

Regulatory requirements for pharmaceuticals in China

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China is the 3rd pharmaceutical market in the world and is expected to be the 2nd in 2015. More and more western companies are starting to look into the possibility of bringing their drugs to the China market for the large pool of patient population, if they have not done so. To do this, the first and the most important step is to understand the China regulatory requirements for pharmaceuticals, what challenges they may face and what strategies can be taken to overcome the challenges. This presentation provides an overview of China laws and regulations on pharmaceuticals and more detailed introduction of Regulations of Drug registration in China. It shows the process of import drug registration, key stakeholders involved in the process, review timeline, regulatory categories and corresponding clinical requirements for small molecules and biologics, specific topics such as special review, MRCT, OTC drug, import drug and supplementary application. It presents the recent update of registration timeline and approved therapeutic areas by CFDA in 2012. It outlines challenges faced by multinational companies to bring their products to the China market followed by various strategies that can help deal with the challenges. The presentation gives an insight into the possible trend of CFDA and interaction keys with CFDA.

Biography

Wendy Wang is currently Managing Director at Accelovance China, with US parent based in Rockville, the US. She has been helping western pharmaceutical companies with global clinical trial registration and import drug registration in China, and assisting the companies on clinical site management, project management, safety reporting, and quality assurance of multicenter global clinical trials and local trials in China. She had her clinical medicine degree from Shandong Weifang Medical College, Master degree on gastroenterological physiology from Peking Union Medical College and Ph.D. on regulation of angiogenesis by VEGF from the University of Bristol in the UK.

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