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Regulatory intelligence to introduce new technologies: Challenges and solutions to speed ANVISA's registration

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The medical devices area has suffered with the strong regulatory changes from the last decade. Since 2009, with the implementation of the Good Manufacturing Practice (GMP) for all domestic and international products, there was the starting point of a new regulatory era onto the health products market. It is important to pay close attention to the fact that the tax and fees payment, prior, instead of not mandatory, to issue the GMP certificates, the manufacturers were not exempt from following these GMP (Board Resolution - RDC n° 59/2000 currently RDC No. 16/2013). For this, it is clear how unbalanced is the regulatory understanding in Brazil. Many companies failed to bear with the high costs of GMP implementation, nevertheless, if the company has produced, it should be already following the principles of GMP. The high implementation costs were justified from the moment that fees were paid to ANVISA, are proportional to company's market size and positioning, as the labour hiring or consultants, so that the system quality operated as it is required by the state. The impact was greater on importers, since the tax fee is unique and independent from the company size, summing R$37k; Despite the company staff travel costs to visit international manufacturers, has became routine mainly, by different marketing and regulatory realities. In Europe, there is much talk about "real manufacturer" and "Legal manufacturer", this particular item generated questioning between regulated and regulators. Small importers are eventually closed, since it became impractical to maintain some projects. If we think of medical equipment, besides the ANVISA Obligations, there are also INMETRO issues, dealing internationally unified regulations, but also create more costs. In 2013, ANVISA published new rules that sought to speed up the process, instead the reality has not matched exactly what was planned. When it initiated the mandatory certification and GMP, ANVISA stated a time frame of 1080 days to perform the international inspections, this time frame was not fulfilled and today is reportedly higher than 1600 days. The big difference and advantage was the ability to request new registrations of health products using only the protocol of Certifications, without waiting for CBPF publication, and only then applying with for registration, which delayed at least five years so that the product could enter the Brazilian market. What is known, is that in 2014 the 151 inspections conducted by ANVISA, 126 of them were made through court emergential appelling. This shows how critical is the entry of new technologies. The regulatory central point issue is how to create schedule relying on the legal deadlines, and make them comply. Undoubtedly, regulatory intelligence is fundamental for these processes to be successful, since only the ranked risk products classes III and IV need CBPF, after the publication of RDC No. 39/2013. That´s because a thoroughly product review product framework may feature the exchange lower risk class framework (classes I and II) that do not require CBPF. Target audience evaluation, patient exposure time, functionality, retention and product destination are the items that will make all the difference to the correct frameworks as determined by the 13 rules RDC n°185/2001.

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Not a "medical device" – Guidance for low risk, general wellness devices

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FDA issued draft guidance about "low risk" "general wellness" products in January 2015 and stated the CDRH "does not intend to examine low risk general wellness products to determine whether they are devices..." This talk will review these types of products and explain the process to determine if the product is low risk and about general wellness to fit into this category.

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