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Regulatory consideration of the assessment of biosimilar products

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Recently, the expiration of patents for a number of blockbuster biologics has ushered in an era of the subsequent production of biosimilar products, which might contribute to increased access to these products at an affordable price. However, unlike small molecular drugs with clearly and well-defined composition and structure, biosimilar products that are made in or isolated from living systems have much more complex ingredients. Therefore, there is general consensus that the standard methodology for the assessment of bioequivalence is not appropriate for the assessment of biosimilars, which highlights the need of more complex and specified regulation and approval tracks. The EMA has taken the lead in the regulatory approval framework for biosimilar products, and WHO has published guidelines on the evaluation of biosimilars in order to facilitate the global harmonization. Many other countries such as US, Canada, Japan and Korea have also issued their own guidance for evaluating biosimilar products. The basic concepts and main principles of approving biosimilars are similar among various regions, notwithstanding some differences in regard to the scope, the choice of reference product, and the date requirement. The first part of the session is going to review the fundamental differences between small molecular drug and biotechnology medicinal products. The second part is going to focus on the comparison of regulatory requirements in various regions and recommendations regarding global harmonization.

Biography

Jun Wang is a chancellor scholar of Duke University and a Ph.D. student majored in pharmacology and cancer biology. Her research is focusing on two areas: (1) tyrosine kinase inhibitors and oncology study (2) regulatory requirement of the assessment of biosimilar products. She combines her biotechnology background with keen interest in the assessment of biosimilar products. She has involved in several research projects and published papers in this field.

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