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## Evolution of the global biosimilars market: Lessons learned

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Driving the burgeoning biosimilars industry is the lucrative biologics market, worth billions, with multiple patents expiring or set to expire soon. Historically, European and Canadian regulatory authorities have taken global leadership roles in biosimilars drug development. For example, EMA published test procedures and acceptance criteria for biological products in 1999. Europe leads the pack with the most advanced and detailed biosimilar regulatory guidance - spearheading a "totality of evidence" approach and has granted the most approvals. Other countries are moving ahead rapidly to provide cheaper copies of biologics to their citizens. The US has made significant advances towards issuing draft guidance, though it still appears that near-term, approvals will be made on a case-by-case basis. Commensurate with limited guidance and extensive innovator lobbying, the FDA has granted only one biosimilars approval – a less complex protein (filgrastim-sndz or "Zarxio" from Novartis) - in March, 2015 under the 351(k) registration pathway approved under the Biologics Price Competition and Innovation Act (BPCIA) of 2009. Further hampering progress towards US approval of a monoclonal antibody biosimilar, an FDA Advisory Committee meeting on a Remicade biosimilar from Celltrion was recently delayed. CDER recently announced that four additional biosimilar documents are set to be published in 2015. This presentation will describe the evolution of biosimilar development over the last 15 years, discussing key milestones leading to the first approvals in various markets. Outstanding issues will also be addressed relating to the race to identify and obtain the patients needed for global biosimilar registration trials.

### Biography

Raymond A Huml, MS, DVM, RAC is Executive Director of Strategic Drug Development and Head of Global Biosimilars Strategic Planning for Quintiles' Global Biosimilars Unit. He has over 25 years of experience in the clinical and biopharmaceutical industries. He has published over 50 articles and two books: One on due diligence and one on competitive intelligence. He holds an MS in Biology from East Stroudsburg University and a DVM from North Carolina State University's College of Veterinary Medicine and has earned the RAC (US) certification.

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