

Analytical characterization of biosimilar products to establish biosimilarity

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Abstract

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 its 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

Dr Fiona M. Greer was a founding Director of M-Scan (Mass Spectrometry Consultants and Analysts), a group of contract analytical laboratories specializing in the analysis of biopharmaceuticals. Since the acquisition of the group by SGS Life Science Services in October 2010, she is now the Global Director for Biopharma Services Development, SGS Life Sciences.

Following a Ph.D. in Protein Biochemistry from Aberdeen University in 1984, she joined M-Scan Ltd, an independent company started by Professor Howard R. Morris, to found the Biochemical Services Department. Here, she pioneered and applied developments in Mass Spectrometry 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 a facility in the United States (M-Scan Inc, founded 1984 in West Chester, PA) where she was appointed Vice President. Dr Greer was also responsible for establishing the Quality Management systems at all four laboratories (UK, US, Switzerland and Germany) and for directing Quality Assurance across the group.

With over 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.