OMICS Group Conferences
Accelerating Scientific Discovery

3rd International Conference on
Pharmaceutical Regulatory Affairs
October 21-23, 2013 DoubleTree by Hilton Hotel San Francisco Airport, CA, USA

Regulatory environment in the emerging markets: A focus on Middle East and North Africa in the emerging market region to highlight the recent updates in regulation and its shadow on future business in the region

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Emerging market ; including the Middle East and north Africa region , is considered the getaway dream for the multinational companies to make out for the declining growth and the negative profit generated from the more matured countries in Europe and the US. But this dream could be turning to a nightmare if the companies are not preparing for the new regulatory requirements in the region. The Two digit growth is no longer seen nor expected in the western world countries but is easily generated with a less resources investment in the emerging markets. As companies are starting to get the fruits of their investments in the emerging markets they are stating to get the stings from the up rising regulation in the region. There is a stretch in the regulatory workload and demands from the health authorities that is affecting the headcount resources dedicated for the drug regulatory affairs function. The emerging markets are accelerating towards harmonization with the European regulatory requirements and moving away from the US FDA yet this is adds more resource pressure both on the HA and the pharmaceutical companies.

New sophisticated regulations, formation of food and drug authorities in different countries, more demanding variation requirement and implementation of the NeeS and eCTD in the MENA region are samples of the changes in the region that happened in the recent years and will be discussed in details in this article and presentation. In addition to the recent drug price harmonization in the Gulf region is facing the companies with challenging profit line and supporting the local manufacturing model that would require a different set of regulatory expertise.

Biography

Hany Gamal has completed his Master of Business Administration (MBA) from Leicester University, UK in 2002 and Bachelor of Pharmaceutical Science from Cairo University, Egypt in 1993. He is currently the Regional Drug regulatory Affairs Manager head for an innovative multinational pharmaceutical company. He has an extensive experience in the pharmaceutical field with over 20 years; 12 years of which in the sales and marketing side of business while 8 years within the RA, with good exposure to all the front lines of the pharmaceutical business. During these 20 years, he was fortunate to come across several company cultures. Companies with head quarters located in US, Germany, Iceland, UK and South Africa. This made him more adaptive to perform under different business models whilst keeping a watchful eye on the changes in the western world and it implications on the region.

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