

# 5<sup>th</sup> European Biosimilars Congress

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## High throughput assays for the determination of the potency and comparability of biosimilars and innovator products

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Successful development of biosimilars is dependent upon the establishment of validated and standardized assays that allow direct comparisons of the relative potency and comparability of innovator molecules and biosimilars. A validated standardized high throughput assay platform will be described in this presentation that is applicable to most biopharmaceuticals and that allows direct comparison of drug potency and comparability of innovator molecules and biosimilars in the same assay. Case studies will be presented for biopharmaceuticals ranging from novel forms of human insulin and FGF-21 to bevacizumab, trastuzumab, and structurally diverse TNF- $\alpha$  antagonist.

### Biography

Michael G Tovey, PhD, is INSERM Director of Research, Laboratory of Biotechnology, Ecole Normale Supérieure, Cachan, France. He is author of >250 articles on cytokines, biotechnology, and immunogenicity, a member of numerous scientific boards, Chair of the International Cytokines Standards Committee, a Member of the ICIS International Council, the European Adjuvant Advisory Committee, Editor-in-Chief of Detection and Quantification of Antibodies to Biopharmaceuticals, Associate Editor Cytokine, Associate Editor *Journal of Interferon and Cytokine Research*, Associate Editor *The Scientific World Journal*, a member of the Editorial Board of the *Journal of Immunoassay & Immunochemistry* and chair of Coral Gables Symposia.org.

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