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Establishing finger-print like biosimilarity: Critical characterization steps for biosimilar assessment

The development pathway of a biosimilar is unlike that of a novel biotherapeutic. Many regulatory authorities reference a "step-by-step" approach to establishing biosimilarity. In the early stages there is an increased requirement for analytics. This enhanced analytical effort entails physical, chemical, and biological characterization of the biosimilar in comparison to the originator reference product. Strategies at this stage must include assessment of primary and higher-order structure as well as batch-to-batch variation for both products. If found to be "similar" during this extensive characterisation, subsequent non clinical and clinical data are then required to demonstrate the same safety and efficacy profiles as the reference. This presentation will highlight the benefit of using modern instrumental approaches to provide analytical data to support regulatory submissions. Biosimilar development requires comprehensive physicochemical structural characterization of the (glyco)protein to demonstrate "Biosimilarity" with the originator. Initially, batches of the target molecule are studied to determine the exact structure, post-translational modifications such as glycosylation and variability of quality attributes to establish the Quality Target Product Profile (QTTP). Subsequently, comparative data for the biosimilar side-by-side with the originator is required. This includes both structural and functional activities. Strategies for primary and higher order structure determination will be discussed particularly for antibodies where their size and complexity requires LC/MS/MS approaches. Appropriate orthogonal analytical techniques for "finger-print like" assessment will be reviewed.

Biography

Fiona M Greer was a founding Director of M-Scan, contract analysts specializing in biopharmaceuticals. With a PhD in Protein Biochemistry from Aberdeen University (1984) she joined M-Scan to establish and direct biologics characterization services. Here, she pioneered new developments for structural analysis and sequencing of proteins and carbohydrates resulting in numerous publications and patents. Following acquisition (2010) by SGS, she is now Global Director, Biopharma Services Development, SGS Life Sciences. With over 36 years' experience in glycoprotein analysis using mass spectrometry and other instrumental techniques, she is involved with a diverse range of biotech products, both novel and biosimilars. She consults to companies throughout the world and is regularly invited to give presentations. She was named in both the 2016 and 2017 Medicine Makers "Power List – Top 100 Industry Influencers".

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