

4th International Conference on Pharmaceutical Regulatory Affairs

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

Regulatory Affairs in emerging markets

Ahmed Muhammad Farag
Cairo University, Egypt

Emerging markets are facing challenges in registration including non black and white regulation especially in Middle East and African markets (AfME). To overcome this challenge, we managed to collect all registration requirements for NCEs, renewals & other common variations as well in the whole region. These had been classified into 4 main groups include (regional documents “ancillaries”, CMC, non-CMC, and analysis related requirements “samples, reference standards & Columns”. Each group had been evaluated per market to get a consolidated content for the regulatory requirements for the whole region. Ancillaries include CPPs, GMPs, MLs, and declaration, for the CPPs, a list of reference markets have been identified and re-arranged by the most common between AfME markets, GMPs & MLs criteria have been identified, with regard to other declaration, a common template have been identified for each type of declarations and all ancillaries was marketed in terms of its requirements (document type, authentication type, validity, etc.). This has been compiled in a user friendly database, in which user can extract all required documents per market/s and/or the whole AfME region. In addition to the manufacturing site status and requirements (if any) for the markets that require manufacturing site registration. This has a very good impact on the submission lead time (time from registration decision and submission date) and approval timelines as well. Currently, AfME has a unified registration dossier, in which all required documents for AfME have been included and this dossier to be updated regularly along with the database as well.

Biography

Ahmed Muhammad Farag has completed his bachelor's degree in Pharmaceutical Science at the age of 21 years from Cairo University and finalized his pre-masters studies in quality management from Arab Academy for Science, Technology and Maritime Transport. He is currently occupying the position of senior regulatory affairs strategist for Middle East and Africa region.

ilovemesr@hotmail.com