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# The use of mass spectroscopy in the GMP analysis of biosimilars

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## Abstract

Biosimilars are complex protein structures that present significant analytical testing challenges. When developing an analytical strategy for testing a biosimilar product in comparison to the reference product, it is important that such strategy not only deal with the basic product attributes of identity, purity, potency and safety but that it go beyond these basic attributes in that it allow for detailed analysis of the primary structure of the product, identification and quantification of post-translational modifications, and secondary and tertiary (as well as quaternary, if necessary) characterization.

Mass spectroscopy lends itself as a valuable approach for the analysis of primary structural characteristics, post-translational modifications of biosimilars, as well as identification of minor impurities either product or process derived.

In this presentation, the speaker will discuss a GMP testing strategy for the analysis of biosimilars and also provide a few examples (case studies) of how mass spectroscopy has been effectively used for the GMP analysis of a product in development as a biosimilar.

## Biography

Mario DiPaola has a Ph.D from New York University, as well as an MBA from Baruch College (CUNY). He is currently CSO/COO of Blue Stream Laboratories, Inc. which he helped co-found in 2006. Through his career in the biopharmaceutical industry that spans more than 20 years, he has been with a number of organizations including Charles River Labs, Biogen/Idec and Agenus in various management roles.