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Bioavailability assessment for subcutaneously administered biologics in animal models

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Abstract

Subcutaneous (SC) administration is very often used for therapeutic biologics due to its convenience. Many factors may influence SC absorption of a novel biologic, such as intrinsic subject characteristics for a given species (e.g. body weight); species characteristics with regard to skin morphology and physiology (e.g. presence or absence of the *panniculus carnosus* muscle in the skin, metabolic/catabolic capacity at the injection site, blood and lymph circulation flows); drug substance and product characteristics (e.g. molecular weight, presence or absence of Fc portion in the construct), formulations (e.g. controlled release approach), and injection modes (e.g. rate, dosing volume, and injection site). A thorough understanding of key processes and factors that impact SC absorption and the application of this knowledge for design of SC-administered biologic drug products with improved systemic exposure has significant commercial implications. In this presentation, case studies for SC bioavailability assessment of biologics in animal models will be discussed. Examples will focus on the challenges involved in the drug development of SC administered biologics: species selection, pre-systemic metabolism/catabolism, impact of immunogenicity in data interpretation, and bioavailability determination for novel formulations and drug delivery devices. Through these examples, the importance of a comprehensive evaluation of factors and mechanisms influencing SC absorption will be illustrated. Knowledge gained from animal bioavailability studies will strength our understanding of SC absorption processes and, in combination with clinical studies, will enhance the translational medical research.

Biography

Xin Xu obtained PhD degree in Pharmacokinetics from Faculty of Pharmacy, University of Toronto, Canada. She has over 20 years of industrial experience in non-clinical drug metabolism and pharmacokinetics (DMPK). She was the non-clinical PK representative for three Merck products: Singulair, Cancidas, and Invanz. She also contributed to the filings of Infuse and Enbrel at Genetics Institute/Wyeth. She has extensive experience in IND filings of novel therapeutics, ranging from small molecules to biologics, such as monoclonal antibodies, nanobodies and protein-drug conjugate (ADC). She has over 60 publications in peer-reviewed journals or book chapters, and over 80 conference presentations and abstracts.