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Standardized assays: The key to success

Michael G. Tovey
ENS-Cachan, France

Successful development of biosimilars is dependent upon the establishment of validated and standardized assays that allow direct comparisons of the relative potency and immunogenicity of innovator molecules and biosimilars. Validated standardized assays is the key to obtaining reliable data and regulatory approval, in particular in the case of cell-based assays that are recommend by regulatory authorities for the detection of neutralizing anti-drug antibodies. A validated standardized cell-based assay platform has been developed that allows the quantification of both drug potency and anti-drug antibodies and that reduces assay variation and serum matrix effects to a minimum and is applicable to most biopharmaceuticals. This will be illustrated by reference to case studies for interferon beta products and TNF-alpha antagonists.

Biography

Michael G. Tovey, Ph.D, is INSERM Director of Research, Laboratory of Biotechnology and Applied Pharmacology at the Ecole Normale Supérieure de Cachan, Cachan, France. He is the author of more than 200 articles on interferon, cytokines, biotechnology, and immunogenicity. He is a member of numerous scientific boards and is French representative for the ISICR International Council. He is chair of the International Cytokine Standards Committee, a member of the ISICR Meetings Committee, and a member of the European Adjuvant Advisory Committee. He is editor-in-chief of Detection and Quantification of Antibodies to Biopharmaceuticals: Practical and Applied Considerations, and Associate Editor of the Journal of Interferon and Cytokine Research.

michael.tovey@ens-cachan.fr