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FDA/EMA current thinking on totality of evidence for development of biosimilars

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The regulatory landscape for the development of biosimilars in the US and EU is dynamic as many of the guidance issued by European Medicines Agency (EMA) and US Food and Drug Administration (FDA) have undergone revisions based on experience gained through review and approval of biosimilars for the respective regions. Sponsors have indeed demonstrated that quality (safe and effective) biosimilars can be developed using state of the art analytical and biological methods. This session is designed to provide current status of biosimilar guidelines in the US and EU. The focus will be to identify major updates in order to help sponsors navigate through the complex requirements for the regulatory approval of biosimilars in the US and EU.

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