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Key strategic consideration for NCE registration in Asia Pacific countries to reduce drug lag

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The regulatory environment in AP region is diversified. Pharmaceutical companies want to reduce the drug lag in AP region for their NCE products. There are many regulatory constraints during drug registration process such as local trial requirements, CPP requirements and site specific stability requirements which will impact the NDA submission and approval process. This presentation will discuss the key regulatory factors which should be considered during the NDA submission strategy decision making process in the key AP countries such as China, Korea, Taiwan and SEA countries. Key risk areas and possible risk mitigation plan will be introduced. The experiences on how to manage those regulatory hurdles, to reduce regulatory risks and to work out successful strategy will be shared. The presentation will combined with introduction of the key regulatory consideration in key Asian markets and case studies on NDA strategy. This presentation will enrich the knowledge of the person who is working on the regulatory strategy for Asia and will also encourage the industry persons to discuss and brainstorm on how to reduce the drug lag to Asia Pacific markets.

Biography

Jin Shun is a pharmacist with MBA degree. He has been working in regulatory affairs field in pharmaceutical industry for 18 years. During his career life, he has been worked in a few companies including Nycomed, J & J, GE Healthcare and Parexel. He has been engaged all kinds of regulatory activities including submissions, regulatory consultation and strategy in Asia Pacific region especially in China. He has been leading the regulatory affairs team in Asia Pacific region in different companies. Now he is the Associate Director in Takeda Asia Development Center responsible for regulatory strategy for Asia Pacific region.

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