The EU Clamps Down on Medical Device Regulations

At this moment in the global economy, one of the most talked about subjects is the Trump administration's tariffs around the globe. Disregarding the political chatter, their stated objective is to create fair-trade agreements, by way of tariffs, between the USA and our import/export leaders: China and the European Union (EU).

Recently, the Trump administration and the EU have come to an agreement in these ongoing negotiations. This agreement includes, in part, the regulation of medical devices. As specifics of the regulation are not within the scope of this article, the bottom line is that, historically, medical devices had far fewer hurdles to overcome in the EU. The much sought after CE mark was much more easily attained than FDA approval, meaning devices were more readily marketed in the EU than the USA.

Some products would be fast-tracked to market by going to Europe or elsewhere first. This route yielded two notable results:

1) The US population was losing out on technology and treatments because of a substantial increase in the time it took for medical devices to get to market.

2) The EU lost out on safety and quality, though as of May 2020, that situation will be reversed. This is all due to the fact that medical devices in Europe will have to go through a process similar to that of FDA approval in the US. In the EU, it will most likely fall under, or be added to, MDR (Medical Device Regulation) 2017/745. This means that medical devices once unavailable to the US because of pre-approval regulations must now undergo regulations that will be monitored and checked before the devices can come to market.

For any new devices coming to market, or legacy devices requiring this new approval, General Digital Product Development & Software Services is one of the few companies worldwide that can help. Our 45+ years of expertise in safety-critical software development, IV&V testing and documentation has prepared us to assist any organization seeking FDA approval for medical devices. We provide the most efficient and cost-effective means to get the safest, highest quality medical devices to market.

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