

6th International Conference on

Biologics & Biosimilars

October 19-21, 2016 Houston, USA



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Use of biophysical techniques for the analysis of biosimilars

Biosimilars are quickly gaining position as a cornerstone of the evolving biopharmaceutical industry. Like other generics, these drug products can lower costs for life-saving therapies, but must have an efficient and well-developed characterization platform in order to deliver on economic savings. Due to the complex nature of biologics, the three dimensional structure of the protein and the higher-order structural interactions must be taken into consideration when trying to show comparability (similarity). Biophysical techniques are geared for just this type of analysis and, therefore, should be part of any biosimilars analytical characterization platform. Various biophysical techniques and their applicability to the analysis of biosimilars will be discussed during the presentation. To inform on the value that these techniques can add to a comparability program between a biosimilar product and innovator product, a case study will be presented.

Biography

Mario DiPaola is CSO and Co-founder of Blue Stream Laboratories, Inc. He holds a PhD in Chemistry and also an MBA and has been in the biopharmaceutical industry for 20+ years in various roles from Scientist to Company Executive.

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