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# Biologics & Biosimilars

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## Biosimilars: Challenges and developments

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Biosimilars are “similar but not the same” to the original biologic innovator product. Some of challenges that effect on biosimilars development such as Verification of similarity, not having of unique name, findings of biosimilars guidelines, safety, labeling of biosimilar and regulatory framework for assessing of biosimilar. Development of biosimilars achieved by finding of unique name, using of powerful analytical tools for biosimilars comparability to the reference, quality by design studies, using of statistical method for reducing of simple size of bio-similar clinical trial and post-marketing surveillance studies to establish biosimilar safety, and single use bioprocessing (single use bioreactor) for biosimilar production for meeting their clinical manufactures. Pharmacovigilance programs are important for establishing clinical databases. A new generation of biosimilars such as bio-betters, monoclonal antibody biosimilars are having more acceptability and are approved.

## Biography

Samer M Al-Hulu, Assistant Professor of Microbiology, has completed his PhD from Babylon University/College of Science. He has published more than 14 papers in Microbiology field. He completed his training at Ministry of Health at Laboratory of Babylon Maternity and Children Hospital. Currently, he is working at Al-Qasim Green University/College of Food Science.

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