

6th International Conference and Exhibition on

GMP, GCP & QUALITY CONTROL

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Global regulatory challenges and implications

Becoming a global company is an impressive task specially to make strategic decisions for the product approval. One of the huge challenges is the lack of uniform standards and regulations when selling and marketing in another country than of the product origin. It is impossible for to standardize a single application form of a product registration for different countries. Because of this the regulatory process can be costly and the product approval can take time. So, companies that intend to launch a product in an international market must think to develop a good regulatory strategy that allows dealing with each country separately (most of the time) and their regulatory staff needs to acquire knowledge to help accomplish with the regulations, locally. The purpose of this topic is to find common elements in the most varied regulatory systems that enable companies to more accurately identify the documents and information required by international regulators and understand technics that can help to reduce cost and time in the registration approval process globally. An analysis of the legislation of the different countries for the approval of registration of medical equipment and an identification the common elements will be discussed in a practical way.

Biography

Eliana has her expertise in Food and Drug Law. She has 26 years' experience in 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. She has played an active role in setting up Brazil's Public Health Regulator (ANVISA), organizing the agenda of its first Anvisa's President in USA to explore the US specially the Food and Drug Administration (FDA) and Paho, in December 1998. She is 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.

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