

4th International Conference and Exhibition on

Biologics & Biosimilars

October 26-28, 2015 Baltimore, USA

Issues in the clinical development of the first wave of biosimilars

Nigel J Rulewski
Quintiles Inc., USA

Biosimilars in the US are still in their infancy with only one product approved for the US market to date. However, the first wave of bio-similar products, EPO, filgrastim, anti-TNFs and several oncology products are now well underway. The issues faced in the development of these products have evolved over time and now provide a firm basis for the next generation of biosimilar products. The issues surrounding the choice of indication in which to demonstrate biosimilarity, the basis of extrapolation and the need for transition data have all now been established. Interchangeability, a situation unique to the US approval systems still remains to be clarified, although the FDA's likely requirements are becoming clearer. Levels of interests expressed by clinical investigators have increased significantly as the financial consequences of biosimilars become better understood. The issues encountered in the clinical development of this first wave of biosimilars and the implications of those lessons learnt for the next wave of products will be discussed.

Biography

Nigel J Rulewski has 25+ years' experience in Drug Development and Regulatory Affairs, in both large and small pharma, Venture Capital and Pharmaceutical Business Development. He is presently VP, Strategic Drug Development Group and Head, Biosimilar Center of Excellence, at Quintiles. He has planned the development of biosimilar versions of EPO, GCSF, peg-GCSF, remicade, humira, enbrel, rituximab, avastin and herceptin. He earned his Medical degree at St. Bartholomew's Medical School, University of London and also holds a Diploma in Child Health, Royal College of Physicians and a Diploma of Royal College of Obstetricians and Gynecologists.

nigel.rulewski@quintiles.com

Notes: