to starting development with 100’s of ISO’s to build in compliance with, with the new MDR and IVDR comes a new set of challenges for compliance that need to be considered on a case-by-case basis. Often this will include discussion with regulators (for example, scientific and protocol advice for clinical investigations). Perhaps there is room for BioPharma to learn from MedTech as much as MedTech can learn from existing BioPharma practices.

This topic is further covered in the IDEA Regulatory article by Tamsyn Frost "Medical Device Regulation: Leveraging expertise from Pharma" which can be found [here](#).

Conclusion:

Something needs to change in the regulatory space. Regulatory affairs consultants need to be better at articulating what they do. Companies need to be better at incorporating regulatory affairs earlier into their programs. This would save the industry millions of pounds and hours of time every year.