Biosimilars-2013
OMICS Group Conferences
Accelerating Scientific Discovery
2nd International Conference and Exhibition on
Biowaivers & Biosimilars
September 23-25, 2013 Raleigh, North Carolina, USA

Challenges in demonstrating biosimilarity and interchangeability of biosimilar products

Rodeina Challand

PRA International, UK

Abstract

The market of biologics is growing at nearly twice the rate of pharma as a whole. The expiration of patents and other intellectual property rights for originator biologicals over the next decade opens up opportunities for biosimilars to enter the market and increase industry competition. In order to be cost effective a biosimilar product needs access to global markets based on a single development programme that meets the requirement of regulators internationally. Despite increasing alignment in the regulatory requirements for biosimilars between EMA, FDA, WHO and other jurisdiction, there are still many scientific and practical challenges for demonstrating biosimilarity and interchangeability including scientific factors, drug interchangeability and statistical considerations.

Biography

Rodeina Challand B.Sc., 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. As director of clinical projects at Hospira Inc., her responsibilities included creating clinical development strategies for biosimilars and serving as head of clinical operations in Europe. 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 was the lead in the development of Hospira's first biosimilar, Hospira GCSF, from lab to clinic. She has experience in all aspects of biosimilar development including study design and regulatory agency discussions (Europe, US, Japan, Australia, Singapore, and South Korea) and has worked on six biosimilar molecules. She was also 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. More recently in her role in PRA, she has worked on 7 Biosimilar programmes in various capacity including consulting, strategy, feasibility, IMP management and study delivery. She has also represented PRA as a speaker in several International Biosimilar conferences across the Globe.