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Production of biosimilar MAbs in transgenic animals: Opportunities and challenges

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Expression of recombinant proteins in the milk of transgenic dairy goats has been established as a viable and cost-effective alternative to mammalian cell culture systems. The first transgenically produced therapeutic protein, recombinant human Antithrombin (ATryn), has been approved by the European Authorities in 2006 and by the FDA in 2009. Since then it has been successfully used to treat patients with hereditary deficiency of antithrombin. Due to the high capacity of the mammary gland for protein expression and milk output, the transgenic system is particularly suitable for production of complex proteins in large quantities. This production system and large capacity for recombinant protein expression has been put to use generating monoclonal antibodies to develop several biosimilar products that will be described herein. This presentation will specifically explore the scientific and regulatory pathway for the development of therapeutic monoclonal antibodies (MAb) expressed in the milk of transgenic animals under the provisions of the Biologic Price Competition and Innovation Act of 2009 (BPCI Act).

Biography

Roman T Drews joined LFB USA in 2013 where he holds position of Senior Director of Regulatory Affairs. Before joining LFB USA, he was a Team Leader at the Office of Blood Research and Review of CBER FDA. His research included molecular biology, cell biology, and expression of recombinant therapeutic proteins. Before joining the FDA, he worked at Holland Laboratory of American Red Cross (ARC). He received his PhD in Experimental Endocrinology from Polish Academy of Sciences and subsequently held positions at University of Georgia in Athens and University of Montreal.

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