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Development registration of biosimilars to global regulatory standards

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Outlining the importance of biosimilars, the current legislation, commercial and technical/scientific status of biosimilars in the EU this presentation outlines the growing potential of products within this market. There will be examples of currently approved biosimilars, the basis of their approval and details of the developmental pathway differences between innovator products and biosimilars. The process for the determination of biosimilarity and details of the approaches used successfully will be shared. A knowledge-based approach to biologics testing is described that uses analytical, bioassays, and preclinical tests to minimise the need for extensive clinical evaluation therefore reducing the cost of development. Some of the limitations including regulatory, scientific, and quality concerns will be highlighted with particular emphasis on interchangeability and an overview of the requirements for on-going comparability and conformance.

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