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Analytical characterization of biosimilar products to establish biosimilarity

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Any manufacturer seeking to develop and market a biosimilar product requires comprehensive physicochemical structural characterization of the (glyco) protein. For biosimilar products, this task should be performed at three distinct stages of development. Initially, batches of the target originator molecule should be studied to determine the exact sequence of protein and establish the Quality Target Product Profile (QTPP), the post-translational modifications and the variability of quality attributes in batches over time. Then, once the biosimilar product is manufactured, characterization needs to be performed to confirm it's structure. Finally, manufacturers must provide comparative data for the biosimilar side-by-side with the originator molecule as required by various regulatory guidelines.

This presentation will detail analytical methods including MALDI-TOF MS, ESI-MS, ESI-MS/MS, GC-MS, HPAEC-PAD, cIEF, CD and AUC which can be used to establish comparative analysis on glycoprotein products. Strategies for primary and higher order structure determination will be discussed particularly for antibodies where the size and complexity of the molecule requires LC/MS/MS approaches. Examples will demonstrate the sensitivity of these methods to detect small changes in post-translation modifications such as glycosylation or other differences between the biosimilar and originator molecules.

Biography

Fiona is a founding Director of M-Scan (Mass Spectrometry Consultants and Analysts), a group of contract analytical laboratories specializing in the analysis of pharmaceuticals and biopharmaceuticals. She joined M-Scan Ltd, an independent company started by Professor Howard R. Morris, in 1984 to found the Biochemical Services Department and develop and exploit new and emerging mass spectrometry techniques for biopolymer analysis. Here, she pioneered and applied developments in MS for the structural characterisation and sequencing of peptides, proteins and carbohydrates. With expansion of the group, she was appointed Director of Biochemical Services in 1988. At the same time, she was instrumental in establishing an M-Scan facility in the United States (M-Scan Inc, founded 1984 in West Chester, PA) where she was appointed Vice President.As M-Scan grew from a small start-up to become a world leading contract analytical laboratory for biopharmaceutical characterisation, comprising four laboratories (UK, USA, Switzerland and Germany)she was responsible for establishing the Quality Management system and for directing QA across the group.With thirty years experience in the structural analysis of proteins and glycoproteins using instrumental techniques, she is involved in the analysis of a diverse range of biotechnology products. She has published many articles in journals and books on the use of mass spectrometry and other instrumental techniques to fulfil regulatory characterisation requirements and consults to companies throughout the world. She is regularly invited to give presentations and workshops at international meetings and has designed and presented various technical training courses, both for M-Scan and other organisations.In additional to her scientific responsibilities, she is also interested in the development of biotechnology businesses and served as a non-executive director of a UK Business Link organisation to promote this objective.

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