

3rd International Conference and Exhibition on **Biowaivers, Biologics & Biosimilars**

October 27-29, 2014 Hyderabad International Convention Centre, Hyderabad, India



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Biosimilars in emerging markets: Regulatory and commercial considerations

Governments, health payers and social and health reforms combined with increased incidence of conditions such as cancer and diabetes are paving the way for increased uptake of biologic medicines in the emerging markets. However the high cost of biologic medicines can be prohibitive to many patients creating a high level of unmet clinical needs. Biosimilars and the cost benefit they bring is a very attractive alternative in the emerging markets. Due to the complex nature of biologic medicines, biosimilar development is highly regulated. EMA, FDA and WHO have published guidelines and while there are some minor differences, overall they all require comprehensive comparability exercise to the originator: Quality, Non-Clinical and Clinical. The cost can be high and the time to complete the programme can be long. Most of the pharmaemerging countries have also developed or are in the process of developing their own regulatory pathway for the approval of biosimilars. While the concept is similar to the European and WHO framework, in certain countries the barrier is lower to enable lower cost of development and shorter time to market. This presentation will address the different regulatory requirements in the emerging markets and critically debate the pros and cons in having “looser” structure and the potential impact on the global sustainability of biosimilars.

Biography

Rodeina Challand BSc, Executive Director, Biosimilars Development, Scientific Affairs, has 25 years of experience in healthcare, cancer research, and the pharmaceutical industry across a wide range of roles including clinical development strategies for biosimilars and serving as head of clinical operations globally. For over 10 years, she directed the conduct of Phase I-IV clinical trials, including large pivotal biosimilar multi-national, multi-center trials and several post-authorization safety studies for biosimilars. She is experienced in all aspects of biosimilar development including global strategies, study design and regulatory agency discussions (Europe, US, Japan, Australia, Singapore, and South Korea) and has worked on 10 biosimilar molecules across a range of products and indications, including ESAs, Filgrastims, Heparins, Insulins and monoclonal antibodies. In her role in PRA, she is currently working on several Biosimilar programs in various capacity including consulting, regulatory and clinical strategies, feasibility and supporting study delivery across all phase of development (phase I to IV). She has also represented PRA as a speaker in several International Biosimilar conferences across the Globe. While in the Pharmaceutical industry she was the company's representative in several EMA consultations with regard to the development of the EMA Biosimilar Guidelines and was a member of the European Biopharmaceutical Group, which is a sector of the European Generic Association.

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