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Eliana Silva de Moraes

Food and Drug Law, Brazil

Legal tools for risk management in the global regulatory affairs framework

A medicinal product is authorised on the basis of the benefit-risk judged at the time of approval process registration. Besides, pharmaceutical companies need to deal regularly with necessary measures to mitigate risks and preserve the benefits of the product specially when working in a global market. Trasforming risk management concepts into regulatory actions is crucial for a successful pharmaceutical projects. This presentation will cover the recent and relevants laws, international standards, and regulations contributing to the achievement of the essential tools to treat risks and evaluate the pharmaceutical products benefits; comprehensive survey of legal benefit-risk definition; evaluation and control of the registration approval process globally;. identification and analysis of differents tools in the legislation to controls the risk; critereas for risk evaluation such as clinical trial, pharmacovigilance and other important procedures.

Biography

Eliana Silva de Moraes has her expertise in food and drug law. Twenty Six years experience helping international pharmaceutical, health and food companies to gain presence in markets of Latin America and Europe, specially. She has an active participation in the harmonization of regulatory affairs process through the organizations that she represents, ABPVS. Played an active role in setting up Brazil's Public Health Regulator (ANVISA), organizing the agenda of its first Anvisa's President in USA in order to explore the US specially the Food and Drug Administration (FDA) and Paho, in December 1998. President of the ABPVS a Regulatory Affairs Organization for Brazil and Latin America Countries and Lawyer at Silva de Moraes. Member of the Brazilian Bar Association and The Portugal Bar Association. Speaks Portuguese, English, French and Spanish

eliana@silvademoraes.com.br

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