



## The glycosimilarity subset of biosimilarity: the role of N-glycosylation in the regulatory approval of biosimilars

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### Abstract:

N-glycosylation is one of the important post-translational modifications of therapeutic proteins, which may directly affect the safety and/or efficacy of both the innovator products and their biosimilars. In IgG1 type monoclonal antibody therapeutics, the conserved oligosaccharide moiety at Asn297 can determine major Fc related mechanisms of action including anti-inflammatory properties, antibody-dependent cell-mediated cytotoxicity (ADCC), complement-dependent cytotoxicity (CDC) and serum half-life. Batch-to-batch alterations in this particular glycosylation is a good indicator of the robustness of the manufacturing process. Therefore, N-glycosylation of monoclonal antibody therapeutics is among the important critical quality attributes, so the carbohydrate moieties of such biopharmaceuticals should be closely monitored during all stages of the development and manufacturing processes. Determination of the level of similarity between two N-glycosylation profiles (e.g., innovator and biosimilar), however, is still challenging due to the complexity of their glycosylation profiles as well as the nature and potential effect of the different structures on safety and efficacy. Thus, assessing similarity at the N-glycosylation level is one of the most crucial part of analytical biosimilarity studies for glycosylated reference products. This presentation describes a glycoanalytical profile based similarity scoring approach (Glycosimilarity Index) that can be used to accurately calculate the level of similarity between the N-glycosylation profiles of any given reference and test items from manufacturing and regulatory point of views.



### Biography:

András Guttman, MTA-PE Lendület professor of Translational Glycomics, directs the Horváth Csaba Laboratory of Bioseparation Sciences in Hungary and leads the application efforts in Sciex in California. His work is focused on capillary electrophoresis and CESI-MS based glycomics and glycoproteomics analysis of biomedical, cell biology and biopharmaceutical interests. Professor Guttman has close to 300 scientific publications, wrote 35 book chapters, edited 4 textbooks and holds 23 patents. He is on the board of several international organizations, on the editorial boards of a dozen scientific journals, has been recognized by numerous awards and member of the Hungarian Academy of Sciences.

### Publications:

Rapid separation and purification of oligonucleotides by high-performance capillary gel electrophoresis

Use of complexing agents for selective separation in high-performance capillary electrophoresis: Chiral resolution via cyclodextrins incorporated within polyacrylamide gel columns

Bioanalysis in microfluidic devices

High-performance capillary electrophoresis in the biological sciences.

Analytical and micropreparative ultrahigh resolution of oligonucleotides by polyacrylamide gel high-performance capillary electrophoresis

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