Varley Dias Sousa, Pharmaceut Reg Affairs 2014, 3:3
http://dx.doi.org/10.4172/2167-7689.S1.015

OMICS Group Conferences
Accelerating Scientific Discovery

4th International Conference on
Pharmaceutical Regulatory Affairs
September 08-10, 2014 DoubleTree by Hilton Hotel Raleigh-Brownstone-University, USA

Regulatory transparency: Technical, legal and ethical aspects of access to regulatory applications (medicines dossier) - Brazilian approach

Varley Dias Sousa
University of Brasilia, Brazil

Brazil is 5th biggest pharmaceutical market in the world, and the Brazilian Heath Surveillance Agency (ANVISA) is responsible to evaluate the products quality and safety. The process of expanding access to data on the regulatory framework was highlighted by publication of Federal Law 12.527/2011. Hence, in the field of health regulation, the wide access to data of drugs and related technical documents, especially clinical trials data, is in the expansion at FDA, EMA and ANVISA. A fact to be evaluated is how disclosure policies are built, emphasizing the regulatory impact analysis and detecting the risks and benefits involved. Therefore, is essential the analysis of the legal, technical and ethical aspects involved in the publicity of data, such as: patent rights, confidentiality of commercial information, privacy of research subjects, rules of engagement for accessing, clinical trials registers, electronic application, as well as defining the limits of access and disclosure. The openness will enable public scrutiny and secondary analysis probably resulting in improvement of the products quality and public health development as well as the social accountability, but some boundaries should be respect in order to not frustrate investments on bio-pharmaceutical research and development (R&D) along with not to bias the Agency's decision-making process, hereafter, disclosures policies has substantial impact over regulatory environment. Clinical study report is essentially significant as contain vital information regard new products, methods and formulations over and above is the primary source of information about the product efficacy.

Biography

Varley Dias Sousa is a Pharmacist and has completed his MSc and PhD studies from from University of Brasilia (ongoing). He is a senior Auditor on Brazilian Health Surveillance (ANVISA) since 2005, been certified in Good Manufacturing Practices (inspecting international facilities in almost 10 different countries) and Good Clinical and Laboratory Practices (Inspecting more 30 international CROs). He has evaluated more than 150 bioavailability and bioequivalence (BA/BE) studies and more than 150 Medicine Applications. He is Member of the commission in charge of confidentiality classification on Medicine Dossier.

Varley.Sousa@anvisa.gov.br