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Comparison of biosimilar registration guidelines between EU and USA

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When a Bio-Pharma plans to develop biosimilar for global market, it is important to understand the regulatory requirements from different destination of the markets. While FDA requires tremendous biological, analytical and clinical trials data on the tier basis, EMA requires clear quality, non-clinical and clinical data on the head-to-head comparison basis. However, US is a single market where as EU is multinational market, this has important impact on the selection of RMPs, which sometimes are critical to the success of biosimilar development and submission.

Biography

Frank Cheng is the Founder and Principle Senior Consultant of Alban Pharma, Hong Kong, which is a leading consulting company on biosimilar development and submission to EU and US. With his PhD from Canada and PDF experiences from JHU in USA, he is now directing and managing several biosimilar projects from GMP compliance to design and implementation of regulatory submission roadmaps.

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