

# 5<sup>th</sup> International Conference and Exhibition on **Pharmaceutical Regulatory Affairs**

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## **Strengthening regional collaboration among ASEAN regulatory laboratories to ensure quality assurance in pharmaceuticals**

**Maria Soledad Lopez Distor**  
MMPA, Philippines

ASEAN's development, though gradual and slow, has consistently demonstrated an uphill shift from a focus on regional peace and stability to closer economic integration. The ultimate goal is to achieve an integrated ASEAN community by the year 2015 with a common regional identity. Efforts toward ASEAN harmonization were initiated through the ASEAN Consultative Committee for Standards and Quality (ACCSQ). Hence, it was agreed that a Product Working Group on Pharmaceuticals, now referred to as Pharmaceuticals – Product Working Group (P-PWG) be set up. The ASEAN's PPWG is contributing to the ASEAN Economic Community 2015 vision by establishing the pharmaceutical harmonization scheme. The goal is to create common regulations for pharmaceuticals in the region, reduce barriers to trade and to ensure that pharmaceutical products penetrating the ASEAN markets show sufficient safety, quality and efficacy. With growing inter-dependence among nations as well as expanding global opportunities in pharmaceutical trade, efforts toward developing a new strategic partnership in pharmaceutical regulatory harmonization has recently become an important agenda of ASEAN. Inspired by these concerted efforts and taking into consideration the current international best practices of expediting product registration process, the ACCSQ – PPWG has thus taken a harmonized approach to facilitate the availability and accessibility of quality, safe and efficacious products, in the interest of patient and public health. And one of the milestones in the harmonized approach is the establishment of pharmaceutical reference standards. The project on the Production of ASEAN Reference Standards (ARS) was initiated in 1980 under the Technical Cooperation among ASEAN countries on Pharmaceuticals, and was supported by UNDP and WHO with Thailand as the coordinator. The objective of the project is to enable the ASEAN countries to produce pharmaceutical reference standards for utilization within the region. Through thirty three (33) years of cooperation among member countries, the overall implementation of the activities in terms of manpower training and the production of ARS were considered satisfactory. The outcome of the project has benefited all participating countries.

[soledadistor@yahoo.com](mailto:soledadistor@yahoo.com)

## **Impact of novel Mexican policies on the healthcare and pharmaceutical landscape: Is the industry ready for the big boom?**

**Ricardo Ibarra-Cabrera**  
INBIOXICA SA de CV / Asociacion Mexicana de Comites de Etica en Investigacion, Mexico

In the last ten years, the Mexican healthcare sector has gone through several big transformations. The development and implementation of new initiatives have changed the sector's dynamics. For instance, universal health coverage in the country requires medical attention and provision of medicines to more than 15 million people who did not have access to them before. In this regard, the Federal Commission for the Protection of Sanitary Risks (COFEPRIS) has taken several measures such as abbreviating the approval pathway for generics, derogating the local plant rule for drug production, phasing out copy drugs that are not bioequivalent, and establishing a clear regulatory framework for biopharmaceuticals and biosimilars. Moreover, for the sake of increasing expenditure on R&D activities, new funding programs have emerged from different Mexican Institutions that stimulate the development of the biotech and biomedical sectors. Consequently, the fastest healthcare spending growth in the Latin American region will be in Mexico, at more than 10 percent a year. Therefore, new challenges and business opportunities have arisen for the healthcare and pharmaceutical industries in the country. The upcoming years are a milestone for this sector to flourish and succeed in improving people's quality of life.

[ricardoibarra27@gmail.com](mailto:ricardoibarra27@gmail.com)