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Update on biosimilar pre-market requirements in South-East Asia

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South-east Asia has in recent years boasted one of the highest economic growth rates for the pharmaceutical and regulated industries in the world. At the same time, the regulatory scenario has also been changing at a rapid pace, with changes at the national level and at a regional level all occurring at the same time. Vast socioeconomic and language gaps amongst countries have traditionally been a major barrier to harmonization efforts, but after years, progresses are now catching momentum.

Following the foot-steps of advanced economies of the West, regulators have been hard at work to develop and implement control of biosimilar products. This presentation provides an overview on the recent regulatory developments in South-east Asia on the pre-market control for biosimilar products, including national guidelines and the ASEAN harmonization effort.

Biography

Kenny Peng is Director of Asia for Pharm Eng Technology, an international consultancy based in Toronto, Canada. Born in Taiwan and educated in Canada as an engineer, he has spent his career on international projects in North America and across East and Southeast Asia, and across diverse disciplines spanning GMP engineering, validation, compliance, as well as manufacturing and commercial regulatory affairs.

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