Raymond A Huml, J Bioanal Biomed 2017, 9:5 (Suppl)
DOI: 10.4172/1948-593X-C1-031

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Biosimilars: Accelerating early clinical development

This presentation will discuss how early clinical development with biosimilars is paramount to later development and registration success. It will provide an overview of ECD services successfully used for implementing Phase-I biosimilar trials in Asia Pacific as well as the West (e.g., US and EU) for global registrations. It will present an overview of site selection and feasibility data using a Next Generation approach driven by IMS legacy data to aid recruitment especially in tough areas to recruit patients for biosimilar trials such as the US and Europe. Finally, a model to accelerated biosimilar development will be presented that has been successfully used by one of the world's largest providers of pharmaceutical services.

Biography

Raymond A Huml is the Vice President, Strategic Drug Development and Head, Global Biosimilars Strategic Planning at QuintilesIMS. He has written over 60 articles on a variety of subjects and three books. He has more than 27 years of experience in the biopharmaceutical and healthcare industries and holds an MS in Biology from East Stroudsburg University, a DVM from the North Carolina State University College of Veterinary Medicine and has earned the RAC (US) certification.

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