

# 3<sup>rd</sup> International Conference and Exhibition on **Biowaivers, Biologics & Biosimilars**

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

## Challenges faced in the development of biosimilars

**Hima Bindu Gujjarlamudi**

Rajiv Gandhi Institute of Medical Sciences (RIMS), India

**B**iosimilars are biological products manufactured after expiry of the patent of innovator biopharmaceuticals. As the patents of a growing number of biologic medicines are due to expire, there is an increased interest in the development of biosimilars. The manufacturing process of biosimilars is complex and more challenging. It is a multistep process that starts with a unique cell line and takes many proprietary steps to ensure that the final product has the target protein and minimal to no impurities. Even minor changes in substrate and manufacturing process can cause significant changes and may affect patient safety and clinical efficacy of the product. For efficacy concern, high quality bioanalytical methods are required to assess the biological activity, physicochemical integrity and stability of biosimilars. The important safety concern is immunogenicity. Sensitivity and specificity of assays for testing immunogenic responses may be insufficient to predict rare cases of immunogenicity due to lack of standardization and validation of methods to measure anti-drug antibodies. The quality, efficacy and safety comparison between biosimilars and innovator product is crucial and must be performed in a step wise manner to demonstrate biosimilarity.

## Biography

Hima Bindu Gujjarlamudi has completed her MD in Pharmacology from Gandhi medical College, Hyderabad. She is working as an Assistant Professor at RIMS, Ongole, and has guided many clinical research students in completion of their projects. She has presented papers in national and international conferences and published papers in reputed journals.

[drgujjarla@yahoo.co.in](mailto:drgujjarla@yahoo.co.in)