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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 refer a "step-by-step" approach to establishing biosimilarity. In the early stages there is an increased requirement for ana¬lytics. 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. The premise is that the amount of clinical data required will be less than for a novel stand-alone application. 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 analytical laboratories specializing in biopharmaceutical characterization. Following acquisition in 2010, she is now Global Director, Biopharma Services Development, SGS Life Sciences. Following 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 in Mass Spectrometry for structural analysis and sequencing of proteins and carbohydrates resulting in numerous publications and patents. She was instrumental in expansion of the group, establishing a US facility where she was appointed VP. With over 35 years experience in glycoprotein analysis using mass spectrometry and other instrumental techniques, she has been involved with a diverse range of biotechnology products, both novel and biosimilar 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.

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