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# Biologics & Biosimilars

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## Emerging biosimilar in therapeutics: Where we are and what is future?

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A biosimilar product is a biological product that is approved based on showing that it is highly similar to an already approved biological product, known as the reference product. The biosimilar also must show it has no clinically meaningful differences in terms of safety, efficacy and quality from the reference product.

A biosimilar product can only be approved by the FDA if it has the same mechanism of action, route of administration, dosage form and strength as the reference product.

Omnitrope, (Somatropin) was the first product approved in the EU as a biosimilar in 2006. To date, the EMA has approved 21 biosimilar within the product classes of human growth hormone, granulocyte colony-stimulating factor, erythropoiesis stimulating agent, insulin and tumor necrosis factor (TNF)-inhibitor, for use in Europe. Two biosimilar approvals have been withdrawn; one for Filgrastim in April 2011 and one for Somatropin in May 2012, leaving a total of 19 biosimilar product approved for use in Europe.

On March 6, 2015, US FDA approved Zarxio, the first biosimilar product approved in United States. Sandoz Inc.'s Zarxio is biosimilar to Amgen Inc.'s Neupogen (Filgrastim), which was originally licensed in 1991.

Biosimilar's are a relatively new emerging market. Two major growth drivers for the Biosimilar Market are Healthcare cost savings and Biologic patent expiration. The biologic products tend to have a very high price (about 20 times more than small molecule drug) and biosimilar are about a third less costly than the Originator drug and can potentially provide increased access to biologic therapies that treat life threatening cancers, anemia and immunological disease. Additionally, through 2015, about 45 Biologic drugs worth more than \$60 Billion in Global sales will lose Patent protection, presenting a major opportunity for the growth of the Biosimilar Market.

### Biography

Dipti Gulati completed her Ph.D at the age of 25 years from Allahabad University and postdoctoral studies from Indian Institute of Sciences, India and Albert Einstein College of Medicine on Protein-Carbohydrate Interactions, USA. Currently, she is the President of PJI Biotech, a Consulting Services Organization. Previously, she held various Management Positions at Amgen, BioMerieux, Emergent Bio Solutions, Diosynth and SmithKline Beecham Pharmaceuticals. She has published more than 25 papers in reputed journals and is serving as a Committee Member for several interest groups of PDA.

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