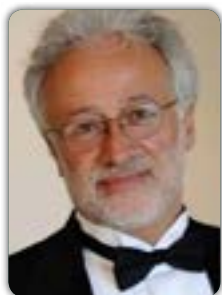


# 11<sup>th</sup> EUROPEAN BIOSIMILARS CONGRESS

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## *Andras Guttman*

SCIEX, USA

### **The glycosylation aspects of biosimilarity**

Recent expiration of a number of protein therapeutics opened up the door for biosimilar development. Biosimilars are biologic medical products, which are similar but not identical copies of already authorized protein therapeutics. Critical Quality Attributes (CQA) such as post translational modifications of recombinant biotherapeutics, are important for clinical efficacy and safety of both the innovative biologics and their biosimilar counterparts. The first part of this presentation summarizes biosimilarity CQAs, considering the regulatory guidelines and the statistical aspects (e.g., biosimilarity index). The second part discusses glycosylation as one of the important attributes of biosimilarity in detail. Finally, the term of glycosimilarity index is introduced, based on the averaged biosimilarity criterion.

### **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. He 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.

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### **Notes:**