Latest Chinese Guidance for Development, Evaluation, License Approval of Biosimilars

Description: Responding to strong desire of overseas and multinational pharmaceutical manufacturers and domestic pharmaceutical manufacturers to carry out research and development of biosimilar products, this is first time in history, Chinese pharmaceutical authorities, China Food and Drug Administration officially issued a technical guidance for development and evaluation of biosimilars and defined the pathway of license approval for biosimilars. Chinese pharmaceutical authorities require that when conducting the research and development of biosimilar products in China, the applicant of biosimilar registration application and its sponsor should be in compliance with the Guidance and follow the pathway of license approval of biosimilars.

How to grasp the opportunity to smoothly conduct the research and development of biosimilar products in China and speed up your biosimilar product approval time? The overseas and multinational pharmaceutical manufacturers and their senior executive officers engaging in regulatory affairs must have a comprehensive and thorough knowledge of the latest Chinese guidance for development, evaluation, license approval of biosimilars.

Latest Chinese Guidance for Development, Evaluation, License Approval of Biosimilars provided a comprehensive and thorough knowledge of the latest Chinese guidance for development, evaluation, license approval of biosimilars and guide you use the Chinese trial venues to keep biosimilars development lean and to smoothly operate in China.

Report Highlights:
- The applicable scope of Guidance.
- An overview of general principles of development and evaluation of biosimilar products in China.
- The detailed requirements for research and evaluation of pharmacy.
- The detailed requirements for non-clinical research and evaluation.
- The detailed requirements for clinical research and evaluation, from clinical pharmacology study covering pharmacokinetics study, pharmacodynamics study and (PK/PD) study, efficacy study, safety study, immunogenicity study to extrapolation of indications to smoothly navigate complex regulatory requirements step by step.
- An overview of marketing license approval of biosimilars in China, from China's registration category of biological products, specific pathway of license approval for imported biosimilar registration to application dossiers and data for license approval of biological products to guide you achieve a successful entry into the Chinese drug market, and smoothly operate your biosimilar products in China.
- China's Application Form of Drug Registration in English.

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