

4th International Conference on Pharmaceutical Regulatory Affairs

September 08-10, 2014 DoubleTree by Hilton Hotel Raleigh-Brownstone-University, USA

Key implications in Brazilian regulatory environment from the innovation point of view

Suzana de Lima R de Deus
Actelion Pharmaceuticals do Brasil, Brazil

The regulatory environment is naturally influenced by multiple factors. International experience shows that the chain of innovation in the pharmaceutical industry depends on an efficient regulatory framework in order to be well-developed. Moreover, it has been recognized as the key factor in competitiveness between companies and countries. However, in developing countries, the innovation process is not aligned with the real interests of the public health sector. This paper aims to clarify the innovative flow of pharmaceutical chain and its main actors, with special emphasis on the comparison of the regulation of innovative countries with the current regulation of Brazil. The paper also presents a critical analysis of the Brazilian regulatory framework, as well as suggestions to improve regulation in the various levels at which regulation is related to the development of innovative drugs. In the case of pharmaceutical companies, innovation means a new drug, commercially available, for human consumption in order to treat a disease. Discover a new active ingredient, or a new molecule, is an invention of a new chemical entity, but is only an innovation when it has been proven to combat the disease effectively, and consumption is made possible through a new drug into the market. In practice, the Brazilian market is supplied by imports of innovative products/technologies. From this perspective, what Brazil should do to be innovative in pharmaceutical market?.

Biography

Suzana de Lima R de Deus has completed her graduation from Bezerra de Araújo University and Master Business Administration (MBA) studies from Rio de Janeiro Federal University. She is doing her Master's degree in National Institute of Intellectual Property. She is the senior analyst of Actelion Pharmaceuticals do Brasil, a biopharmaceutical company. She has presented more than 15 papers in reputed events.

suzanadedeus@yahoo.com.br