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Recommendations for the development and validation of neutralizing antibody assays in support of bio-similar assessment

The American Association of Pharmaceutical Scientists (AAPS) biosimilar focus group on nonclinical and clinical assays has developed a manuscript to guide the industry on best practices and testing strategies when developing neutralizing antibody (NAb) assays for biosimilar programs. Establishing that there are no clinically meaningful differences in immune response between a proposed product and the originator product is a key element in the demonstration of bio-similarity. It is critical to collect, evaluate and compare the safety and immunogenicity data from the clinical pharmacology, safety, and/or efficacy studies especially when the originator drug product is known to have potential for immune-mediated toxicity. In this presentation, a comprehensive review and recommendations on assay formats, critical reagents, approaches to method development, and validation of the neutralizing antibody assays will be discussed.

Speaker Biography

Todd Lester is the Bioanalytical Project Manager in BioAgilytix, oversees and leads all technical aspects of BioAgilytix's bioanalytical studies including design, interpretation, analysis, documentation, and reporting. He is a seasoned Biotech/Pharmaceutical Project Management Professional with broad GxP expertise. He is well-versed in the regulations and filing requirements for FDA and EMA, particularly regarding biosimilar development and the related immunogenicity assessment strategy and data interpretation. He has completed his BS in Biological Sciences from Cornell University and is a licensed Project Management Professional (PMP) with the Project Management Institute (PMI).

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