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Use of human protein transgenic animal models for immunogenicity testing and their value for comparative studies of biosimilars

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The use of transgenic animals to predict immunogenicity of new biologics is increasing. In recent years transgenic animals immune tolerant for the protein drug of interest have proven useful tools to investigate the immunogenic potential of protein drugs and factors influencing immunogenicity. This presentation will introduce the basics of transgenic animals and their use in immunogenicity testing. We will show data from transgenic mouse models immune tolerant for human interferon alpha and beta and how we compared different human interferon alpha and beta products in terms of immunogenicity.

These models are very sensitive to formulation issues (e.g. aggregation), and introduction of neo-epitopes and a very useful tools to perform comparative studies of biosimilars. With the upsurge of well-defined transgenic animal models, biosimilars can also benefit from these models.

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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