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The use of LC/MS to characterize and analyze biosimilars (peptides and proteins)

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Protein drugs have emerged as therapeutics due to their enhanced specificity and mode of action compared to small molecule drugs. A disadvantage of protein drugs is the high complexity of their structures. This makes it almost impossible to copy a protein drug 100% and biosimilar producing companies will always be faced by small differences between innovator drug and biosimilar. Peptides are less complex in structure, but biosimilar peptides also need to be analyzed and characterized properly for any structural changes compared to the innovator peptide. Regulatory requirements for approval of biosimilars include demonstration of good quality, efficacy and safety. In addition, data needs to be presented that demonstrates the proximity of the biosimilar to its innovator. The use of liquid chromatography (LC) and mass spectrometry (MS) can give insights into protein identity, sequence variants, glycosylation profile, other posttranslational modifications (PTMs) and impurities. This presentation will give a short introduction into the technology and show case-studies of analysis of peptides and human antibodies in different matrixes (e.g. human blood) and discuss the advantages of using LC/MS technology as a standardized tool to well-characterize a biosimilar against its innovator.

Biography

Sauerborn spent most of her undergrad years in well-known institutes such as the Centers for Disease Control and Prevention in Atlanta to widen her knowledge in immunology. After acquiring her Masters in Science she joined the lab of Prof. Schellekens and Prof. Jiskoot, two experts in immunogenicity of protein drugs, to shed more light on the immunological aspects of antibody formation against aggregated protein therapeutics. After obtaining her PhD she started a spin-off, ADA InVivo BV, a biotech CRO in the field of drug safety. Currently she is a project leader at the bioanalysis and immunogenicity department at TNO Triskelion BV, a Dutch CRO.

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