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Biosimilars analytical strategies

Sung Nyeo Shim
Chong Kun Dang Pharmaceuticals, South Korea

Biosimilar products (follow-on versions of pioneering biopharmaceutical products which are already licensed) are complex structurally and functionally. Regulatory authorities require biosimilars to have appropriate and comparable safety, quality and efficacy with a corresponding reference biologic product. In order to investigate the critical quality attributes of a biosimilar and a reference product for interchangeability and comparability, various analytical approaches are employed, such as LC/MS, Peptide mapping, Thermal analysis, SDS-PAGE, Isoelectric focusing and Capillary isoelectric focusing, Particulate matter analysis, *In-vivo* and *In-vitro* bioassay, etc. An analytical similarity of a biosimilar to a reference biological product is assessed with the state-of-the-art of analytical strategies. One of the key analytical techniques is Mass Spectrometry (MS) for assessment of similarity, detection and identification of primary sequence differences and evaluation of batch variability. Analytical differences observed need to be characterized and understood for a cross-confirmation of the data using orthogonal methods to prove the differences are not clinically relevant. Post-translational modifications, three-dimensional structures and protein aggregation have been identified as three important characteristics in developing strategies for the biosimilar. For quality control of the biosimilar production process and product, in-process samples, drug substance and drug product are evaluated in terms of protein content, purity, potency, identity and impurity. All analytical data includes the stability study data impact on clinical trials, the product expiration date and the product approval.

Biography

Sung Nyeo Shim has approximately 18 years of experience in the field of QA, QC, Compliance Of Biologics; QMS; Gmp Training & Biologics Analytical Test Methods Tech Transfer; Filing Support with Regulatory Affairs. She is enthusiastic, energetic, organized, the multifunctional individual with integrity, highly self-motivated. She has delivered milestones in a timely manner. She has QC lab qualification, analytical method development, qualification and validation per International Council for Harmonization (ICH) guidelines. She has also Monitored biologics manufacturing, data integrity/analysis/troubleshooting.

sungshim8888@gmail.com

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